Unitaid
Innovation in Global Health

MULTI-DISEASE DIAGNOSTIC LANDSCAPE FOR

INTEGRATED MANAGEMENT OF HIV, HCV, TB AND OTHER COINFECTIONS

JANUARY 2018

(Acting as the host Organization for the Secretariat of Unitaid)

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Abbreviations and acronyms

AMG	aminoglycosides
AMR	antimicrobial resistance
ART	antiretroviral therapy
ARV	antiretroviral
CE	European Conformity
CE-IVD	CE marked in vitro diagnostic medical device
CIA	chemiluminescence immunoassay
CLIA	Clinical Laboratory Improvement Amendments
CMV	cytomegalovirus
DBS	dry blood spot
DNA	deoxyribonucleic acid
DST	drug susceptibility testing
EIA	enzyme immunoassays
EID	early infant diagnosis
ELISA	enzyme-linked immunoassay
FDA	Food and Drug Administration
FIND	Foundation for Innovative New Diagnostics
FLQ	fluoroquinolone
FluA/B	influenza A/B
GSM	global system for mobile communication
HAV	hepatitis A virus
HBV	hepatitis B virus
HCV	hepatitis C virus
HDV	hepatitis D Virus
HEV	hepatitis E virus
HIV	human immunodeficiency virus
HIVDR	HIV drug resistance
HPV	human papilloma virus
HSV	herpes simplex virus
INH	isoniazid
IVD	in vitro diagnostic
LAMP	loop-mediated isothermal amplification
LIS	laboratory information system
LIMS	laboratory information management system
LMIC	low- and middle-income country
LPA	line probe assay
MDR	multi-drug resistant

MDR-TB	multi-drug resistant TB
MRSA	methicillin-resistant Staphylococcus aureus
MTB	Mycobacterium tuberculosis
MTB/INH	isoniazid-resistant Mycobacterium tuberculosis
MTB/RIF	rifampicin-resistant Mycobacterium tuberculosis
N/A	Not applicable
NASBA	nucleic acid sequence-based amplification
NAT	nucleic acid test
NGS	next generation sequencing
NTM	nontuberculous mycobacteria
NTP	national tuberculosis programme
PC	personal computer
PCR	polymerase chain reaction
PLHIV	people living with HIV
POC	point of care
qPCR	real time quantitative PCR
RDT	rapid diagnostic test
RNA	ribonucleic acid
RT-PCR	reverse transcription PCR
RT-qPCR	quantitative reverse transcription PCR
RUO	research use only
SA	Staphylococcus aureus
SMS	short message service
SSM	sputum smear microscopy
STD	sexually transmitted disease
STI	sexually transmitted infection
TB	tuberculosis
TBC	to be confirmed
TBD	to be determined
TP	Treponema pallidum (syphilis)
US	United States
USB	universal serial bus
VL	viral load
VOC	volatile organic compound
WHO	World Health Organization
WHO PQ	WHO prequalification program
XDR-TB	extensively drug-resistant TB

Measurements

CM	centimetre
CP	copies
”	inch
IU	standard international unit
kg	kilogram
L	litre
lb	pound
m	metre
m2	metre squared
mL	millilitre
mm	millimetre
ng	nanogram
µL	microlitre

Key Definitions

AMR: The ability of microorganisms (such as bacteria, viruses, fungi and parasites) to change in ways that renders standard treatment ineffective (1).

Coinfection: Simultaneous infection by two or more pathogens.

MDR-TB: TB that does not respond to INH and RIF, the two most powerful anti-TB drugs, which are part of the core anti-TB drugs (2).

Multiplex testing: Simultaneous detection of different analytes in a single specimen using one test procedure/test run.

Multi-disease platforms: Diagnostic platforms that can test for multiple analytes either simultaneously or sequentially.

POC: Testing that is performed in close proximity to where the patient is receiving care. Testing can be performed by professional or lay health workers and results are typically available relatively quickly (3,4).

XDR-TB: TB that is resistant to at least four of the core anti-TB drugs. XDR-TB indicates resistance to INH and RIF, as well as resistance to any of the FLQs (such as levofloxacin or moxifloxacin) and at least one of the three injectable second-line drugs (amikacin, capreomycin or kanamycin) (5).

Executive Summary

Burden of coinfections and antimicrobial resistance

Coinfections are a major global health concern. While the biomedical success story of antiretroviral therapy (ART) has revolutionized the ability to control HIV-associated deaths, investments in treatment are being threatened by morbidity and mortality associated with coinfections, such as HBV, HCV and other co-morbidities (6). In 2016, there were an estimated 2.3 million people living with HIV (PLHIV) that were also coinfected with HCV. Tuberculosis (TB) is another frequent coinfection, and is in fact the most common presenting illness and cause of death in PLHIV, being responsible for one of every three HIV-associated deaths (7–9). Other related infections, such as human papilloma virus (HPV), herpes simplex virus (HSV), cryptococcus, Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis and malaria, further exacerbate the disease burden of coinfections. Further still, despite estimates, it is thought that the true prevalence of coinfections is largely underreported, with many going unscreened and undetected (10). These overlooked coinfections often lead to full-blown infections that are costly for both health-care systems and patients (10). In addition, it has been demonstrated that HIV coinfections can facilitate the transmission of HIV, disease progression and mortality (11,12). Together, these factors indicate that high-risk populations should not only be screened for HIV, but also for related coinfections.

In addition to the increasing concern of coinfections, antimicrobial resistance (AMR) is also emerging as a major challenge to the effective treatment of a growing number of infectious diseases. Worldwide, around 700 000 lives are thought to be lost to antibiotic-resistant infections annually, and the continued rise in AMR is expected to lead to 10 million deaths per year by 2050 (13). The AMR crisis has predominantly been attributed to the overuse and misuse of medications, as well as to the shortage in new drug developments (14). Carbapenem resistance in Klebsiella pneumoniae, an intestinal bacteria that can cause life-threatening infections, has spread to all regions of the world, while Escherichia coli resistance to FLQ antibiotics is also widespread (1).

In the context of Unitaid's key disease areas of HIV, HCV, TB and malaria, AMR is of critical concern. Globally, 480 000 people develop multi-drug resistant TB (MDR-TB) each year; and even more worryingly, extensively drug resistant TB (XDR-TB) is estimated to affect 9.7% of people with MDR-TB (1). Resistance to the first-line treatment for *Plasmodium falciparum* malaria is also increasing; moreover, multi-drug resistance to this pathogen has been identified along the Cambodia–Thailand border (15). For a number of HIV-coinfections, such as bacterial infections or sexually transmitted diseases (STDs), management is becoming increasingly challenging in resource-limited settings due to growing levels of resistance and lack of capacity to adequately diagnose and handle this situation with current tools. For example, strains of gonorrhoea resistant to third-generation cephalosporin antibiotics are now present in at least 10 countries, and the high level of resistance to quinolones means that this class of drugs is no longer recommended in the World Health Organization (WHO) guidelines for the treatment of gonorrhoea (16). Methicillin-resistant Staphylococcus aureus (MRSA) and carbapenem-resistant Enterobacteriaceae are also major issues, with people with MRSA 64% more likely to die compared to those with the non-resistant form of the infection (1).

Overall, the increasing levels of resistance to current antiretroviral (ARV) treatment is a growing issue of concern, which could severely compromise international treatment targets (1). Importantly, the overuse and misuse of antimicrobials could, to an extent, be prevented through better diagnostic programmes and implementation, although many other factors such as behaviour also play a role (17). Ultimately improved global AMR surveillance could help to minimize the spread of AMR, and optimize treatment choices.

Multi-disease diagnostic platforms

Multi-disease diagnostic platforms, which can sequentially or simultaneously test for multiple infectious agents, pathogen variation and AMR, hol d the potential to streamline and simplify infectious disease diagnosis and management. Improved access to multi-pathogen diagnostics, which can allow for the detection of multiple diseases, coinfections, pathogen variations and AMR, could be an essential next step in the quest to end these pandemics. The approach has the potential ability to reduce the cost of testing via an integrated network approach, to increase access to testing for poorly funded diseases, to improve the management of coinfections and to increase case-finding of individuals with specific coinfections. A

number of multi-disease diagnostics are already available, and the field is rapidly expanding, primarily driven by technological advances enabling point-of-care (POC) testing. Encouragingly, the high potential for multi-disease platforms to improve the diagnosis of infectious diseases has resulted in a global effort to develop new devices and expand assay menus. Over the past 5–10 years there have been a number of technological developments within the field, which are allowing for the improved implementation and use of these platforms, especially in resource-limited settings, where they are most needed. Highlighting the shift towards the use of more integrated multi-disease platforms, WHO has recently released (June 2017) a new information note on this issue: *Considerations for adoption and use of multi-disease testing devices in integrated laboratory networks* (18). Further efforts are warranted to ensure these innovative tools can be adopted and eventually lead to the desired public health impact

Summary of infectious disease menus for multi-disease platforms currently on the market*

LEGEND Marketed In development

	HIV	HCV	TB	MDR-TB	Malaria	HBV	HPV	CMV	HSV	TP	Candida	Cryptococcus	Chlamydia	Gonorrhea	Trichomoniasis	Toxoplasmosis	Influenza A/B	RSV	MDR	Others	Details on pages
Immunoassays																					
Abbott Architect	■	■				■		■		■						■	■		■	Yes	25,71
Abbott Prism	■	■				■														Yes	25,68
Abbot AxSYM (Plus)	■	■				■		■								■	■		■	Yes	25,70
Bio-Mérieux Vidas	■	■				■		■								■				Yes	26,85
DiaSorin – ETI-Max 3000/ Freedom EVOlyzer	■	■			■	■		■	■	■						■	■			Yes	26, 103, 104
DiaSorin – LIASON (XL)	■	■			■	■		■	■	■						■	■			Yes	26, 101
Siemens – BEP Systems	■	■				■		■	■							■	■			Yes	27, 146

* To fit within the scope of this document, only multi-disease platforms that can test for HIV, HCV, TB and/or malaria and at least one other coinfection are listed in this table.

	HIV	HCV	TB	MDR-TB	Malaria	HBV	HPV	CMV	HSV	TP	Candida	Cryptococcus	Chlamydia	Gonorrhea	Trichomoniasis	Toxoplasmosis	Influenza A/B	RSV	MDR	Others	Details on pages
RDTs																					
Alere – SD Bioline HIV/Syphilis Duo	■									■						■	■		■	No	28, 73
BioLytical - INSTI HIV/Syphilis	■									■										No	29, 83
Chembio - DPP HIV/Syphilis	■									■						■	■		■	No	29, 93
CTK Biotech – OnSite HIV/ Syphilis	■									■						■	■		■	No	29, 99
MedMira – Multi-plo Rapid TP/HIV	■									■						■	■		■	No	30, 128
Artron – Detect 3 HIV/HCV/HBV	■	■				■														No	30, 76
Atlas Link – One Step HIV/ HBsAg/ HCV	■	■				■														No	31, 76
Boson – HIV/HCV/ HBs	■	■				■														No	31, 90
Core Diagnostics –Combo HIV/ HBsAg/ HCV	■	■				■														No	31, 96
CTK Biotech – OnSite HBsAg/ HCV		■				■														No	31, 99
Maternova – HIV/ HBsAg/ HCV	■	■				■														No	32, 126
MedMira – Multiplo Rapid HBc/ HIV/ HCV	■	■				■														No	32, 129
Qualpro Diagnostics – Combiquic HIV/HCV	■	■																		No	32, 151
ReLIA HIV-HCV dual test	■	■																		No	32, 153
Spectrum – HBsAg/HCV		■				■														No	32, 150
UAB Euro Genomics – HBsAg/ HCV		■				■														No	32, 153

LEGEND Marketed In development

	HIV	HCV	TB	MDR-TB	Malaria	HBV	HPV	CMV	HSV	TP	Candida	Cryptococcus	Chlamydia	Gonorrhea	Trichomoniasis	Toxoplasmosis	Influenza A/B	RSV	MDR	Others	Details on pages
RDTs																					
JAL Innovation – iCARE Combo	■	■				■				▒										No	33, 124
UAB Euro Genomas –Combo Test	■	■				■				▒										No	33, 153
PCR-based NAT platforms																					
Abbott – m2000 System	■	■	■	■		■	■	■					■	■						Yes	38, 67
Analytik Jena - qTower	■	■	■			■		■	■											Yes	38, 74
BD – BD MAX System			■	■									■	■	■					Yes	39, 82
Beckman Coulter – DxN VERIS	■	■				■		■													39, 82
Bioneer – ExiStation	■	▒	■	■		■	■	■	■				■	■	■		■			Yes	39, 86
Cepheid – GeneXpert Systems	■	■	■	■			■						■	■	■		■	■	■	Yes	40 ,53, 55, 91
Hain Lifescience - FluoroCycler			■	■					■				■	■						Yes	41, 118
LG Life Science – SLAN		■	■			■	■						■	■			■	■		Yes	
Primerdesign – Genesig q16	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■			Yes	
QIAGEN– QIAsymphonySP/AS		■	■		■	■	■	■	■			■	■	■		■	■	■		Yes	
Roche – Cobas Platforms	■	■	■	▒		■	■	■	■				■	■			■			Yes	
Sacace Biotechnologies – SaCycler-96	■	■	■			■	■	■	■	■	■	■	■	■	■	■	■	■	■	Yes	
Seegene – Anyplex/Seeplex System			■	■			■	■	■		■		■	■	■		■	■	■	Yes	
Siemens Healthcare – Atellica MDX 160	■	■				■		■	■				■	■						Yes	

	HIV	HCV	TB	MDR-TB	Malaria	HBV	HPV	CMV	HSV	TP	Candida	Cryptococcus	Chlamydia	Gonorrhea	Trichomoniasis	Toxoplasmosis	Influenza A/B	RSV	MDR	Others	Details on pages
Isothermal amplification-based NATs																					
Bio-Mérieux – NucliSENS easyQ	■						■													No	
Eiken Chemical – LA-500			■		■															Yes	
GenMark – XT-8/ ePlex System		■									■						■	■	■	Yes	
Hologic – Panther	■	■				■	■	▒	■				■	■	■		■	■		Yes	
Human Diagnostics – HumaLoop M						■															
Tosoh Bioscience – TRCReady-80			■										▒	▒						Yes	
Ustar – Cross Priming Amplification			■										■		■					Yes	
Line probe assays																					
Autoimmun Diagnostika – AID Scanner			■	■			■	■	■	■			■	■			■		■	Yes	
FujireBio - Auto-LiPA	■	■				■	■			■										Yes	
LG Life Sciences – GenoLine Station			■	■			■											■		No	
YD Diagnostics – MolecuTech HybREAD480			■	■			■													No	
Microarray-based NATs																					
Akonni Biosystems – TruDiagnosis platforms			■	■					■	■										Yes	
AutoGenomics – INFINITI System			■	■			■		■	■	■		■	■	■		■		■	Yes	
Veredus – VerePlex Biosystem			■	■													■			Yes	
Mass spectrometry-based NATs																					
Abbott – IRIDICA Platform			■					■	■		■								■	Yes	

LEGEND Marketed In development

	HIV	HCV	TB	MDR-TB	Malaria	HBV	HPV	CMV	HSV	TP	Candida	Cryptococcus	Chlamydia	Gonorrhea	Trichomoniasis	Toxoplasmosis	Influenza A/B	RSV	MDR	Others	Details on pages
POC/near-POC NAT devices																					
Alere – Alere q Analyzer	■																				
Aquila – Accutas					■				■												
Cepheid – GeneXpert I	■	■	■	■			■						■	■	■		■		■	Yes	
Coyote – Mini8 qPCR Cycler	■	■				■											■	■		Yes	
Epistem - Genedrive		■	■	■																No	
Molbio – Truelab Analyzer	■	■	■	■	■	■	■						■	■	■		■			Yes	
VOCs																					
eNose Company – Aeonose			■																		
Menssana - BCA			■														■			No	
Immunoassay/NAT integrated platforms																					
Akonni Biosystems – TruDiagnosis platforms			■	■					■											No	
Coris - TRAPIST			■	■								■					■		■	No	
DRW - SAMBA	■												■	■			■			No	

Methodology

The Unitaid Multi-disease diagnostics landscape for integrated management of HIV, HCV, TB and other coinfections (2017) was developed by Cambridge Healthcare Research Limited (Cambridge, United Kingdom) in collaboration with Unitaid. The material in this landscape report was gathered from extensive review of publicly available information, published and unpublished reports, and discussions with developers and manufacturers. World Health Organization (WHO) policies and systematic reviews were also extensively studied to help guide research, and discussions with WHO colleagues further aided the development of the report. The operational characteristics of the devices/tests profiled in this report were provided by the developers; in cases where developers could not provide such details, publicly available information was used, as indicated in Appendix 2.

This Unitaid report has been compiled with the objective of developing a comprehensive multi-disease diagnostic landscape for HIV, tuberculosis (TB), HCV and other coinfections. The report is intended to provide a comprehensive overview and inform potential opportunities for market intervention to improve access to effective multi-disease diagnostics. To serve this purpose, the report presents an overview of multi-disease diagnostic technologies that are commercially available or in development. Scoping limitations have meant that the report has been limited to multi-disease platforms/devices, which include HIV, HCV, TB and/or malaria (Unitaid's current key disease areas) as one of the infections they can detect. However, focus on malaria is limited in scope as it is covered in-depth in other landscapes including the upcoming landscape on febrile illness. Assays that solely test for more than one genotype of the same infection have also been excluded (for example, an assay that can test for HIV-1 and HIV-2).

A dynamic understanding of existing and forthcoming technologies is key for Unitaid in facilitating access to appropriate multi-disease diagnostic tools through market-based interventions. As such, this landscape report is intended to be a living document, which can be updated as the multi-disease diagnostics market evolves.

This landscape builds on and complements previous diagnostic landscaped published by Unitaid, including HIV Diagnostic Technology Landscape, TB Diagnostic Technology Landscape, Malaria Diagnostics Technology Landscape, HCV Diagnostic Technology Landscape, and HIV Dual elimination of mother-to-child transmission of HIV and congenital syphilis Diagnostic technology landscape (https://unitaid.eu/publications/#en)

Disclaimer

The scope of this report has been limited to devices that can: (i) test for more than one infectious disease (either simultaneously or sequentially); and (ii) test for at least one disease in Unitaid's key disease areas of HIV and co-infections/comorbidities including HCV, TB and malaria. Although all efforts have been made to ensure that the present report provides an accurate, clear and comprehensive overview of the multi-disease diagnostics landscape, some devices may not have been identified. In several cases, relevant devices were excluded from the report, following explicit requests by the developers. The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by Unitaid.

Overview of HIV diagnostics

Access to diagnostic testing is currently considered as both the essential and key challenge facing the HIV response. While the biomedical success story of ART has revolutionized the ability to control HIV-associated morbidity and mortality, the effectiveness of the treatment is highly dependent upon early diagnosis (19). Encouragingly, the global scale-up of HIV testing services has indeed been significant. While in 2005 only 10% of people living with HIV (PLHIV) in Africa were aware of their status, in 2015, 55% of PLHIV in Africa, and 60% of PLHIV globally, knew their status (20). However, over 14 million PLHIV do not know their HIV status, indicating that a substantial gap in accessing testing services still exists, and that a considerable amount of work is still required in order to fulfil the United Nations' Fast-Track Strategy to end the HIV epidemic by 2030 (9). Although 150 million HIV tests were performed in 129 low- and middle-income countries (LMICs) in 2014, a subset of 81 of these countries reported that approximately 3% of all HIV tests performed were HIV-positive. As such, depending on the local epidemiology and the approaches used to deliver HIV testing, the reported proportion of HIV-positive test results varies considerably. In many settings, although there is a growing number of HIV tests performed every year, they are not necessarily reaching PLHIV who are unaware of their status, or who are at high risk for HIV infection. These challenges require new focus and new approaches to reach PLHIV who remain undiagnosed early in their infection.

HIV involves a continuum of progressive damage to the immune system from the time of infection to the manifestation of significant immunologic damage (21). Within the first weeks following primary infection, the acute phase of the infection is described by a spike in HIV viraemia, when the virus replicates unchecked by any immune system response. The acute phase is characterized by extremely high viral load (VL) (millions of cp/mL HIV RNA) and high concentrations of p24 antigens that are shed by replicating virus during the early weeks post-infection. The acute phase can last 2–12 weeks and HIV is "highly transmissible" during this period. Subsequent to acute infection, antibodies against HIV infection appear (seroconversion) and are then present throughout the course of the disease (although they can be lost in the very late stages); humoral and cell-mediated immune responses (particularly CD8 T-cell response) then partially suppresses the VL, and p24 levels usually become undetectable (22).

Detection of HIV antibodies is the most common method to screen and diagnose HIV infection, and can be performed using a simple rapid diagnostic test (RDT) or laboratory test. RDTs are particularly effective in resource-limited settings, as they do not require laboratory infrastructure, are easy to use and can be performed on fingerstick blood or oral fluid. Importantly, the use of RDTs has substantially increased patient access and the number of HIV tests performed, and the speed of the assays has

enabled earlier initiation on ART and reduction of patient loss to follow-up. While HIV RDTs are accessible and allow for the screening of HIV-1/2 antibodies, most of these tests are not sensitive prior to seroconversion and will not identify HIV infection in the acute stage (23).

RDTs for self-testing are also helping to overcome some of the shortfalls in HIV testing that have arisen due to unfriendly services, fear of stigma, discrimination and criminalization of behaviour. HIV self-testing enables people to test for HIV infection in private, and is hoped to reach individuals who would otherwise not be reached by conventional HIV testing and counselling services. In November 2016, WHO released new guidelines, recommending that HIV self-testing should be offered as an additional approach to HIV testing services (20). However, WHO recommends that all reactive self-testing must be confirmed via further testing from a trained provider.

Depletion of CD4+ T-lymphocytes is the hallmark and the apparent source of the central immune defect of HIV disease and, as such, determination of the CD4+ lymphocyte count (or percentage) has traditionally been used to guide the initiation of ART in national treatment programmes (24). However, in October 2015, WHO revised the eligibility criteria for initiating treatment, recommending that ART should be initiated among all adults with HIV regardless of WHO clinical stage and at any CD4 cell count, removing the need for CD4 testing for treatment eligibility (25). In addition, direct detection of the HIV viral RNA or pro-viral DNA is now considered the best marker to use for ART monitoring and decision-making after initiation of therapy. Thus, although still important, the role of CD4 testing is becoming more restricted to assessing disease progression in patients and managing patients with advanced HIV disease (24).

The measurement of the number of viral RNA cp/mL in patient plasma (commonly known as VL) provides a clinically useful range of values that can indicate the effectiveness of ART in HIV progression. Nucleic acid tests (NATs) – generally polymerase chain reaction (PCR) or isothermal amplification methods – are used for VL testing, and are considered the most sensitive method for detection of HIV. At the present time, virtually all VL testing is laboratory based, performed using sophisticated, high-throughput instruments. One of the most important barriers to implementing VL testing in resource-limited settings is the relatively high cost of testing, and the fact that samples have to be collected and transported long distances to central laboratories. Increasingly, VL platforms that were validated only for plasma are being validated for whole blood and dried blood spot (DBS) specimens. DBS specimens may result in a decrease in assay sensitivity and specificity compared to plasma. However, these samples allow for simpler and less-invasive blood collection, and can be preserved for long periods of time (without the need for cold-chain storage), with little deterioration of the analytes (26)(27). In addition, compared to conventional venepuncture, less volume is required and the risk of bacterial contamination is minimal. Blood samples usually have to be transferred via couriers to the laboratory for testing (highlighting the advantage of being able to transport DBS without the need for cold-chain storage), and test results are then returned to the clinic or other collection site for dissemination to caregivers. Since this process can sometimes be slow, especially the return of results from laboratories, some countries have introduced short message service (SMS) printers (or other mobile technologies) to achieve markedly improved turnaround time for return of results. Point-of-care (POC) or near-POC systems are also increasingly being developed, as another way to help overcome the difficulties associated with cold-chain transport, lengthy processes and loss to follow-up.

Nucleic acid testing is also important for early infant diagnosis (EID) (28). The persistence of maternal HIV antibodies in infants under the age of 18 months means that the use of antibody tests, such as HIV RDTs, cannot be used to accurately screen infants for HIV. Instead, DNA or RNA testing should be used to diagnose HIV in infants of this age group. Globally, just over 50% of infants born to HIV-positive mothers had access to an infant diagnostic test in 2015 within two months of age (29). Over 90% of paediatric HIV infection happens during pregnancy, delivery or breastfeeding. This is known as mother-to-child transmission. Prompt identification and treatment of infants who are infected via mother-to-child transmission is crucial. One in seven people who die from HIV-related illnesses worldwide are children under the age of 15 (30). WHO currently strongly recommends that all HIV-exposed infants have HIV virological testing at 4–6 weeks of age, or at the earliest opportunity thereafter (31). Furthermore, it is a conditional recommendation that all infants with unknown or uncertain HIV status being seen in health-care facilities at or around birth, or at the first postnatal visit (normally at 4–6 weeks), should also have their HIV status determined by virological testing, for instance, VL or p24 antigen testing. Finally, POC NAT platforms are now conditionally recommended by WHO for diagnosing HIV in infants (<18 months of age).

As well as the importance of RDTs and VL tests for HIV, there is also a need to test for HIV coinfections, and to monitor HIV drug resistance (HIVDR). As ART use increases with the "treat all" approach (regardless of CD4+ T-cell count), a concurrent increase in HIVDR is also expected, particularly in low-resource settings where there is limited access to a broad range of ARV drugs from different drug classes, and whereby HIVDR may necessitate a switch to more expensive treatment options (1)(32)(33). Encouragingly though, new-generation HIV drugs are increasingly finding their way into low-resource settings, thanks to market interventions from global partners. One such drug is dolutegravir, whose cross-resistance profile is limited and for which clinical resistance mutations in treatment-naïve patients are yet to be observed (34)(35). Aside from drug resistance testing, coinfections, which are more serious in PLHIV and often go undetected for long periods of time, must be better diagnosed. Importantly, multi-disease or multiplex platforms that can integrate the testing of HIV and coinfections and/or AMR may help to address these issues.

More information about Unitaid-supported projects can be found here: https://unitaid.eu/core-investment-areas/#en

Overview of HCV diagnostics

WHO estimates that globally, in 2015, 71 million people were living with chronic HCV infection, and nearly 400 000 people died from end-stage HCV infection (36). Despite the significant burden that HCV places on communities, the disease has not been considered as a health and development priority until recently. Target 3 of the United Nations 2030 Agenda for Sustainable Development now calls for specific action to eliminate viral hepatitis (37). This aligns with WHO targets that aim to reduce viral hepatitis infections by 90% and reduce deaths due to viral hepatitis by 65% by 2030 (38). In addition, in May 2016, the World Health Assembly endorsed the Global Health Sector Strategy on viral hepatitis for 2016–2021, which further contributes to achieving the 2030 Agenda for Sustainable Development (6). Crucially, HCV infection is usually asymptomatic and may only be diagnosed many years after a person has been infected, when symptoms of serious liver damage are already present. As such, in order to achieve the aims set out in the 2030 Agenda for Sustainable Development, improved access to screening and diagnosis will be key, especially in high-risk populations. WHO recommends that HCV screening should be targeted towards individuals who are either part of a population with high HCV seroprevalence or who have a history of HCV risk exposure and/or behaviour (for example, infants born to HCV-infected mothers or people who have injected illicit drugs) (39). It is also worth noting that aside from HCV, HBV is also a key target for the elimination of viral hepatitis, as it is estimated that 240 million people are chronically infected with HBV, resulting in 780 000 deaths each year (40).

The nature of HCV disease progression, and the treatment regimens available, mean that testing procedures are currently multifaceted, with the use of a single test being insufficient for full diagnosis. The current WHO guidelines for HCV screening (February 2017) suggest that the detection of HCV infection should begin with serological testing to detect anti-HCV antibodies (either via a laboratory-based immunoassay or POC RDT), followed by confirmatory NAT for those with a positive serological test (39). Antibodies to HCV can be detected in the blood, usually within six months after exposure to the virus (41). While antibody tests can be effective, they are still considered as imperfect tools. Although a positive antibody test or tests mean that the individual has been exposed to HCV in the past, it does not mean that the person has active HCV infection because the individual may have spontaneously cleared the infection. These factors mean that reactive HCV antibody serological test results should be followed up by a confirmatory quantitative or qualitative RNA NAT. Alternatively, if a person was infected with HCV in the recent past, the individual may not yet have produced anti-HCV antibodies, and an antibody test will be negative. Detection of core HCV antigen in assays that have comparable clinical sensitivity to NATs can also be considered (39).

Although the availability of direct acting antivirals has simplified the treatment algorithm for HCV-

infected patients, determining the HCV genotype of a patient is still important, since there is still no true pan-genotypic direct acting antivirals and treatment remains dependent on genotype (42). It is hoped and expected that pan-genotypic direct acting antivirals will reduce the requirement for genotyping, as genotyping currently represents a significant barrier to scaling up HCV treatment, due to the high cost and significant expertise required to run these tests (42). However, for this to become a reality, countries will need to change their policies and algorithms, and better educate physicians about new drugs. Genotyping assays are based on four different technologies: quantitative reverse transcription PCR (RT-qPCR); line probe assays (LPAs); and DNA chip or sequencing. Aside from genotyping, fibrosis staging may also be necessary, for which both biomarker testing and imaging technologies are available (43).

In addition to the multiple types of tests that are currently required to accurately screen and diagnose HCV in mono-infected patients, the fact that HCV often goes undiagnosed as a coinfection is also of concern. HIV and HCV share common routes of transmission, and it is estimated that globally 2.3 million PLHIV are coinfected with HCV, and HIV-infected people are six times more likely than HIV un-infected people to have HCV infection (8). In addition, HBV reactivation reportedly can occur in coinfected people with chronic HCV who are initiated on direct acting antivirals, also highlighting the importance of multiplex testing for HBV (44,45). However, it is important to note that for HBV reactivation, alanine aminotransferase/aspartate aminotransferase monitoring and HBsAg testing are required, therefore, multiplex enzyme immunoassays (EIA) platforms would be needed (46). Ultimately, despite the existence of an effective cure, the number of people living with HCV is increasing, and a global response is clearly required. The complexity and cost of HCV testing and diagnosis means that few individuals living in resource-limited settings currently have access to either. This is further exacerbated by the limited government or donor funding for hepatitis testing and treatment. It is hoped that the increasing emergence of multi-disease diagnostic platforms can help expand access to HCV testing.

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Overview of TB diagnostics

According to WHO estimates, in 2015 alone, there were 10.4 million new incidences of TB (47). Although a largely curable disease, TB still remains one of the top 10 causes of death worldwide, and is now responsible for more deaths than HIV and malaria (47). In 2015, 1.4 million people died from the disease, and a further 0.4 million deaths from TB were reported among PLHIV (47). These figures indicate that diagnostic and treatment gaps still clearly exist, and while access to rapid and accurate diagnosis is critical for the timely initiation of treatment, many people with TB do not yet have access to adequate diagnosis (48,49). Indeed, WHO estimates that approximately 37% of all TB cases were either not diagnosed or not reported to national tuberculosis programmes (NTPs) in 2014 (50). The WHO 2016 Global tuberculosis report noted: "If everyone with TB had a timely diagnosis and high-quality treatment, the case fatality rate would be low in all countries" (47).

Of increasing concern is the rapidly rising prevalence of multi-drug resistant TB (MDR-TB). WHO estimates that there were 480 000 new cases of MDR-TB worldwide, and an additional 100 000 people living with rifampicin-resistant Mycobacterium tuberculosis (MTB/RIF) in 2015 (51). Worryingly, the treatment success rates for MDR-TB and extensively drug-resistant TB (XDR-TB) are only 52% and 28%, respectively (51). Without drug susceptibility testing (DST) to assess drug resistance, patients with MDR-TB may receive inappropriate treatment, leading to a risk of treatment failure in the individual, and drug resistance in the wider community. Recognizing the critical importance of early diagnosis and access to DST, the End TB Strategy has included early diagnosis of TB and universal access to DST as key components of its targets (52).

Some progress in the detection of MDR-TB has been attributed to the use of rapid molecular diagnostics such as LPAs and the Cepheid GeneXpert® MTB/RIF assay. These assays are available and endorsed by WHO, with 6.9 million Xpert/RIF cartridges delivered to countries in 2016 (53). However, a number of NTPs still do not offer universal DST and, as a result, fewer than one in four cases of MDR-TB are detected (52). In many countries, the diagnostic infrastructure in the public sector still relies primarily upon clinical (in 57% of cases) or sputum smear microscopy (SSM), rather than bacteriological confirmation, and SSM cannot detect drug resistance (47). Patients often only receive MDR-TB screening when they fail to respond to standard first-line TB treatment, or have a recurrence of TB; this contributes to morbidity, mortality and continued transmission. While the Xpert® MTB/RIF assay is a much-needed breakthrough, it was not designed to reach lower tiers of the health-care system, and not intended to meet all needs – for example, it cannot detect resistance against multiple drugs. Cost is also a hurdle for many NTPs and private sector providers, especially since the latter is typically excluded from subsidized pricing agreements. A recent survey of Xpert® MTB/RIF use in 22

high-burden countries suggested that most NTPs only use the assay for selected patients at risk of multi-drug resistance or HIV and not as a tool for early case detection in all patients with presumed TB (54). In these HBCs, confirmation using Xpert® MTB/RIF is desirable, but not always possible due to the unavailability of a GeneXpert system or a lack of resources in certain settings (55). Thus, a majority of the high-TB burden countries still rely on SSM as the primary and, often, sole diagnostic test.

Aside from MDR-TB, access to accurate diagnosis is also a major challenge in children with suspected TB, and in PLHIV coinfection. An estimated 1.2 million new cases of TB in 2015 were among HIV-positive people, and 35% of HIV deaths were due to TB (51). HIV coinfection also leads to the increased likelihood of false-negatives when testing for TB, further complicating the diagnosis of TB (56). Treatment is also more difficult with HIV coinfection as there are considerable interactions between drugs used to treat each infection (57). Rifamycins, which form the crucial component of TB treatment regimens, induce several enzymes involved in ARV drug metabolism, which may result in a significant reduction in exposure to ARV medication (58). Therefore, this must be taken into consideration in HIV and TB-infected individuals, and doses adjusted accordingly or drugs that interact less readily chosen instead (57,58). As such, devices that can allow for the detection of coinfections can be considered important. In addition, it is estimated that 1 million children contracted TB in 2015, although the true case burden of childhood TB is likely higher than estimated, with childhood TB being notoriously difficult to diagnose (47). TB in children is often missed, due to non-specific symptoms and lack of a sensitive and child-friendly diagnostic tests (59).

With appropriate and timely diagnosis, TB is largely curable with currently available medicines. However, initiation of appropriate TB drug regimens is impossible without timely access to the right diagnostic tools for both TB disease and drug resistance. Ultimately, TB diagnosis, in particular for asymptomatic TB patients* (60), and knowledge of the appropriate treatment are poor. Better access to more appropriate, effective diagnostic tools will, therefore, be critical to improved detection and care of TB in the near future. Multi-disease diagnostics, which can integrate the screening of TB with the sequential or simultaneous screening of other infectious diseases as well as DST are, therefore, gaining particular interest in this field.

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* Asymptomatic TB patients could be as high as two thirds of all people infected with TB (60); this group includes people who are less likely to be symptomatic or smear positive, e.g. HIV patents and children.

Multi-disease diagnostics

As may be evident from the previous sections, the use of traditional singleplex tests/assays for diagnosing individual infectious diseases, although highly effective, may not always be optimal programmatically. The need to screen for multiple infections at the same time may be especially important in high-risk populations, where more than one infectious disease is highly prevalent. In addition, in high-income settings, mortality in PLHIV is increasingly being caused by non-HIV related diseases, with HCV coinfection being highlighted as having a particularly significant impact (61,62). Although there are data limitations due to weak surveillance, similar trends are also being observed in low-resource settings, particularly in populations with a growing epidemic of people who inject drugs (63). Infectious diseases, most prominently TB, bacterial and fungal infections, are known to be the main causes of morbidity and mortality in PLHIV in low-resource settings (64,65). A systematic review and meta-analysis, investigating the contribution of different co-morbidities to hospital admission/mortality worldwide, indicated that HV-related illnesses (predominantly TB) and other bacterial and fungal infections were the leading causes of hospital admission and mortality (66). Together, these co-morbidities contributed to 80% of hospital mortalities in adults living with HIV. The contribution of coinfection and co-morbidities to HIV morbidity and mortality are anticipated to remain or even increase despite ART expansion, and PLHIV age on treatment. Adding to the concern, the burden of coinfections is likely underrepresented, especially in low-resource settings where diagnostic testing facilities for many coinfections are scarce. Leveraging cross-disease testing could help to expand the epidemiological knowledge of the coinfection burden and, therefore, encourage an increase in coinfection screening in PLHIV.

As well as the detection and identification of targeted pathogens, an understanding of the clinical importance of pathogen variation, and AMR, is also required in order to guide appropriate treatment selection, and to help reduce the emergence of new drug-resistant strains (67). These needs are becoming increasingly important, since AMR is emerging as a major worldwide concern. According to the United Kingdom Review on AMR, around 700 000 lives per year worldwide are thought to be lost to antibiotic-resistant infections, and the continued rise in AMR is expected to lead to 10 million deaths per year by 2050 (13). To curb these projections, AMR testing needs be implemented more routinely, ideally alongside testing for infectious diseases, in order to better inform treatment decisions.

It is hoped that multi-disease platforms can help to address these issues, thereby leading to greater efficiencies in clinical and programmatic management of these diseases. Running single RDTs for a number of infectious diseases requires larger patient samples, multiple kits/buffers and reagents, and increased labour. While multi-disease RDTs could potentially be more expensive than singleplex

RDTs, if it is feasible to identify target populations with coinfections, then multi-disease RDTs could potentially offer a cost-effective solution. However, if not, the testing cost may end up being higher if it is necessary to test multiple sets of target populations with a more expensive multiplex RDT in order to find a small proportion of coinfected patients. Overall, with the potential for low implementation costs, and time-saving abilities, multiplex RDTs may allow for the transformation of the diagnostic screening landscape and the detection of infections that would have otherwise been missed (10).

There are, however, significant programmatic considerations that need to be addressed to ensure the success of multi-disease platforms, including: coordinated planning led by the local Ministry of Health to support efficient implementation of multi-disease testing; streamlined and coordinated regulatory approval and validation of devices/assays to avoid duplication of efforts; appropriate product and site selection to maximize the capacity of devices/assays, clinician training and demand generation to ensure multi-disease testing is utilized when appropriate; and inventory management and procurement to allow cost savings. The full list of considerations and detailed explanation of each consideration is available from WHO (18).

High-throughput, automated NAT systems that allow for multi-disease testing also hold promise in the infectious disease diagnostic field. To minimize capital equipment investment, it is more cost effective for a laboratory to run multiple assays on one platform, rather than having to invest in a different platform for each test. In addition, a single platform minimizes issues of training, maintenance and supply chain logistics. Moreover, while the high-throughput platforms should not be overlooked, more sophisticated multi-disease platforms are also emerging, combining newer technologies – such as microfluidics, nanotechnology and biosensors – that are portable and can be used at or near the POC. Furthermore, the differences in chemistry and processing requirements for proteins and nucleic acids mean that most instruments have traditionally supported either multi-disease protein testing or multi-disease nucleic acid testing. However, several new systems are now being developed for both protein and NAT testing, enabling an integrated platform for screening, confirmatory and monitoring tests, often at or near the POC.

The high potential for multi-disease platforms to improve the diagnosis of infectious diseases, and in certain circumstances to reduce the cost of diagnosis, means that their development is gaining interest around the world. The primary focus of this landscape report is, therefore, to gather information regarding the current technologies that are being used for multi-disease diagnostics and the devices/tests that are currently on the market. In addition, emerging technologies and products in development are also discussed, in order to provide a better understanding of the landscape in this rapidly evolving field.

Technology landscape

Numerous technologies have been deployed in the design of multi-disease platforms, including immunochromatography, PCR, microfluidics, nanotechnologies and next generation sequencing (NGS), making it an exciting area of development for infectious disease diagnostics. The next sections provide an overview of the technologies and devices that are on the market or in development within the multi-disease infectious diseases diagnostics landscape. This landscape report can be broadly split into the immunoassay-based diagnostics and the NATs, with further subcategorization. Also noted are several emerging platforms that can test for both molecular and immunoassay targets, offering an interesting multi-disease approach, and allowing for increased diagnostic sensitivity for patients at different stages of disease progression (68).

Immunoassays

Immunoassays have been in use for well over 50 years, and have remained as one of the most successful and widely used techniques for diagnosing infectious diseases (68). Although the method has traditionally involved multi-step processes, which are time consuming and labour intensive, there has been an impressive amount of progress within the field, with more rapid and high-throughput immunodiagnostic platforms now available. Regardless of the underlying technology, immunoassays are usually based upon four core components: (i) the antigen to be detected; (ii) the antibody used for detection; (iii) the separation of bound antibody-antigen complexes from unbound reactants (some assays do not require this step, e.g. binding event detection assays); and (iv) the detection method (69). However, integration of new technologies and automation has meant that there is now a variety of immunoassay-based diagnostic systems/tests available, offering increased simplicity, speed and sensitivity. Multi-disease immunoassay-based platforms that may have the potential to help meet global health demands for infectious disease diagnosis are outlined in the sections below.

Enzyme immunoassay (EIA)/ chemiluminescence immunoassay (CIA) automated platforms

Automated EIAs and CIAs have reduced the extensive time, labour and training requirements that traditionally have been associated with processing such assays. Broadly speaking, EIAs use enzyme-labelled antibody/antigen to detect antibody/antigen, with the enzyme-linked immunoassay (ELISA) being the most common detection method of EIA. CIAs use the same fundamental test principle, but while the end-point detection in EIAs is measured as colour change, luminescence is used in CIAs.

While these automated platforms still typically require specialized instrumentation, infrastructure and trained laboratory technicians, and can only be implemented in centralized laboratories, considerable value can still be derived from these more centralized systems/higher-level technologies. These platforms typically support high-throughput, walk-away solutions that are accurate and compatible with large test menus. Available automated EIA/CIA platforms are outlined below, while the more extensive specifications of these devices can be found in Appendix 2.

Abbott ARCHITECT Immunoassay Range (Abbott)

The Abbott ARCHITECT Immunoassay Range includes the ARCHITECT i1000SR (which allows for up to 100 tests/hour), the ARCHITECT i2000SR (up to 200 tests/hour), the ARCHITECT i4000SR (as shown in the picture) and a multi-module system consisting of two ARCHITECT i2000SR systems for high-volume immunoassay demands (up to 400 tests/hour). The systems use CIA technology known as CHEMIFLEX. The test menu for infectious diseases includes assays for HCV, HBsAg, HIV, Treponema pallidum (syphilis; TP), toxoplasmosis and Epstein-Barr virus. The ARCHITECT Immunoassay Analyzers can also be integrated with the ARCHITECT clinical chemistry analyzers to consolidate clinical chemistry and immunoassay testing into one module.

Abbott PRISMnEXT (Abbott)

The Abbott ARCHITECT Immunoassay Range includes the ARCHITECT i1000SR (which allows for up to 100 tests/hour), the ARCHITECT i2000SR (up to 200 tests/hour), the ARCHITECT i4000SR (as shown in the picture) and a multi-module system consisting of two ARCHITECT i2000SR systems for high-volume immunoassay demands (up to 400 tests/hour). The systems use CIA technology known as CHEMIFLEX. The test menu for infectious diseases includes assays for HCV, HBsAg, HIV, Treponema pallidum (syphilis; TP), toxoplasmosis and Epstein-Barr virus. The ARCHITECT Immunoassay Analyzers can also be integrated with the ARCHITECT clinical chemistry analyzers to consolidate clinical chemistry and immunoassay testing into one module.

AxSYM/AxSYM Plus System (Abbott)

The Abbott ARCHITECT Immunoassay Range includes the ARCHITECT i1000SR (which allows for up to 100 tests/hour), the ARCHITECT i2000SR (up to 200 tests/hour), the ARCHITECT i4000SR (as shown in the picture) and a multi-module system consisting of two ARCHITECT i2000SR systems for high-volume immunoassay demands (up to 400 tests/hour). The systems use CIA technology known as CHEMIFLEX. The test menu for infectious diseases includes assays for HCV, HBsAg, HIV, Treponema pallidum (syphilis; TP), toxoplasmosis and Epstein-Barr virus. The ARCHITECT Immunoassay Analyzers can also be integrated with the ARCHITECT clinical chemistry analyzers to consolidate clinical chemistry and immunoassay testing into one module.

VIDAS®/miniVIDAS®/VIDAS® 3 (Bio-Mérieux)

The VIDAS®, VIDAS 3® and miniVIDAS® are automated, multiparametric immunoassay systems based on the enzyme linked fluorescent assay (ELFA) principles. The mini VIDAS® is a compact version of the VIDAS® with a built-in computer, keyboard and printer. Up to 12 samples can be processed simultaneously on the mini VIDAS® and all EIA reaction stages are performed automatically – pipetting, incubating, washing, reading – and results are sent immediately to an integrated printer (results are provided within 17–90 minutes). The CE marked, US FDA approved and China FDA approved VIDAS® 3 is the new generation VIDAS® instrument, designed specifically for low- to medium-throughput testing, and is equipped with increased automation, traceability and productivity (up to 36 tests/hour). The VIDAS® systems test menu includes assays for HCV, HBV, HAV, HIV-1/2, CMV and Epstein-Barr virus. The VIDAS® B.R.A.H.M.S PCT assay is also able to distinguish between bacterial infections and sepsis.

ETI-Max 3000/Freedom EVOlyzer 2-150/8 (DiaSorin)

The CE marked and US FDA approved ETI-Max 3000 and the CE marked Freedom EVOlyzer 2-150/8 (pictured) are both fully automated microplate-based ELISA analyzers, able to perform sample processing, measurement and evaluation. More than 150 tests are available for both analyzers, including CE marked tests for HCV, HBV, HAV, HIV-1/2, toxoplasmosis and TP. Many tests are also US FDA approved (see Appendix 2 for details of this and all other devices). The Murex HIV Ab/Ag assay is designed to detect both HIV antibodies and the p24 antigen (Ag) in a single assay run, thereby allowing detection of HIV infection prior to seroconversion (70). The Murex anti-HCV assay, Murex HIV Ag/Ab Combination assay, and Murex HBsAg Version 3 have all been accepted for WHO Prequalification (WHO PQ). In addition, their HCV Ag/Ab Combination assay is also currently under WHO PQ assessment. The machines are capable of running at least 50 samples/hour.

LIASON®/LIASON® XL (DiaSorin)

The CE marked and US FDA approved LIASON® and LIASON® XL utilize a CIA technology with magnetic microparticles. The LIASON® analyzer provides the possibility of running up to 15 different assays at a time and can process up to 180 samples/hour. The LIASON® XL (pictured) is fully automated, performing complete sample processing (sample pre-dilutions, sample and reagent dispensing, incubations, wash processes, etc.) as well as measurement and evaluation. DiaSorin offers a range of CE marked and US FDA approved tests for the LIASON® analyser, including HCV, HBV, HAV, HIV-1/2, toxoplasmosis, TP, CMV, sepsis, Chlamydia trachomatis and HSV-1/2. The Murex assays mentioned above for the ETI-Max 3000/Freedom EVOlyzer 2-150/8 can also be run on this platform.

BEP® III System/BEP® 2000 Advance System (Siemens Healthcare)

The BEP® III System (pictured) and BEP® 2000 Advance System are both automated platforms for microtitration plate processing (from incubation and washing, through to reagent pipetting and result evaluation). The BEP® III System can achieve high-throughput, running up to 10 microtitration plates in parallel. The system can also be connected to the Quadriga BeFree® System to manage higher volumes, allowing for up to 3000 results to be generated in an 8-hour shift for maximized walk-away operation. The BEP® 2000 Advance System is designed for low- to mid-volume labs, being able to process up to four microtitration plates simultaneously, plus one microtitration plate by reloading, and up to 100 patient samples at the same time. Siemens Healthcare markets the CE marked Enzygnost® and Novagnost® ELISA assays for use on the BEP® III and BEP® 2000 Advance Systems, allowing for testing of a range of infectious diseases, including HIV-1/2, HBV, HAV, HCV, HSV-1/2, CMV, Epstein-Barr virus, dengue virus, Chlamydia trachomatis and chikungunya virus. Of particular note are the company's Enzygnost® HBsAg 6.1, and HIV Integral 4 immunoassay (that can test for HIV antibodies and p24 antigen), which both received WHO PQ in March 2016. In addition, the Enzygnost® anti-HCV immunoassay is currently under WHO PQ assessment.

Rapid diagnostic tests (RDTs)

RDTs have been in use for many years and are considered important tools for screening of infectious diseases in all settings. In low-resource settings, where access to quality and timely medical care is challenging, RDTs allow simple and quick testing, with diagnosis at the POC, during the same clinical visit. These factors are especially important where patients are frequently lost to follow-up, and there is generally minimal infrastructure and a lack of trained practitioners. Over recent years, RDTs have significantly improved diagnosis of diseases such as HIV and malaria, and combined multiplexed RDTs are now more commonplace (71). Although individual POC tests for many key infectious diseases are available, in certain populations there is the need to screen for multiple diseases. For example, many sexually transmitted infections (STIs) are often asymptomatic or atypical in presentation and are linked to HIV. Carrying out multiple singleplex RDTs in this instance will be time consuming and require larger samples of blood and multiple kits/reagents. Multiplex POC RDTs could help to solve these problems, acting as broad screening tools, able to detect infections that are frequently missed. However, it is important to note that multiplex RDTs may be more expensive than singleplex tests and, as such, their use in LMICs may be cost prohibitive, and their implementation may only be suitable in high-risk populations. Thus, if combined multiplex tests are more expensive than singleplex assays, yet the total cost is still less than the cost of the combined individual tests, then this may be an affordable and economical solution.

There are a number of RDTs available that use either the standard immunochromatography (lateral flow) technology or immunofiltration (vertical flow) technology to detect the presence of antibodies in a sample. Generally, a specimen (whole blood, plasma, serum or oral fluid) is collected and mixed with a developing solution, such as colloidal gold labelled with protein-A (72)*. This mixture is then applied to the absorbent membrane of the test device, which contains immobilized antigens in the test area of the assay. Typically, as the sample fluid moves through the test area a coloured line or dot appears, if antibodies from the sample react in the test area. Tests also have an internal control area that contains a monoclonal antibody and confirms that the test sample has adequately passed through the test area by showing another coloured line or dot. If there is no coloured line or dot, then the test is invalid. If there is only a control line or dot, then the test is valid and negative.

* Some tests do not require this step and the sample can be added directly to the device.

Many RDTs can be performed on fingerstick blood, which is generally considered as less invasive and requires less staff training compared to venous blood collection (26). However, some multiplex RDTs require serum or plasma samples, meaning that a centrifuge is required to separate plasma or serum from the patients' blood specimen before testing. In addition, some of the RDTs require cold-chain storage of test kits. Furthermore, although RDTs approved by rigorous regulatory bodies typically have good performance characteristics (73), certain RDTs have sometimes lacked sufficient clinical performance (sensitivity and specificity), and have been prone to human error in terms of poor sample handling, inaccurate buffer or sample handling, inconsistent visual reads, poor test design and unclear manufacturer's instructions, among other things (74). Insufficient quality control measures of test accessories and buffer packaging has also affected the effective use of antigen-detecting malaria RDTs (75). In addition, the reagents themselves are often not of sufficient quality to develop the best assays possible on these devices. Reagents that work best in one immunoassay format, such as EIA, are not necessarily the best in another format, such as RDT. Available multiplex RDTs are described below (full profiles of these tests can be found in Appendix 2).

HIV/syphilis combination RDTs

Syphilis is an infection caused by the spirochete Treponema pallidum (TP). Although curable, the infection can be hard to differentiate from other STIs and, as such, the availability of diagnostic tests is critical to the correct identification and management of the infection. The implementation of HIV screening programmes at POC has been successful in many LMICs. The use of combined RDTs, which can allow for the detection of HIV and syphilis simultaneously, and which could allow for the integration of syphilis screening (and currently affects 5.6 million people) into already existing HIV screening programmes may, therefore, be beneficial in high-risk settings such as antenatal care (9,76,77). Potential benefits of combined HIV/syphilis RDTs include streamlined procurement, minimalized storage space, simplified training of health-care personnel, only a single fingerprick required, receipt of test results and treatment in a shorter time period, and reduced unit cost for the reagents compared to two single RDTs (78). Several HIV/syphilis combined RDTs are currently on the market, however, only the Alere/Standard Diagnostics SD Bioline

HIV/Syphilis Duo Rapid Test has passed WHO PQ and received CE marking. BioLytical's Insti HIV/Syphilis Multiplex RDT and Chembio Diagnostic Systems' HIV/Syphilis RDT also have received CE marking. HIV/syphilis combination RDTs are outlined in the sections below. The detailed characteristics and sensitivity/specificity values (as reported by the companies) are outlined in Appendix 2. It must be noted that sensitivity/specificity values reported by companies may be unreliable and that independent studies and/or stringent regulatory approval is important to determine the true, real-world values.

SD BIOLINE HIV/Syphilis Duo (Alere/Standard Diagnostics)

Standard Diagnostics SD BIOLINE HIV/Syphilis Duo solid phase immunochromatographic assay is CE marked, received WHO PQ in 2015 and is on the United States Agency for International Development Waiver List. The assay allows for the qualitative detection of antibodies to all isotypes (IgG, IgM and IgA) specific to HIV-1/2 and TP simultaneously in human serum, plasma or whole blood, and has a turnaround time of around 20 minutes. The test performance has been independently evaluated in numerous studies (79–86).

INSTI HIV/Syphilis Multiplex Test (BioLytical)

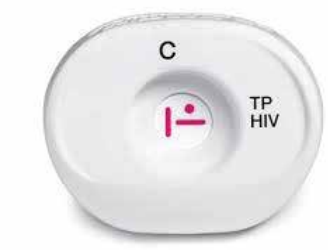
BioLytical's Insti Multiplex RDT is CE marked and can simultaneously test for HIV and syphilis from whole blood, serum or plasma in less than 60 seconds, using downward flow immunofiltration. Alcohol swabs, pipette and lancet are included in the packet and no timers are required. The test has been independently evaluated in at least one study (77).

DPP® HIV/Syphilis Assay (Chembio Diagnostic Systems)

Chembio Diagnostic Systems has developed a dual HIV/Syphilis RDT using their immunochromatographic Dual Path Platform® technology. The company claims that their DPP® technology has a number of advantages over conventional lateral flow tests, including increased sensitivity and resolution of aggregation/agglutination migratory issues, which have been associated with lateral flow assays. The turnaround time for the assay is approximately 15 minutes and allows for the detection of antibodies to HIV-1/2 and TP in fingerstick whole blood, venous whole blood, serum and plasma. The assay recently received CE marking (January 2017) and is on the United States Agency for International Development Waiver List. Some independent performance studies have been conducted (83,87). Studies with a Chembio HIV-HCV RDT and Chembio HIV-HCV-Syphilis triplex RDT have also been reported (73), but these tests are not listed on the company's website, and the company could not be contacted to provide an update on the status of these products.

OnSiteTM HIV/Syphilis Ab Combo Rapid Test (CTK Biotech)

Standard Diagnostics SD BIOLINE HIV/Syphilis Duo solid phase immunochromatographic assay is CE marked, received WHO PQ in 2015 and is on the United States Agency for International Development Waiver List. The assay allows for the qualitative detection of antibodies to all isotypes (IgG, IgM and IgA) specific to HIV-1/2 and TP simultaneously in human serum, plasma or whole blood, and has a turnaround time of around 20 minutes. The test performance has been independently evaluated in numerous studies (79–86).



Multiplo Rapid TP/HIV Antibody Test (MedMira)

BioLytical's Insti Multiplex RDT is CE marked and can simultaneously test for HIV and syphilis from whole blood, serum or plasma in less than 60 seconds, using downward flow immunofiltration. Alcohol swabs, pipette and lancet are included in the packet and no timers are required. The test has been independently evaluated in at least one study (77).

HIV/HCV/HBV combination RDTs

The integration of HBV/HCV screening is also becoming more prevalent and is considered a potentially valuable method of diagnosing viral hepatitis in high-risk populations, such as drug users. HIV, HBV and HCV are all bloodborne viruses with common routes of transmission (intravenous drug use, sexual contact and direct contact with the blood of an infected person). As a result, people at risk of HIV infection are also at elevated risk of HBV and/or HCV infections. Highlighting this, in PLHIV, an estimated 2–15% are also coinfected with HCV, and 5–20% of people develop chronic HBV infection (89). Most HIV/HBV coinfected people live in sub-Saharan Africa (71%; 1.96 million), while Eastern Europe and Central Asia account for the largest proportion of HIV-infected people who have serological evidence of past or present HCV infection (27%; 0.62 million), due to injection drug use (36). The lack of access to diagnostics in these regions means that the majority of individuals only become aware of their HBV and HCV status in the late, advanced stages of the disease when liver cirrhosis or hepatocellular carcinoma are noticed (90). The WHO Global Health Sector Strategies for HIV and Viral Hepatitis include goals to reduce the number of new HCV and HBV infections per year from 6–10 million in 2015 to 900 000 in 2030, and to reduce the number of deaths as a result of HBV and HCV from 1.4 million in 2015 to below 500 000 by 2030. A paradigm shift towards screening individuals for HIV and HCV/HBV simultaneously at the POC may help to achieve these goals. Several combined HIV/HCV/HBV RDTs are commercially available, as outlined in the sections below; none have yet received WHO PQ. The detailed characteristics and sensitivity/specificity values (as reported by the companies) are outlined in Appendix 2.

Artron Detect 3 HIV/HCV/HBV Combo (Artron Laboratories)

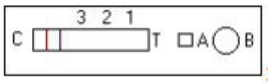
Artron Laboratories has developed the Detect 3 HIV/HCV/HBV Combo kit, a CE marked lateral flow RDT. The test can be used with plasma or serum samples. The time taken to perform a test was unknown at the time of writing.

One Step HIV/HBsAg/HCV Serum Test Panel (Atlas Link (Beijing) Technology)

Atlas Link (Beijing) Technology has developed the CE marked One Step HIV/HBsAg/HCV Serum Test Panel, a lateral flow RDT for the simultaneous detection of HIV-1/2, HBV and HCV infection in serum samples, in less than 20 minutes.

HIV/HCV/HBsAg Panel Test (Boson Biotech)

Boson Biotech's HBsAg/HIV/HCV Panel Test is an immunochromatography assay for the qualitative detection of HBsAg, and antibodies against HIV-1/2 and HCV in serum, plasma or whole blood. The panel has been approved by the China FDA. Results must be read 20 minutes after adding the sample.



Core Combo HIV/HBsAg/HCV (Core Diagnostics)

The Core Diagnostics Core Combo HIV-HBsAg-HCV assay is a lateral flow immunochromatography assay for the qualitative detection of antibodies to HCV, HIV-1/2 and HBsAg in human serum, plasma or whole blood specimens. Results can be read after 15 minutes. The regulatory status was unknown at the time of writing.

OnSiteTM HBsAg/HCV Ab Rapid Test (CTK Biotech)

Similar to their HIV/Syphilis RDT test, CTK Biotech's OnSiteTM HBsAg/HCV Ab Rapid Test is a lateral flow immunochromatographic RDT for the qualitive detection of HBsAg and anti-HCV antibodies (IgG, IgM, IgA). The test can be performed using whole blood, serum or plasma and results are available within 15 minutes. The assay is RUO.

HIV/HBsAg/HCV Combination Rapid Test (Maternova Inc.)

The Maternova inc. HIV/HBsAg/HCV Combination Rapid Test is a lateral flow RDT for the qualitative detection of HBsAg, HCV and HIV-1/2 in human serum or plasma samples. The time taken to perform the test was unknown at the time of writing. The device is CE marked.

Multiplo Rapid HBc/HIV/HCV antibody test (MedMira)

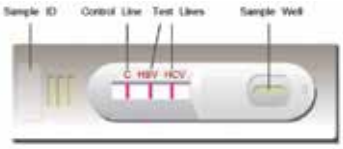
Similar to their Multiplo Rapid TP/HIV antibody test, MedMira's Multiplo HBc/HIV/HCV test uses the company's patented Vertical Flow Technology platform and allows for the simultaneous detection of HIV-1/2, HBV and HCV. The test takes approximately three minutes to carry out. The product is currently RUO.

Combiquic HIV/HCV (Qualpro Diagnostics)

Qualpro Diagnostics Combliquic HIV/HCV test is an immunoconcentration (flow through) assay for the simultaneous detection of antibodies to HIV-1/2 and HCV in human serum or plasma. The test takes about five minutes and results are read from the assay immediately. The product is currently RUO.

HIV-HCV Dual Test (ReLIA Diagnostics)

ReLIA Diagnostics HIV-HCV dual test is a colloidal gold-based immunoassay that detects HIV-1, HIV-2 and HCV antibodies in whole blood, plasma or serum. Results can be read by the ReLIA II multi-functional immunoassay instrument removing human error due to result judgment. The test takes less than 20 minutes. The product is currently RUO.



HBsAg/HCV Ab Rapid Test (Spectrum)

Spectrum's HBsAg/HCV Ab Rapid Test is a lateral flow immunochromatographic assay for the qualitative detection of HBsAg and IgG, IgM and IgA anti HCV antibodies in serum, plasma and whole blood. Results can be read in 15 minutes. The regulatory status was unknown at the time of writing.

HBsAg and HCV Combo Test (UAB Euro Genomas)

UAB Euro Genomas has developed the HBsAg and HCV Combo Test, a lateral flow RDT for the simultaneous detection of HBsAg and HCV in human serum and plasma. The time taken to carry out the test was unknown at the time of writing. The test is CE marked.

TP/HBV/HIV/HCV quadruple RDTs

As outlined below, some quadruple RDTs able to simultaneously detect for TP, HBV, HCV and HIV have also been developed (see Appendix 2 for full available specifications on these assays).

iCARE HBsAg/HCV/HIV/Syphilis Combo Rapid Test Cassette (JAL Innovation)

JAL Innovation's iCARE HBsAg/HCV/HIV/Syphilis Combo lateral flow immunochromatographic RDT allows the user to test for HIV-1, HIV-2, HCV, TP and HBsAg. The test is not CE marked or US FDA approved, but is on the market in select regions. The test takes around 10 minutes to carry out.

HBsAg/HCV/HIV/Syphilis Combo Test (UAB Euro Genomas)

UAB Euro Genomas has developed the HBsAg/HCV/HIV/Syphilis Combo Test, a lateral flow RDT for the simultaneous detection of HBsAg, HCV, HIV-1/2, and TP in human serum and plasma. The test is CE marked. Time to result was unknown at the time of writing.

Accessories for RDTs

AX-2X (Axxin)

POC RDTs offer an effective and simple method for multiplex testing. However, these assays rely on visual interpretation, and can be prone to errors. To help overcome some of these issues, devices have been developed to automate the process. Axxin has developed a portable instrument designed to provide qualitative and quantitative results for colorimetric and fluorescent immunoassays.

Deki Reader V100 (Fio Corporation)

Fio Corporation has developed the Deki Reader V100 that is CE marked and on the market in Africa and Latin America. The device can currently identify and interpret (in IVD/diagnostic mode) five malaria and two dengue virus RDTs from various manufacturers. The company is also working to add new RDTs to the Deki Reader menu, including HIV tests, some of which can already be run in "Research Use Only" mode (but not yet in IVD/diagnostic mode). The company indicated that most customers use the Deki Reader in "Assist Mode" in which the device shows step-by-step guidance on how to process the RDT, provides a pre-programmed countdown timer for the specific RDT and displays the results consistent with the RDT package insert – positive, negative or invalid. Of note, the Deki Reader also uses algorithms to detect typical errors that users make while processing an RDT, for example, adding too much whole blood, or adding the wrong ratio of blood to buffer. If the Deki Reader detects one of these errors, it will show an "Error Detected" message on the results screen and tell the user to repeat the test. Since all Deki Readers are wirelessly connected to Fionet – a cloud database and information system, remote stakeholders can visualize all patient test results and user performance data as well as perform analytics and generate reports from all Deki Readers deployed in the field. Fio Corporation is also currently developing the Deki Reader V200, which is expected to be available in late 2017 and will have some added hardware features such as a larger screen, swappable battery and USB ports.

Universal Reader (Global Solutions for Infectious Diseases [GSID])
GSID has been developing and field testing mobile health tools to digitize and transmit diagnostic results for important infectious diseases. By aggregating results from multiple sites, their system is designed to help manage disease control programmes and provide real-time infectious diseases surveillance directly from the POC in LMICs.

mReader (Mobile Assay)
Mobile Assay's "lab-on-Mobile-Device" platform allows real-time analysis and quantification of RDTs on tablets and phones running the Android Platform. The company states that its software works with virtually any RDT, lateral flow test strip or colormetric strip. A number of tests have been validated for use with mReader, including SD Bioline's Malaria Ag P.f.

ReLIA Multi-Functional Immunoassay Instrument (ReLIA Diagnostics)
ReLIA Diagnostics has developed an RDT reader that is able to run different assays simultaneously, providing both quantitative and qualitative results within 20 minutes. The device is currently RUO. It is designed to avoid operator error by detecting whether the user has used the correct volume of sample and buffer.

Pipeline RDTs

Developer	Product name	Image	Technology	Launch date
BioSynex	HIV+cryp-to+HCV	No image available	BioSynex makes singleplex RDTs for cryptococcus, HIV and HCV, and are evaluating the possibility of combi-ning these tests on one cassette.	TBD
Chembio Diagnostics Systems	N/A	No image available	Alongside their DPP® RDT HIV-Syphi-lis multiplex assay, the company has also reported a number of grant-funded projects to expand its portfolio into multiplex DPP® assays for “fever” diseases such as malaria, dengue virus, Ebola virus, Zika virus and chikungunya virus.	TBD
MedMira	Miriad Rapid TP/HBV/HIV/ HCV quadruple multiplexed test	No image available	According to some reports, MedMira is developing the Miriad Rapid TP/ HBV/HIV/HCV quadruple multiplexed test using the same Vertical Flow Technology as in its Multiplo assays. The test has been used as an inve-stigational device, and was deemed feasible, and preferred over conven-tional testing methods when evalua-ted in at-risk populations. Its current development status is unknown (71).	TBD

"Next generation" immunoassays

In addition to the RDTs and more traditional immunoassay technologies, several "next generation" immunoassay-based platforms that can be used at the POC or near-POC, are also emerging. These platforms are integrating novel technologies such as microfluidics, nanotechnologies and surface plasmon resonance with immunoassay-based techniques, enhancing diagnostic capabilities in resource-limited settings (68). In addition, strategies that can combine both NATs and immunoassays are being developed, allowing for the more sensitive detection of infection at different disease stages 63. In particular, biosensor-based immunoassay technologies are looking very promising in the infectious disease field. The advantages of this technology include the short assay time, low energy consumption, high portability and throughput, multiplexing ability, increased sensitivity and specificity, and reduced fluid volume requirement (less reagent and reduced cost) (91). A biosensor can be defined as an analytical device that uses a transducer to convert the molecular recognition of a target into a measurable signal, such as a change in mass, refractive index, current flow or heat transfer (91). Typically, biosensors consist of three components:

- the detector or biorecognition element (which identifies the stimulus/analyte);
- the transducer (which converts the stimulus into a useful output); and
- the signal processor (which displays the output in a readable format) (92).

Ideally, biosensors should be selective, rapid, portable and require minimal sample processing. Recent advances in biosensor technologies are helping to achieve these goals, and the potential to deliver biosensor-based POC diagnostics that match or surpass conventional standards in terms of time, accuracy and cost is now being realized (91). New emerging biosensors typically combine diverse signal transduction techniques, such as electrical, optical and mechanical transducers, with micro- and nanofabrication technologies (93). Biosensor-based immunoassays that are in development for diagnosing infectious diseases are profiled in the sections below (some of the devices are already on the market, but assays for infectious pathogens are still in development).

Pipeline “next generation” immunoassay-based platforms/tests

Developer	Product name	Image	Technology	Launch date
Axela	dotLab® mX System		The dotLab® mX System from Axela uses its proprietary diffractive optics technology to perform traditional immunoassays within 30 minutes. Capture molecules, such as antibodies, are immobilized on an ordered pattern of lines that form a diffraction grating on the surface of the dotLab® sensor. The patterned molecules are illuminated with a laser, and subsequent binding of antigens then increases the height of this surface pattern, producing an increase in the diffraction signal intensity, which can then be detected in real time. Multiplex assays for infectious disease screening can be carried out with Axela’s customizable panelPlusTM Sensors. The company is also reportedly in the process of developing its next generation diffractive optics instrument and sensor disks, allowing for improved speed, throughput and multiplexing capabilities.	Launched; multiplex assays for infectious disease screening currently have to be customized using panelPlusTM Sensors. Next generation device in development.
Biosensia	RapiPlex Platform		A multiplexing diagnostic POC immunoassay platform that uses fluorescence detection.	Late 2017
Columbia University	Smartphone Dongle		Smartphone dongle device able to perform an ELISA at the POC using microfluidics and energy from a smartphone.	TBD
Diagnostics for All (DFA)	Rapid Nucleic Acid test kit		DFA is developing a nucleic acid amplification-based paper-microfluidic device. The company is developing tests for a number of diseases including EID HIV, Ebola and HCV.	TBD

Developer	Product name	Image	Technology	Launch date
McGill University	Smartphone Dongle		A paper-based microfluidic electrochemical immunoassay-based biosensor array for multiplexed detection of disease markers.	~2021
OPKO Diagnostics (formerly Claros Diagnostics)	Claros®1 Analyzer		A POC immunoassay system that uses proprietary microfluidics and amplification chemistry, and allows for results within 10 minutes. The first assay to be developed for the system was a prostate-specific antigen (PSA) test, for which the analyzer is already CE marked and pending US FDA approval. The company is continuing to expand its menu, and a multiplex STI panel is reported to be in the pipeline, allowing for the simultaneous detection of HIV, HCV and TP.	Device is already on the market, although infectious disease panels are still in development.
Two Pore Guys			Digital, handheld, testing platform that can test for a number of pathogens.	TBD

(Also see page 63 for immunoassay/NAT integrated platforms)

Nucleic acid tests (NATs)

Nucleic acid-based technologies have helped to enhance the diagnosis of infectious diseases, allowing for diagnosis to go beyond pathogen identification, and enabling VL monitoring, genotyping, AMR testing of infections such as HIV, HCV and TB, as well as EID of HIV. Quantification of viral nucleic acid (RNA/DNA) can help to stage disease progression and monitor efficacy of treatments. In addition, NAT-based tests can also allow for the identification of pathogen variance, allowing for genotyping and the detection of AMR pathogens, and importantly helping to ensure that the correct treatment is provided. NAT-based tests are also important for EID, where the persistence of maternal HIV antibodies in infants under the age of 18 months invalidates antibody tests.

NAT technologies consist of three main steps: sample preparation; amplification; and detection. Numerous techniques have been developed for these purposes, with PCR the most commonly used method. Traditionally, NATs had to be performed in centralized laboratories, involving a high level of complexity and the requirement for skilled personnel. However, advances in technologies are now allowing for higher-throughput and automated sample-to-result platforms, as well as devices that are suitable for POC use. In addition, while NAT technologies have traditionally only been suitable for sequential testing of multiple diseases, multiplex assays (testing for multiple diseases simultaneously in the same specimen) are now also emerging, allowing for simplified workflow, increased screening abilities and the potential for cost-saving approaches (94). Biosensor technologies, microarrays, microfluidics and NGS are also pushing the boundaries of molecular diagnostics and facilitating the usage of NATs in low-resource settings. NATs that are on the market or in development for infectious disease diagnostics are described in the following sections (see Appendix 2 for more detailed specifications on each of these platforms/devices).

PCR-based NAT platforms

A wide range of PCR-based platforms, which are applicable to infectious disease diagnostics, are commercially available, all allowing the detection of a vast number of pathogens, with high diagnostic yield, high specificity and rapid turnaround times. In an increasingly competitive market, developers are working hard to differentiate their technology from others, and the last two decades have seen huge improvements in terms of simplicity, automation, multiplexing capabilities and throughput capabilities. In addition, quantitative assays – including those carried out using DBS samples – are also increasingly being developed by manufacturers. Multiplex PCR assays, especially for AMR and STIs, in which, for example, the presence of a pathogen is detected in addition to whether it also has a resistance

mutation, are also emerging rapidly. The increasing use of NATs for infectious disease diagnostics has prompted the development of increasingly sophisticated platforms, many of which are available in a range of formats to meet laboratory needs. Given the extensive range of PCR systems available, choosing which system to adopt is complex and heavily depends on the needs and resources in each individual setting. Assay menu, sensitivity and specificity, expected throughput, staff expertise and financial resources are just some of the factors to consider (94).

m2000 System – m2000sp (extraction) and m2000rt (amplification) (Abbott)

The CE marked and US FDA approved Abbott m2000 System consists of the m2000sp for sample preparation/extraction and the m2000rt for amplification and detection. The m2000sp can also be substituted with the m24sp instrument (for laboratories with low- to medium-throughput requirements), although not all assays are available for use on this system. When the m2000sp is combined with the m2000rt, the system takes from 6.2 to 9.5 hours to process 96 samples and can provide automation from barcoded laboratory tube through to patient result. Abbott also offers mPlus (amplification reagent extended use), which gives the user the capability of reusing the amplification reagent more than once, allowing the 24-test pack to be reused in order to run batch sizes smaller than 24 for higher efficiency. mPlus gives labs flexibility and added efficiency that allows for customized workflow and faster results. Abbott has several assays available for running on the system. They offer HIV-1 (VL), HCV (VL), HCV (genotyping), HBV, Chlamydia trachomatis and Neisseria gonorrhoeae assays, which are all CE marked and US FDA approved. In addition, they have assays for HIV-1 (qualitative, EID), Mycobacterium tuberculosis (MTB), MTB/RIF, isoniazid-resistant Mycobacterium tuberculosis (MTB/INH), HPV, CMVs, Epstein-Barr virus, which are CE marked. The company's CMV assay is under US FDA review and also has Emergency Use Authorization for its Zika assay. Abbott's HIV assays are also WHO PQ and applicable to DBS sample collection.

qTower3/qTower3 auto (Analytik Jena)

Analytik Jena's qTower3 (pictured) is a standalone real time quantitative PCR (qPCR) device that can be operated via an integrated tablet control and/or PC control. The qTower3 auto is an automated version of the device with a liquid handling system. Prior nucleic acid extraction is required, although this can be automated using their InnuPure® devices. The device has a throughput of 96 in approximately 120 minutes. CE marked tests that are available for the device cover VL monitoring of HBV, HCV and HDV. VL monitoring tests for HIV-1, CMV, Epstein-Barr virus and parvovirus B19, as well as confirmation assays for HSV-1, MTB and norovirus are also available, but currently only for RUO.

BD MAXTM System (BD)

The BD MAXTM is a fully integrated, CE marked and US FDA approved platform combining automated extraction and qPCR. The system is capable of running multiple specimen types and assays in a single run and includes a 5-colour detection qPCR platform to allow for multiplexing. In 3.5–4.5 hours, 24 samples across multiple syndromes can be processed. Singleplex/multiplex assays are currently available for infections such as MRSA, Staphylococcus aureus (SA), Clostridium difficile, Chlamydia trachomatis, Neisseria gonorrhoeae and Trichomonas vaginalis. Assays for MTB, MTB/RIF and MTB/INH are also in development with an expected release date in late 2017.

DxN VERIS Molecular Diagnostics System (Beckman Coulter)

Beckman Coulter's, CE marked DxN VERIS is a fully automated random access molecular diagnostics system, integrating sample introduction, nucleic acid extraction, reaction setup, qPCR amplification and detection/results interpretation into one system. No specialized expertise is required. The device has a throughput of ~150 tests in eight hours for DNA targets (result in ~70 minutes), and ~100 results in eight hours for RNA targets (result in ~110 minutes). CE marked assays for the DxN VERIS system include HIV-1, HCV, HBV and CMV. Assays, including multiplex tests, in the area of sexually transmitted diseases (STDs) and women's health as well as respiratory viruses, are also currently being developed. The system has been submitted for WHO PQ.

ExiStation™ Universal Molecular Diagnostic System (Bioneer)

Bioneer has a range of nucleic acid extraction and qPCR instruments available. The ExiStation™ Universal Molecular Diagnostic System is a semi-automated platform consisting of up to three ExiPrep™ 16 diagnostic nucleic acid extraction instruments (CE marked, US FDA approved and WHO PQ) and one Exicycler™ 96 qPCR instrument (CE marked and WHO PQ). The ExiStation™ is able to process on average 36 samples per hour, and is able to handle up to six different types of clinical samples in a single run. It is a pipetting-free system that mixes the extracted nucleic acids with the diagnostic reagents automatically. Bioneer is also developing the ExiStation™ 48, which will consist of the Exicycler™ 96 qPCR instrument (already available) and the ExiPrep™ 48 Dx nucleic acid extraction instrument (CE marked). In addition, the ExiLT™ 48 BT (automated blood sample handler) and ExiLT™ 48 ST (automated sputum, urine, faeces sample handler) are being developed, which will dock with ExiPrep™ 48 Dx and automate the whole process of clinical sample tube loading and nucleic acid extraction and purification (the only user hands-on process will be to seal PCR reaction tubes and put them on the PCR rack); together, this system will be known as the ExiStation™ 48 A. Bioneer also has an integrated, standalone platform for nucleic acid extraction and qPCR analysis, known as the ExiStation™ HT (CE marked) (pictured). Additional instruments for transferring primary samples into the sample plates (such as the ExiLT™ 48 BT/ST or Automatic Puncher for DBS samples) can also be combined with the system.

The test menu available for Bioneer's platforms includes CE marked assays for TB, MDR-TB, Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, HSV-1/2, HPV, Epstein-Barr virus, Ebola virus and a number of other infectious diseases. Bioneer also has a number of multiplex assays available, including AccuPower™ STI8 assays and the AccuPower™ Zika virus (dengue virus, chikungunya virus) assay that is also WHO PQ. Assays for HCV and XDR-TB are currently in development. In addition to the multiplex assays available, a single nucleic acid preparation can be used for two separate qPCR analysis. Up to eight targets can be simultaneously analysed and any two test combinations can be performed in a single run.

GeneXpert® Systems (Cepheid)

The GeneXpert® system fully integrates and automates sample extraction, amplification and detection in one cartridge. The GeneXpert® system is available in a 1, 2-, 4- or up to 16-module configuration (GeneXpert® I, II, IV, XVI – all are CE marked). The CE marked Infinity is an automated, multi-mode molecular diagnostic analyzer that uses exclusive "load and go" technology for total walk-away operation, with complete random access availability. Infinity systems allow configurations in sets of 8-modules, from 16 to 80 modules (Infinty-48s and Infinity-80). All instrument configurations use the same patented cartridge technology for every Xpert® test. Each sample takes between 30 and 90 minutes to run and a maximum of 80 samples can be run at a time on the Infinity-80. Cepheid's assay menu includes cartridges that are US FDA approved and/or CE marked to test for HIV-1 (qualitative, DBS), HIV-1 (VL), HCV, MTB, MTB/RIF, Ebola virus, Neisseria gonorrhoeae, Chlamydia trachomatis, HPV, MRSA and multi-drug resistant (MDR) bacteria (carbapenems, vancomycin), among others. An MTB/RIF Ultra assay with improved sensitivity is also in development, as well as an XDR-TB assay to detect mutations for resistance to INH, FLQ and AMGs (release date TBD). Cepheid's HIV (qualitative) assay is also now prequalified by WHO PQ and differential pricing is available for high-burden disease countries for the systems and assays. Cepheid is also developing the GeneXpert® Omni® POC system (see page 56 for more details)

GenoXtract® and FluoroCycler® (Hain Lifescience)

The Hain Lifescience platform includes a 96-well format for nucleic acid extraction (GenoXtract® 96) and subsequent amplification and detection via qPCR (FluoroCycler® 96). It also offers a lower-throughput extraction platform and qPCR cycler, the GenoXtract® 12 and the FluoroCycler® 12 (pictured), respectively. These platforms can process or amplify up to 12 samples at once. The company uses a novel amplification and probe technology, which was licensed from Brandeis University. Linear after the exponential (LATE)-PCR is an advanced form of asymmetric PCR, whereby a limiting primer and an excess primer are used for the exponential amplification of double-stranded DNA, followed by linear amplification of a single strand. Each single-stranded amplified sample can then be detected in real time (95,96). This allows larger regions of target DNA to be interrogated compared with the conventional method of using a single probe, yet with similar reported accuracy (97). Hain Lifescience currently offers FluoroType assays for MTB, MDR-TB and XDR-TB. In addition, it offers CE marked assays for MRSA, Chlamydia trachomatis, Neisseria gonorrhoeae, Borrelia, Clostridium difficile and HSV-1/2. Throughput data were unavailable at the time of writing.

SLAN®/SLAN®-96P (Hongshi Tech/Sansure)

Hongshi Tech/Sansure has multiplex AdvanSure qPCR assays for Chlamydia trachomatis/Neisseria gonorrhoeae, respiratory virus types and MTB/NTM, as well as singleplex assays for Clostridium difficile, HBV, HCV and HPV. The assays use the principle of PCR and hybridization of probe. The company offers the SLAN® (48-well sample capacity) and the SLAN®-96P (96-well sample capacity) for sample detection, with all reagents for DNA extraction included in the assay kits. The regulatory status and throughput data were unavailable at the time of writing.

Genesig® q16 (Primerdesign)

The Genesig® q16 is a qPCR instrument, designed to accompany the Genesig® easy product range, which includes kits for more than 400 different DNA testing applications. These tests include assays for human infectious disease screening, including HIV-1, HIV-2, HCV, MTB, MRSA, HAV, HBV, HPV, HSV, adenovirus, Clostridium difficile, E. coli, dengue virus, chikungunya virus, ZIKA, CMV, Chlamydophila pneumoniae, Chlamydia trachomatis, Neisseria gonorrhoeae, FluA/B, Ebola virus, Epstein-Barr virus and human herpesvirus 6. The instrument is currently for RUO and prior RNA/DNA extraction is required. Tests take 90–120 minutes to run and 16 samples can be run at a time

QIAsymphony® SP/AS and Rotor-Gene® Q instruments (QIAGEN)

The QIAsymphony® SP enables sample preparation of DNA, RNA, and bacterial and viral nucleic acids from a wide range of starting materials. The QIAsymphony® AS extends the capabilities of the QIAsymphony® SP by integrating automated PCR assay setup, which, in combination with the real-time PCR cycler, Rotor-Gene® Q and real-time and end-point PCR kits, optimizes the workflow allowing for 50–100 samples to be run per hour. QIAGEN manufactures a number of CE-IVD marked, reverse transcription PCR (RT-PCR)-based assays, including assays for the detection of HIV, HCV, malaria and TB. An example of a complete QIAsymphony® Rotor-Gene® Q system is pictured.

Cobas® Platforms (Roche Molecular Diagnostics)

Roche offers a range of technology platforms and workflow solutions. The cobas® 6800/8800 Systems (pictured) are integrated, fully automated molecular testing platforms for sample preparation and qPCR. The systems are designed for blood screening, VL monitoring, women's health and microbiology testing. Two different models are available to meet medium- and high-throughput demands; the cobas® 6800 can process up to 384 tests in an 8-hour shift, while the cobas® 8800 can process up to 960 samples in the same amount of time. Available tests include the cobas® MPX, a multiplex qPCR test for HIV-1/2, HCV and HBV, the cobas® DPX, a duplex assay for parvovirus B19 and HAV, cobas® Chlamydia trachomatis/Neisseria gonorrhoeae, as well as US FDA approved and/or CE marked assays for West Nile Virus, HEV, Zika virus, HIV-1, HBV, HCV, CMV, MTB and HPV. In addition, assays are in development for HIV-1/2 (qualitative), MDR-TB, HPV and Trichomonas vaginalis/Mycoplasma genitalium.

The company also has the cobas® 4800 System, which allows for fully automated sample preparation and qPCR, but is not fully integrated and instead consists of the cobas® x 480 instrument (for sample preparation) and the cobas® z 480 analyzer for qPCR. Up to 384 samples can be processed in eight hours. Assays available for the cobas® 4800 include HIV-1, HCV, HCV (genotyping), Chlamydia trachomatis/Neisseria gonorrhoeae, HPV, HSV-1/2, HBV and MRSA/SA.

The cobas® s 201 system is a complete NAT solution designed for automated blood screening. Assays available for the system include the DPX test (for parovirus B19 and HAV), the MPX test (HIV-1/2, HCV, HBV) and a test for West Nile virus.

In addition, Roche Molecular Diagnostics offers the cobas Liat® AmpliPrep® instrument that automates sample preparation for qPCR analysis on the cobas® TaqMan® analyzers, enabling 147 patient samples to be run in eight hours. Assays available for use on these systems include CMV, HBV, HCV (qualitative), HCV (quantitative), HIV-1 (qualitative) and HIV-1 (quantitative). The HIV assays have received WHO PQ and the cobas® AmpliPrep®/COBAS® TaqMan® HIV-1 Qualitative Test v2.0 is validated for use in EID.

It is also worth noting that the company has developed the compact cobas® Liat®, a fully automated benchtop analyzer designed for the POC setting, which can allow for results in 20 minutes or less. However, assays for HIV/HCV/TB or malaria are not yet available for use on this system.

SaMag-12/24 and SaCycler-96 (Sacace Biotechnologies)

Sacace Biotechnologies offers a range of qPCR assays that are "platform independent" (i.e. they can be run on different platforms such as the SaCycler-96 [Sacace Biotechnologies], the Rotor-Gene® [QIAGEN] or the SmartCycler [Cepheid]). Although their assays are "platform independent", the company also markets the SaMag-12/24 for nucleic acid extraction and the SaCycler-96 (pictured) for qPCR analysis; both are CE marked. The company has a number of tests for infectious disease diagnostics, including CE marked tests for HCV (confirmatory), HIV-1 (VL), HIV-2 (VL), HIV abacavir sensitivity, MTB, HAV, HBV, HPV, Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, TP, CMV, HSV-1/2, Ebola virus, Epstein-Barr virus, human herpesvirus 6, parvovirus B19, FluA/B, respiratory syncytial virus (and others); and RUO tests for HCV (genotyping), HIV-1/2 (EID) and multi-drug resistance (among others). The assay portfolio also consists of multiplex assays, for example, there are kits for the simultaneous detection of HCV/HBV/HIV-1/HIV-2, CMV/Epstein-Barr virus/human herpesvirus 6, Chlamydia trachomatis/Neisseria gonorrhoeae/Trichomonas vaginalis/mycoplasma and others. At full theoretical capacity (with two SaMag-24 extraction systems plus one SaCycler-96 PCR instrument) ~280 tests can be performed per 8-hour shift.

Anyplex™/Seeplex™ System (Seegene)

Seegene has combined multiple detection technologies to develop multiplex qPCR assays. Multiple Detection Temperatures Technology (MuDT) allows for the simultaneous quantification and detection/discrimination of multiple targets, in a single channel, without the need for additional melt curve analysis after the amplification step. In addition, its Tagging Oligonucleotide Cleavage and Extension (TOCE) Technology uses Cyclic Catcher Melting Temperature Analysis (cyclic-CMTA) to enable the confirmation of multiple target genetic detection and genetic variation, while its Dual-Priming Oligonucleotides DPO Technology is used to inhibit PCR product mismatching/non-specific priming. The company uses Real Amplicon Detection (READ) for its qPCR method, allowing for improved sensitivity and specificity. Seeplex™ assays involve sample extraction on the SEEPREP12, and multiplex PCR on the SEEAMP. Following PCR, the samples can be run on an automated electrophoresis system such as the MultiNA (Shimadzu Corporation), a microchip electrophoresis system for DNA and RNA nucleic acid size confirmation and quantification. The system uses microchip technology to carry out automated high-speed electrophoresis separation and fluorescence detection. Available CE marked Seeplex™ assays include a number of multiplex respiratory pathogen assays, STI assays, HSV-

1/2, HPV (screening and genotyping) and meningitis. There are also assays for MTB/NTM and vancomycin resistance, which are not CE marked. The Anyplex™ assays involve sample extraction and PCR setup on the Microlab Nimbus (Hamilton), followed by qPCR analysis on an instrument such as the CFX96TM (Bio-Rad). CE marked Anyplex™ assays include multiplex respiratory pathogen assays, STI assays, HPV genotyping, MDR-TB, XDR-TB and MTB/NTB/MDR-TB. Throughput was unknown at the time of writing.

Atellica MDX 160 Molecular System (Siemens Healthcare)

The Atellica MDX 160 Molecular System consists of two modules: the Sample Preparation Module, used to extract both RNA and DNA from a wide variety of samples; and the Amplification Detection Module. In addition, Atellica MiPLX software allows for improved workflow and multiple assays to be run from one extracted sample. It is possible to run 96 tests in approximately six hours. The open platform design also allows laboratories to expand their testing menu through third-party assays. Siemens Healthcare uses a proprietary extraction technology that consists of silica-coated magnetic particles for efficient nucleic acid isolation. Assays available for the system are the VERSANT® HIV-1 RNA assay, VERSANT® HCV RNA assay, VERSANT® HBV DNA assay, VERSANT® Chlamydia trachomatis/Neisseria gonorrhoea DNA assay and kPCR PLX assays (CMV, Epstein-Barr virus, HSV-1/2, varicella-zoster virus, HHV-6, BK virus, JC virus, adenovirus, parvovirus B19). The VERSANT® HIV-1 RNA assay received WHO PQ in 2012.

Isothermal amplification-based NATs

Aside from PCR-based amplification, many isothermal nucleic acid amplification technologies have also been reported and applied to infectious disease diagnostics. Unlike PCR, these technologies operate at a single reaction temperature and, as such, do not require expensive or complex thermocyclers. One such isothermal amplification method, particularly suited to RNA amplification, is nucleic acid sequence-based amplification (NASBA) (98). The NASBA reaction is an isothermal transcription-based amplification method that amplifies RNA from an RNA target. The amplicons produced through this process are detected in real time by molecular beacons, which are hairpin-shaped molecules with an internally quenched fluorophore, whose fluorescence is restored upon binding to a target nucleic acid. Kinetic analysis of the fluorescent signals reveals the transcription rates of both the RNA target and a calibrator RNA added during the extraction step. This transcription rate is used to determine the quantity of the RNA target in the original specimen. Reports have indicated that NASBA is equally as sensitive or more sensitive than RT-qPCR, is less labour intensive and has a shorter reaction time, allowing for a quicker turnaround (99,100). Other isothermal amplification techniques include loop-mediated isothermal amplification (LAMP) and transcription-reverse transcription concerted reaction (TRCR).

NucliSENS® easyQ® (Bio-Mérieux)

The NucliSENS® EasyQ® is a closed system made up of a NASBA amplification step and automated data analysis. Prior RNA extraction is required, but this can be automated using the NucliSENS easyMAG® or miniMAG® extraction system. Both of these extraction systems employ magnetic silica-based beads with proprietary BOOM® technology. For high-throughput needs, the easyMAG® is an automated benchtop nucleic acid extraction device that can perform 24 extractions in approximately 40 minutes (and offers the possibility to extract different samples types, to be used in several applications, in the same run). The easyMAG® system has one generic extraction protocol (DNA/RNA) and one set of reagents for all applications that, together with touchscreen technology, simplifies the process. The miniMAG® system is a small, semi-automatic extraction device for both DNA and RNA extraction from various specimens. The miniMAG® is capable of 12 extractions in 45 minutes (using one miniMAG® system) and 24 extractions in 60 minutes (using two miniMAG systems). The instrument has a standardized extraction protocol for multiple downstream applications. When these extraction systems are combined with the NucliSENS® EasyQ® system, extraction to results can be achieved in two hours for 48 samples. Currently available for use on the NucliSENS® platform are assays for

HIV-1 (VL) and HPV. Its HIV assay is WHO PQ and the HPV assay is CE-IVD marked. BioMérieux also provides NucliSENtral™, which is an integrated software-based laboratory information system (LIS) that can be used to link NucliSENS easyMAG® and NucliSENS® EasyQ®.

LA-500 (Eiken Chemical)

Eiken Chemical has developed a nucleic acid amplification method called LAMP. The technique has high specificity and is characterized by the use of a DNA polymerase and four specifically designed primers (101). The process is performed at a constant temperature using a strand displacement reaction, and the amplification and detection of a target gene can be completed in a single step. The CE marked LA-500 takes advantage of this technology, and up to six amplification units can be connected to the device allowing for flexible scale-up. The company's Loopamp™ MTB assay was developed in collaboration with the Foundation for Innovative New Diagnostics (FIND) and went on sale in Japan in 2011. The assay has received WHO endorsement for the diagnosis of pulmonary TB (102). Also in collaboration with FIND, it has since developed malaria detection test kits that can detect four Plasmodium species and *Plasmodium falciparum* alone within one hour. In 2016, Eiken Chemical concluded a distribution agreement with Human Diagnostics Worldwide for an MTB and malaria LAMP molecular diagnosis system in the global market.

XT-8 System/ePlex System (GenMark Diagnostics)

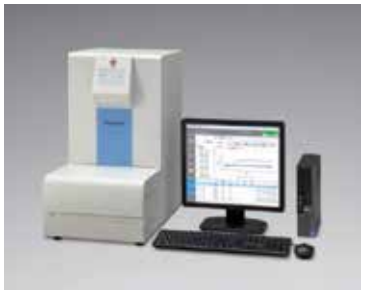
The XT-8 System (pictured) uses GenMark Diagnostics's proprietary eSensor technology, whereby the target DNA is mixed with the signal probe solution in the cartridge and analysed via microfluidics and electrochemical detection. The XT-8 System can be scaled to meet testing requirements with the addition of extra modules, and can process multiple test types simultaneously. Prior nucleic acid extraction is required before samples can be added to the cassettes for analysis. Cassettes available for the XT-8 System include a US FDA approved multiplex Respiratory Viral Panel and an HCV genotyping test that is currently for RUO. The company has developed the US FDA approved ePlex System that fully integrates nucleic acid extraction, amplification and detection. The ePlex system can be scaled to provide between 48 and 192 results during an 8-hour shift. The ePlex device uses the same eSensor detection technology included for the XT-8 system, as well as electrowetting (a digital microfluidic technology). The CE marked Respiratory Pathogen Panel, Fungal Pathogen Panel, Gram Positive/AMR Panel and Gram Negative/AMR Panel are available for the ePlex system, while panels for HCV genotyping and gastrointestinal pathogens are in the ePlex pipeline.

Panther System (Hologic)

Hologic has introduced the Panther system, a molecular diagnostic platform with true random-access testing capability on a fully integrated and automated NAT system (pictured). The platform brings the flexibility of clinical chemistry instrumentation to molecular diagnostics. The technology involves three main steps, all of which take place in a single tube on the Panther system: (i) target capture; (ii) target amplification by transcription-mediated amplification (TMA); and (iii) detection of the amplification products by the fluorescent-labelled probes (torches). Within the Panther, all nucleic acid testing steps, from primary sample tube to results, are fully automated in one system. At least 320 samples can be run within an 8-hour shift or 560 samples in a 12-hour period (an additional 240 samples can be run without operator attendance). Four reagent lanes allow up to four of the Aptima® test kits to be on board and randomly accessed at any time. CE-marked and FDA-approved assays which are available for the system include the Aptima Chlamydia trachomatis/Neisseria gonorrhoeae combo assay, Aptima Trichomonas vaginalis, Aptima HPV, and the Aptima HPV (genotyping) assays. Hologic also have CE-marked assays for HIV-1 (VL), HBV (VL), and HCV (VL) and FDA approved assays for HIV-1 (qualitative), and HCV (qualitative). In addition, the Aptima Zika assay has been approved for Emergency Use Authorization. Assays for Clostridium difficile, MRSA, RSV, Parainfluenza, Cytomegalovirus and others are also in development. Proof of principle testing of the DBS HIV-1 (VL) assay has also been carried out, and showed sensitivity comparable to the Roche DNA assay (103). Aptima assays can also be used on the Tigris DTS System, another fully automated NAT system, and the DTS 400/800 systems, which provide automated solutions for low- and medium-volume laboratories.

HumaLoop M (Human Diagnostics Worldwide)

In 2016, Human Diagnostics Worldwide, in collaboration with Eiken Chemical, concluded a distribution agreement whereby it distributes testing systems for MTB, malaria Pan and malaria Pan/Pf worldwide (excluding China, Japan, the Republic of Korea, Taiwan and Thailand), using the company's patented Loopamp™ technology. A separate system has to be used for TB and malaria testing, since the temperature profiles for TB and malaria are different. However, the CE marked HumaLoop M system for malaria can be considered as multi-disease, with assays for Leishmania (as well as P. vivax malaria) currently in development. Test results for 16 samples take approximately one hour.



TRCReady®-80 (Tosoh Bioscience)

The TRCReady®-80 combines transcription-reverse transcription concerted reaction (TRCR) and intercalation activating fluorescence (INAF) probe technologies to achieve real-time, one-step, rapid detection of RNA. In the TRC method, RNA is amplified isothermally, and the INAF probe is a DNA oligonucleotide to which an intercalative fluorescence dye is linked, and of which the sequence is complementary to that of the target RNA. The platform requires a computer for operation and two test units can be combined into one system. The platform permits fully automated sample purification, amplification and detection. Results for eight samples can be achieved after 40 minutes. Tests for the system include an MTB kit (CE marked), an M. avium (MAC) kit (Japanese FDA approved) and a norovirus kit RUO only. An assay for Chlamydia trachomatis/Neisseria gonorrhoeae testing is also in development with a launch planned in Japan for 2017 and in the European Union for 2018.

Cross priming amplification (CPA) technology – EasyNAT™ TB-CPA (Ustar Biotechnologies)

Ustar Biotechnologies has developed their cross priming amplification technology (CPA), which is based on the isothermal DNA amplification. Using multiple cross-linked primers (five to eight primers), DNA or RNA target sequences are amplified at a constant temperature. The detection of amplification products is performed using nucleic acid lateral flow strips that can be housed in the company's XCP nucleic acid detection device (pictured) to avoid cross-contamination. Currently, Ustar Biotechnologies manufactures a CE marked kit to detect TB (EasyNAT™ TB-CPA) as well as other kits that can detect Chlamydia trachomatis and toxoplasmosis, among other infections. Four samples can be run in one to two hours. Tests for HCV, HIV and TB are currently in development (anticipated launch 2019).

Line probe assays (LPAs)

LPAs are relatively low-cost molecular diagnostics that are most frequently used for genotyping and AMR purposes. LPAs have shown most success in the areas of TB/NTM diagnosis and MDR-TB/XDR-TB genotyping; with WHO endorsing several LPAs for these purposes in 2016. LPAs are also being investigated for the detection of other groups of pathogens, such as common bacterial meningitis pathogens, although these assays require further improvement (104). In principle, the appropriate use of LPAs needs dedicated areas and equipment for the various processes used in LPA methodology (DNA extraction, PCR amplification, hybridization and data interpretation). As such, LPAs are only used in the upper- and middle-tier facilities (laboratory 3 and 4) where these conditions can be met and there are trained staff for their use. Throughput of LPA testing can be increased using automated instrumentation for DNA extraction. In addition, most developers now offer associated equipment for use with the assays, including PCR machines, wash/hybridization platforms, digital scanners and the software to score test results from processed strips. These advances in processing have simplified the implementation of LPA testing in many upper-tier laboratories and reduced risks around incorrect use or interpretation.

AID Scanner (Autoimmun Diagnostika GmbH)

The CE marked AID Scanning system is a tool for the automated interpretation of the AID Lineprobe/Western blot strips. It consists of a standard scanner and software that has to be installed on a PC or similar device (laptop). The company offers CE marked LPA kits for STDs, HPV screening and genotyping, community acquired pneumonia bacterial pathogens and viruses, as well as a number of other pathogens. A range of CE marked MDR LPAs are also available, including strips for MRSA, resistance against cephalosporins in extended-spectrum ß-lactamase (ESBL)-producing Enetrobacteriacease, carbapenem resistance, MDR-TB (INH/RIF) and XDR-TB (AMG, FLQ, ethambutol). For these LPAs, DNA extraction, PCR amplification and DNA hybridization must be carried out before being analysed on the AID Scanner. The test usually takes around four hours to complete, and the device has the capacity to run more than 100 strips per hour.

Auto LiPA 48 (FujireBio Diagnostics)

Auto-LiPA 48 from FujireBio Diagnositcs is CE marked and offers automated processing of the range of INNO-LiPA and INNO-LIA tests from hybridization to colour development within 3.5 hours, with a maximum of 48 samples per run. The Auto LiPA platform is compatible with a number of CE marked INNO-LIA and INNO-LiPA tests and the menu currently includes tests for HCV, HIV, syphilis, HTLV, HBV and HPV. The company also markets the Auto LIA 48, which is limited to running INNO-LIA tests.

GenoLine Station (LG Life Sciences)

LG Life Sciences offers GenBlot AdvanSure assays for MTB, MDR-TB and HPV (regulatory status was unknown at the time of writing). The technique involves both a nested multiplex asymmetric PCR method in a single tube and reverse hybridization line blot assays. Prior DNA extraction is required, but all materials for this are included in the kits. Automation from hybridization, to result readout, is then possible with the AdvanSure™ GenoLine Station. In approximately 150 minutes, 48 tests can be performed.

MolecuTech HybREAD480 (YD Diagnostics)

The YD Diagnostics MolecuTech HybREAD480 integrates full automation of processing (washing and hybridization steps of LPAs) as well as scanning for interpretation. For samples to be run on the instrument, prior DNA extraction and amplification is required (all reagents for manual DNA extraction, PCR reagents and hybridization reagents are included in the test kits). The device is CE marked and can currently test for MTB, MTB/NTM, MTB/MDR and HPV. Around 384 tests can be carried out per day on the platform. It takes approximately three hours to run 48 tests.

Microarray-based NATs

Microarray-based technologies involve the detection of amplified targets by hybridization to solid or liquid bead-based arrays (105). Similar to LPAs, labelled DNA/RNA is subsequently bound to complementary capture probes that represent a specific allele (e.g. wild type or drug resistant) via hybridization. The principal difference is that each probe is printed in a small discrete spot, as opposed to a comparatively large stripe with LPAs. This decrease in area allows more probes to be printed in a geometric array, offering two advantages. First, each test is amenable to higher multiplexing capabilities. Second, probes are typically printed in duplicate or triplicate on the array and thereby provide greater accuracy when scoring a test result. However, the interpretation of microarray data does require a dedicated instrument as the probe spots are not visible to the naked eye and typically detection uses fluorophores or electrochemical detection. Microarray kits offer primers to amplify the target DNA regions in addition to the arrays and other materials required for performing the test. There are several microarray products on the market or in development.

TruDiagnosis®/TruDx2000®/TruDx3000® Platform (Akonni Biosystems)

Akonni Biosystems's core product lines include TruTip® sample prep kits and the TruDiagnosis® system for multiplexed diagnostics (regulatory status was unknown at the time of writing). TruTip® is a nucleic acid purification technology for RNA/DNA extraction and purification from a wide range of specimens (e.g. blood, saliva, sputum, culture, etc.). TruDiagnosis® is a unique in vitro diagnostic system based on proprietary gel-drop microarray technology. The platform enables the detection of protein, nucleic acid or metabolite targets and is designed for applications in infectious as well as chronic diseases. The TruDx2000® (pictured) is a modular plug and play version of the TruDiagnosis® platform, consisting of the TruDx® Imager and software for analysis, commercially available off-the-shelf thermal cyclers for genetic testing, TruArray® tests for multiplexed testing and TruTip® kits for manual or automated nucleic acid extraction. The company is also developing the TruDx3000® platform, which will combine automated nucleic extraction from the TruTip® Automated Workstation, with the TruDx2000® for a fully integrated, sample-to-result solution. TruArray® tests available include those for MDR-TB, HSV-1/2 and MRSA, with tests taking one to three hours.

INFINITI® PLUS/INFINITI® High Throughput System (HTS) (AutoGenomics)

The INFINITI® System is a multiplexing, continuous flow microarray platform that uses Target Signal Amplification chemistry. The INFINITI® PLUS Analyzer (pictured) is an automated instrument that integrates sample handling and detection of DNA sequences for analysis (prior DNA processing is required). Up to 48 samples can be analysed in 5.5–7 hours post-extraction. The INFINITI® HTS System is a semi-automated multiplexing microarray system comprised of three modules: a convectively heated hybridization chamber; a multi-channel microarray processing system; and a built-in image sensor. The system is self-saleable and allows for a staggered processing and scanning time, for higher-throughput analysis (96 samples run in 6 hours 45 minutes, post-extraction). BioFilmChip® microarrays are available and CE marked for testing for HPV, Candida, bacterial vaginosis, ureaplasma and respiratory viruses such as FluA/B, parainfluenza and adenovirus. RUO assays are also available for MTB, MDR-TB, NTM, HCV (genotyping), Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis and others.

VerePLEX™ Biosystem (Veredus Laboratories)

The VerePLEX™ Biosystem is a multiplexing microarray platform capable of performing qualitative analysis of nucleic acids from various sample types. The system includes a Temperature Control System (TCS) that thermally drives the “lab-on-chip” and can manage up to five tests simultaneously, an Optical Reader (OR) that detects and analyses the microarray fluorescence, and software for managing the instruments and results analysis. The system can host several disease-specific microarrays, including the VereMTB™ Detection chip that can detect 10 different Mycobacterium strains with special emphasis on MTB and MDR-TB, the VereFlu™ chip for detection of FluA/B strains, VereThreat™ for the detection of anthrax, smallpox, plague and tularaemia (identified as potential biological weapons), the VereMURS™ and the VereFoodborne™ (for the detection of multiple foodborne pathogens). The system first involves independent extraction of DNA from samples. The extracted DNA solution is then added to two chambers on the array chip, which is inserted into a processing module on the VerePLEX™ Biosystem, where target amplification occurs via PCR, with subsequent binding of amplified DNAs to their complementary probes. This platform can independently host up to five test arrays for PCR at one time, with a turnaround time of approximately two hours. After PCR, each chip is individually read in a reader and the raw data analysed using VereID™ software to generate results on speciation/resistance.

Pipeline microarray-based NATs

Developer	Product name	Image	Technology	Launch date
Axela	Ziplex System		A microarray platform that consolidates array molecular binding, imaging, data quantification and quality control in a single benchtop unit. Hybridized oligonucleotides or bound proteins within the TipChip arrays are detected using chemiluminescence and a CCD camera. The system requires manual preparation of samples (extraction and labelling of RNA or dilution of protein), but the company reported that only approximately 20 minutes of hands-on-time is required. Up to eight gene expression assays can be analysed in approximately three hours; while for proteins, eight samples can be evaluated in often less than one hour. Proteomic Xpress chips for infectious disease are not yet on the market, but the company indicates that more chips will be released in the near future. In addition, by using panelPlus™ Technology, custom multiplex panels can also be created enabling the development of customized infectious disease assays, and a proteomic TipChip microarray coated with various infectious disease antigens has already been tested (106).	Device is on the market, but proteomic Xpress chips for infectious diseases are not yet available. More Xpress chips are, however, in development and an infectious disease microarray can currently be made in a customized fashion.

Mass spectrometry-based NATs

Mass spectrometry is also being adopted for the molecular diagnosis of infectious diseases. The technique has the capability to analyse proteins and nucleic acids (as well as various other biomolecules) in a highly accurate and sensitive manner, and can be adapted to meet throughput needs. Perhaps most promising for infectious disease diagnostics is electrospray ionization mass spectometry that, in combination with PCR amplification, can allow for the identification of bacteria, fungi, viruses and protozoa using the mass-to-charge ratio of the PCR amplicon (105).

IRIDICA Platform (Abbott)

IRIDICA is a CE marked microbial diagnostic PCR/electrospray ionization-mass spectometry platform, which involves the use of five separate instruments that together automate sample preparation, DNA amplification, desalting/purification and mass spectometry analysis. The IRIDICA system is replacing the Plex-ID system that was recently discontinued by Abbott. First results are available in approximately six hours, and up to six samples can be tested per run. IRIDICA's assay menu includes the three IRIDICA BAC BSI/SFT/LRT kits, which together cover 780 bacteria and Candida, as well as four resistance markers, the IRIDICA FUNGAL assay that tests for over 200 Fungi and the IRIDICA VIRAL IC assay that tests for 13 viral reporting groups.

POC/near-POC devices

The majority of NAT-based platforms currently on the market require testing to be done in a laboratory setting, usually at a central or national reference laboratory, by well-trained technicians. Each requires dedicated space, a clean room or rooms and other specialized and sophisticated infrastructure to diminish contamination and assure accurate testing. NATs that could be conducted at or near the point of patient care would reduce the need for such infrastructure as well as the requisite level of training. In addition, it would ensure that patients on treatment in remote areas have access to appropriate diagnostic and monitoring tools with same-day test results, which can minimize loss to follow-up. WHO has developed a set of criteria, known as ASSURED (affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and deliverable to end users), in order to provide framework and guidance for evaluating POC devices for resource-limited environments (3,4); for this landscape report, these criteria are used for listing devices that are suitable for POC/near-POC NAT testing.

Alere q Analyzer (Alere)

The Alere q Analyzer is a CE marked fully automated qPCR NAT platform that can be used at the POC, and which has multiplex capabilities. The device has a small footprint, is portable, contains integrated uninterruptable power supply/source (UPS), can be run either on mains power or from a dedicated battery pack, and can withstand harsh environments. The Alere q tests are disposable cartridges that contain all reagents required for the assay in a stabilized form. The cartridges are fully self-contained and, once capped, cannot be reopened. At no time does the sample or the reagent actually come into contact with the analyzer, thus greatly reducing any possibility for cross-contamination. Tests take approximately one hour and one test can be run at a time. The results can be viewed on a built-in screen and be printed immediately, but results are also stored in an onboard archive and can be viewed and printed at a later date, exported to a USB memory stick or exported to a remote server via the use of an optional USB connectivity package that makes use of GSM network infrastructure.

Assays for the Alere q Analyzer include the Alere q HIV-1/2 Detect assay, which is already WHO PQ and CE marked, and allows for the qualitative detection of HIV-1/2 simultaneously from 25 µL of whole blood. The

Alere q VL Plasma assay, a quantitative VL test for HIV-1/2 is also in development (launch date to be confirmed), and the Alere q Filovirus (Ebola virus) test is currently undergoing regulatory approval. Alere has also reported some additional pipeline activities for the Alere q Analyzer, however, details of these assays have not yet been released into the public domain.

Accutas (Aquila Diagnostic Systems)

Accutas is a hydrogel-based POC molecular diagnostic platform, based on a hydrogel matrix that contains all of the reagents for performing DNA amplification and analysis by qPCR. Reagents are stored in a gel that is desiccated to enable long-term storage at room temperature. The gel is loaded into a microfluidic chip or strips of 8 or 16 tubes, and diluted sample is then added directly to rehydrate the reagents with no DNA extraction step required. The chips or strip of tubes are run on a portable instrument, whereby pathogen DNA is amplified using qPCR and detected using LED-induced fluorescence. Accutas has a strong focus on the veterinary market, however, it also has developed a malaria assay and carried out proof-of-principle test development for HSV-1/2, ureaplasma and Mycoplasma hominis testing. For malaria, the processing involves collection and transfer of a fingerstick blood sample onto a disposable tube/chip, and once inserted into the instrument, results are returned within two hours.

GeneXpert® I System (Cepheid)

Cepheid's GeneXpert® I is single-module fully integrated qPCR device and considered a POC/near-POC device (see section on PCR-based NAT platforms for more details on the GeneXpert® range). However, the company is also developing the GeneXpert® Omni, which will be battery operated and optimized for POC testing (For more details, see Appendix 2. Operational characteristics of multi-disease diagnostic platforms/ tests).

Mini8 qPCR Cycler/One-step MD-Box-Lab (Coyote Bioscience)

Coyote Bioscience's One-Step qPCR reagent removes the need for nucleic acid extraction and purification. Instead, the process only involves sample collection, qPCR mix preparation and running the PCR assay on the CE marked Mini8 Plus qPCR Cycler. Coyote Bioscience also offers the CE marked One-Step MD-Box-Lab (pictured), a portable device that is compatible with a battery pack or car charger. One-Step qPCR assays available for the system include tests for HIV, Epstein-Barr virus, respiratory syncytial virus, FluA, adenovirus, MERS and norovirus. Both devices allow eight samples to be run per hour.

Genedrive® (Genedrive plc., an Epistem company)

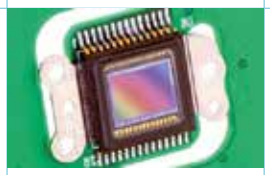
Genedrive® is a small, portable PCR thermocycling device that carries out nucleic acid amplification and detection of DNA or RNA targets by fluorescent end-point PCR. While current Genedrive® tests can be considered singleplex, the company indicates that the technology does allow for multiplexing with a maximum of 9–12 targets. Once the plasma/serum has been processed no other sample preparation is required. The Genedrive plc. MTB/RIF CE marked kit allows for the detection of both MTB and RIF resistance within 75 minutes. An HCV (qualitative and pan-genotypic) has also received CE marking.

Truelab™ Uno Dx Real Time Micro PCR Analyzer (Molbio Diagnostics Pvt. Ltd)

The new Trueprep™ Auto sample prep device, developed by Molbio Diagnostics Pvt. Ltd, is a fully automated, portable, battery-operated sample preparation device that can process a range of clinical specimens and extract purified RNA/DNA. Processing is done on disposable cartridges that process the sample and bind the nucleic acids on a proprietary matrix. The cartridges also store all bio-waste in an enclosed dump area. The entire process is fully contained and biosafe. Sample-to-result takes one hour. The Truelab™ Uno Dx is a new microPCR device (pictured) that has enhanced hardware and software capability and allows for greater multiplexing. Like the previous device, it is portable and battery operated. The older generation devices are already on the market and are CE marked, while applications are in progress for the newer generation devices. Assays for HBV, MTB, Salmonella, dengue virus, chikungunya virus, H1N1, MTB/RIF and malaria Pf/Pv are on the market; while assays for HIV-1, HIV-2, HCV, Trichomonas vaginalis, Chlamydia trachomatis, Neisseria gonorrhoeae, HPV, Zika virus, Klebsiella, MRSA, meningitisand FluA/B are in development. The company also reports that the device has the potential for multiplexing capabilities.

Pipeline POC/near-POC NAT-based platforms/tests

Developer	Product name	Image	Technology	Launch date
Atlas Genetics	Atlas Genetics io® system		NAT; platform comprises of the small io® Reader and a disposable cartridge, designed for POC and near-patient settings, with results in approximately 30 minutes.	TBD
Cepheid	GeneXpert® Omni		NAT; single standalone system that is capable of processing Xpert® cartridges in more austere settings than the current Xpert® instruments, which are not designed for extreme conditions such as elevated temperatures and humidity above 30 °C. Over time, it is intended that the majority of the Xpert® menu will be available on the GeneXpert® Omni. In addition, Cepheid is developing the Xpert® Finger Stick HIV-1 VL assay, and fingerstick HCV VL assay for use on the GeneXpert® Omni, which is more amenable to the POC setting (107).	TBD
Daktari	Daktari Virology		Microfluidics and electrochemical sensing for NAT testing.	TBD
DiscoGnosis	LabDisk System		NAT (LAMP) technology. A POC lab-on-a-disk that tests for several tropical diseases (malaria, dengue virus, typhoid and pneumonia) at the same time.	TBD
Nanobiosym Diagnostics	Gene-RADAR®		A portable nanotechnology platform that can rapidly and accurately detect genetic fingerprints from any biological organism.	TBD

Developer	Product name	Image	Technology	Launch date
QuantuMDx	Q-POC		NAT; onboard sample preparation, qPCR and/or PCR and hybridization. Sample-to-result testing in less than 20 minutes. Assays for MTB, MDR-TB, malaria, Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis and HPV are in development.	2018
Scanogen	Single-molecule biosensors		The company is using its proprietary technology of single-molecule biosensor scanning to develop POC diagnostic assays for infectious diseases and drug resistance. These novel biosensors consist of DNA molecules and micron-sized particles that convert nucleic acid hybridization into an optical signal that can be detected using robust equipment, without the need for nucleic acid amplification.	TBD
Spartan Bioscience	Spartan Cube		NAT test that uses PCR technology. The Spartan device is only four inches cubed and allows for DNA testing (sample-to-result) in 30 minutes.	TBD
Tangen Biosciences	TangenDx Instrument		NAT; DNA isothermal amplification and real-time detection analysis. A small modular platform for the diagnosis of TB and other infectious diseases.	TBD

Next generation sequencing (NGS)

The application of NGS or massively parallel sequencing (MPS) is an exciting new methodology that can combine diagnosis, drug resistance genotyping and molecular epidemiology from a "single" test or sample. A significant focus of NGS for clinical purposes has been on its application for the diagnosis and treatment of noncommunicable diseases such as cancers and screening for genetic inheritable diseases, but the potential value of NGS has now been demonstrated with challenging infectious disease syndromes such as HIV and TB.

Many high-income countries are already devoting resources to NGS centres and academic forums, allowing for genotypic resistance testing, detection of unknown coinfections and strain typing (108). Most NGS studies of microorganisms use either targeted amplicon sequencing or whole-genome sequencing. NGS assays using amplicon sequencing, such as HIV MDR testing, were the first to be introduced to the clinic, and there is increasing evidence supporting their relevance for the detection of low-abundance resistance mutations. Whole-genome sequencing approaches that can provide information on species identification, virulence determination and AMR, all in a single assay, may prove most revolutionary to the infectious disease diagnostic field.

In addition to clinical management, NGS also holds promise for surveillance purposes. For example, development of centres of excellence that can initially be used for surveillance, but which could also serve as an opportunity for individualized testing in the future or as a platform for training and building up of in-country capacity, may prove particularly effective.

As has been seen with other NATs in their infancy (e.g. PCR), the complexity and costs of the test processes have limited their implementation in smaller laboratories, but technology developers are working on platforms and methods to make NGS a routine method in clinical laboratories. Part of this expansion has led to challenges in validation, quality control and data interpretation beyond what clinical laboratories have previously encountered (109). However, as these technologies mature, improved quality assurance methods will also be developed to reduce barriers to its implementation. NGS data provide information at a much higher resolution than that of traditional techniques, allowing the user to fine-scale epidemiological investigations, while also offering improved diagnosis and surveillance of drug resistance to both first- and second-line drugs. Essentially, diagnosis, information on the optimal therapy and lineage of infection may all be available in one test method. The creation of databases such as the ReSeqTB database or the Stanford University HIV Drug Resistance Database highlight how NGS data, when correctly curated, can be pooled to build a tool that will enable developers to customize assay development as new genotypes for drug resistance are identified

(110). As with all large data collections, the information contained therein is most useful only if it is correct and stored in a unified format where it can be easily accessed and used by all.

There are a variety of NGS platforms on the market and in development for infectious disease diagnostics (see the NGS-based platforms table below). While most of the devices are designed for use in a reference-level facility, often at great cost, smaller platforms with potential application in lower-level facilities are available (e.g. MiSeq and the minION/SmidgION). Ultimately, NGS systems are still in their infancy, and are only currently used to supplement rather than replace conventional diagnostic methods. While only currently applicable to high-resource settings, it is hoped that with developments and advancements, NGS may also become a useful tool in low-resource settings in the near future.

NGS-based platforms

Developer	Product name	Image	Technology	Launch date
BioRad	GnuBio		Fully integrated desktop DNA sequencing platform that uses emulsion microfluidics. The platform provides a single-user interface and a single-step process that allows for results within hours.	TBD
Genapsys	GenapSys Gene Electronic Nano-Integrated Ultra-Sensitive (GENIUS) technology		GenapSys Gene Electronic Nano-Integrated Ultra-Sensitive (GENIUS) technology uses a fully integrated portable platform with electronic sequencing chips for genome sequencing.	Pilot introduction 2018
Genia (acquired by Roche Molecular Diagnostics in 2014)	TBD		Nanopore-based platform with NanoTag chemistry for single-molecule DNA sequencing. The sequencing reader is being developed for a range of applications, including infectious diseases.	TBD
Illumina	MiSeq (pictured), HiSeq, NextSeq		Illumina's NGS platforms use sequencing by synthesis technology and can deliver output ranging from 300 kilobases up to multiple terabases in a single run, depending on the instrument type and configuration. Studies on Illumina's NGS platform for infectious diseases have also been reported (108).	Launched
Oxford Nanopore	minION (pictured), PromethION, SmidgION		Oxford Nanopore offers scaleable DNA/RNA sequencing devices, from the pocket-sized minION to the benchtop PromethION system. The SmidgION is the company's smallest device, which is designed for use with a smartphone. The technology is based around a core sensing unit of a nanopore set in an arrayed sensor chip. Nanopore's MinION device has been used for genomic surveillance of ZIKA, Ebola virus, STDs and AMR.	TBD

Developer	Product name	Image	Technology	Launch date
PacBio	Sequel and RS2 (pictured)		PacBio sequencing systems use Single Molecule, Real-Time (SMRT) Sequencing Technology.	Launched
QIAGEN	GeneReader		Designed to perform NGS applications by integrating fluorescence-based sequencing chemistry with detection of the corresponding fluorescent signal templates that have been amplified using the GeneRead QIAcube.	Launched
Thermo Fisher	Ion S5, Ion PGM and Ion Proton Systems		Thermo Fisher uses semiconductor sequencing technology for its NGS platforms. Template preparation for the systems can be carried out using the Ion Chef System. The company has predesigned microbial panels available for TB and Ebola virus.	Launched
Vela Diagnostics	Sentosa SQ301		Instrument for targeted sequencing of human and viral DNA. Nucleic acid extraction, PCR preparation and library preparation can be carried out using the Sentosa SX101. Template preparation can also be carried out using the Sentosa ST401. Vela Diagnostics offers NGS assays for HCV/HIV genotyping and resistance-associated variance. The HCV assay is CE marked.	Launched

Volatile organic compounds (VOCs)

The rapid and non-invasive screening of infectious diseases via metabolic compounds in breath and urine has been an area of recent research, especially for the screening of pulmonary TB. A number of companies are developing instrumented VOC products via a range of methods, including Menssana Research Inc. (gas chromatography), The eNose Company (metal-oxide sensors) and Metabolomx (metabolite detection by chemical reaction). Rapid Biosensor Systems Ltd has also developed an antigen-based breath test for the detection of MTB.

Aeonose™ device (The eNose Company)

The eNose Company Aeonose™ device obtained CE approval in 2015. The device contains a rechargeable battery and is mains electricity independent. The user of the Aeonose™ should be a qualified operator, but a nurse practitioner can easily be trained to operate the device. Carbon fibre filter discs are attached to both the instrument and the mouthpiece to prevent risk of aerosolization. A bacterial filter, located inside the mouthpiece and one-way valve system is used to prevent contamination of the instrument by MTB or other breath-associated microbes. The test takes a minimum of 15 minutes to perform and the company currently recommends that each device is returned yearly for a service and calibration check. Dedicated software to perform service at the test location is close to finalization. Aside from TB diagnosis, the company is also carrying out clinical studies for Helicobacter pylori detection.

BCA (Menssana Research Inc.)

Menssana Research Inc. was one of the first companies to enter the VOC space, with their BCA 5.0 Breathscanner™ being the latest version available. Gas samples collected by the device are analysed by gas chromatography and picomolar concentrations can be detected. A digital display panel guides the user through the collection process, step-by-step. The device can be used to detect for MTB and the company is now developing a test to identify people who are acutely infected with influenza, but who have not yet developed clinical symptoms or signs of disease.

Pipeline VOC platforms

Developer	Product name	Image	Technology	Launch date
Metabolomx	Metabolomx sensor		The Metabolomx prototype uses a colorimetric sensor array to indicate TB infection from VOCs in urine and the company has plans to develop the system for the detection of respiratory infections.	TBD
Rapid Biosensor Systems Ltd	Breathalyzer		An antigen-based breath test. The company developed a device to screen for TB, however, the patented platform technology can be adapted for detecting other diseases, and there are plans to develop a test for bacterial pneumonia.	TBD

Immunoassay/ NAT integrated platforms

Over recent years, the ability to combine NATs and immunoassays into an integrated POC or near-POC device has been realized. Although most of these platforms are still in development, they may help to streamline testing algorithms and workflow, and help to guide the diagnosis, management and treatment of infectious diseases.

TRAPIST v6 (Coris BioConcept)

The TRAPIST v6 is a fully automated instrument that performs multiplex diagnostic testing. It is intended to be used in clinical laboratories, and uses microfluidic chips that can enable results within one hour. The platform enables a wide range of molecular assays and is also designed for immunoassays. Following nucleic acid amplification, oligochromatography, a simple and rapid method of detecting nucleic acids, is used. With this technique, the amplified nucleic acids are allowed to migrate on the oligochromatogaphic membrane and hybridize with capture and detection probes (111). The system is currently for RUO, but is in preparation for CE marking. Cassettes currently available for the TRAPIST v6 are designed for sepsis applications and include a multiplex Gram-positive cassette (which tests for Gram-positive bacteria such as SA and Streptococcus, as well as multi-drug resistance) and a multiplex Gram-negative cassette (which tests for Gram-negative bacteria such as E. coli and Pseudomonas aeruginosa as well as multi-drug resistance). As part of the nanotherapeutics for antibiotic-resistant emerging bacterial pathogens (NAREB) project, a cassette for MTB and MTB AMR is also being developed.

SAMBA I/II (Diagnostics for the Real World [DRW])

DRW's mission is to develop diagnostic assays and technologies for deployment in resource-limited countries. The Simple Amplification Based Assay (SAMBA) platforms enable rapid NAT testing at the POC, and are based on isothermal amplification and visual detection on a dipstick. The CE marked SAMBA I is designed for semi-automated batch testing, and is capable of running up to four samples simultaneously with a throughput of 24–48 samples per day. SAMBA I comprises two instruments: the SAMBAprep for sample extraction; and the SAMBAamp for amplification and detection of the nucleic acid target. SAMBA II, which is also CE marked, is a fully automated system comprising of a tablet module and an assay module, linked via Bluetooth. Each Tablet Module can control up to four Assay Modules, so that each health facility can tailor the system to their specific throughput needs. The SAMBA platforms offer a CE marked whole blood qualitative test for EID and acute infection diagnosis of HIV, as well as plasma or whole blood semi-quantitative (VL) tests for therapy monitoring. In addition, future developments include assays for Chlamydia trachomatis, Neisseria gonorrhoeae and FluA/B.

In addition to the TRAPIST v6 device and the DRW SAMBA POC device, the Akonni Biosystems TruDiagnosis® System (see pages 50 respectively) is capable of carrying out NATs and protein-based tests. Pipeline immunoassay/NAT integrated platforms are listed in the table below.

Pipeline immunoassay/NAT integrated platforms

Developer	Product name	Image	Technology	Launch date
ChipCare	PAx Platform		Multi-disease POC analyzer able to perform three classes of diagnostic tests (cell-based, immune and molecular assays). Technology uses microfluidic cartridges and a patented optical detection method. The company's first assay will provide a CD4 count; while immunoassays for HIV and TP and a NAT for HIV (suitable for EID) are also in development (112).	2017
InSilixa	HYDRA-1K CMOS Biochip Platform		Complementary metal-oxide-semiconductor (CMOS) multiplex biosensor arrays that can be used to detect nucleic acids (DNA or RNA), peptides or metabolites.	TBD
mBio	MBio Multiplex Analyzer		Multiplexed immunoassay/NAT platform that uses LightDeck® Optical Technology.	Research studies in malaria and HCV ongoing, but no product launch scheduled.

Conclusions

Implementation hurdles and programmatic issues have meant that existing methods for accurate diagnosis of infectious diseases are failing to meet medical needs, especially in lower-resource settings, where current platforms/tests are not accessible, not affordable or too complex. Simplified technologies such as RDTs have made great progress; however, in certain populations, there is the need to screen for more than one infection, and an additional level of sophistication is clearly needed to meet the current and anticipated diagnostic needs, such as the ability to test for AMR and more unified systems that can meet the needs of different patients. Multi-disease platforms offer the potential to improve infectious disease diagnosis and monitoring, potentially reducing overtreatment and resistance, improving the overall quality of care, and potentially reducing cost by improving utility of these devices. These platforms may also enable screening for multiple infections at the same time, many of which are currently overlooked in current conventional settings. Ultimately, the success and integration of multi-disease platforms within health-care systems will largely be dependent upon factors such as affordability, ease-of-use, streamlined and simple sample preparation, sensitivity and specificity, and the time taken to receive results, as well as all the clinical and programmatic aspects that surround the test. Fortunately, numerous technologies are being integrated into multi-disease diagnostic platforms to address these factors. Indeed, a number of innovative multi-disease diagnostics are available or emerging and the field is rapidly expanding. However, it remains to be seen whether these platforms will live up to expectation. Therefore, further work is warranted to demonstrate the public health and market impact that can be derived from these technologies, and ultimately the integration into health system in low-resource settings.

* To facilitate the adoption and use of multi-disease testing, WHO has outlined key programmatic considerations that will need to be addressed to successfully implement these tests (http://apps.who.int/iris/bitstream/10665/255693/1/WHO-HTM-TB-2017.06-eng.pdf).

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Appendix 1. Multi-dise for infectious disease

Fio Corporation
Deki Reader V200

Genapsys
GENIUS

InSilixa
HYDRA-1K CMOS
Biochip Platform

Bioneer
ExiStation™

Cepheid
GeneXpert Omni

QuantuMDx
Q-POC

MolBio
New generation
Trupred/ Trulab

Biosensia
RapidPlex Platform

ChipCare
PAx Platform

2017 | **2018**

Nat platform in the pipeline	Immunoassay platform in the pipeline	VOC platforms in the pipeline	Immunoassay/NAT integrated platform in the pipeline

ase platforms/tests diagnostics: pipeline*

Tangen
TangenDx Instrument

Diagnostic For All

Akonni
TruDx 3000

Axela
Next generation diffractive Optics Unit

Columbia University
Smartphone Dongle Device

Mbio
Mbio System

DiscoGnosis
LabDisk System

Metabolomx
Metabolomx Sernsor

Daktari
Daktari Virology

Genia
Nagotag chemistry device

Atlas Genetics
io system

Chembio
HIV/HCV RDT
HIV/HCV/TP RDT

Rapid Biosensor System
Breathalyzer

Nanobiosym
Gene-RADAR

Spartan
Spartan Cube

MedMira
TP/HBV/HIV/HCV RDT

BioSynex
HIV+crypto+HCV RDT

Oxford Nanopore
minion, promethION, smidION

Two Pore Guys

Scanogen
Biosensor Technology

McGill University
Paper-based electrochemical platform

2019

2020 AND BEYOND

NGS platforms in the pipeline

*** Estimated as of February 2017 - timeline and sequence may change. ---------- No market launch date set by company**

Appendix 2. Operational characteristics of multi-disease diagnostic platforms/tests

Abbott	
m2000 System – m2000sp (extraction) and m2000rt (amplification/detection)	
Marketing status	Multi-disease POC analyzer able to perform three classes of diagnostic tests (cell-based, immune an d molecular assays). Technology uses microfluidic cartridges and a patented optical detection method. The company's first assay will provide a CD4 count; while immunoassays for HIV and TP and a NAT for HIV (suitable for EID) are also in development (112). 2017
Type of technology	NAT; qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked: HIV-1 (VL), HIV-1 (EID), HCV (VL), HCV (genotyping), MTB, MTB RIF/INH, HBV, HPV, Chlamydia trachomatis, Neisseria gonorrhoeae, CMV, Epstein-Barr virus
	US FDA approved: HIV-1 (VL), HCV (VL), HCV (genotyping), HBV, Chlamydia trachomatis, Neisseria gonorrhoeae. US FDA has granted Emergency Use Authorization for Zika virus assay
Sensitivity	Assay dependent. For key disease areas: HCV (VL): 12 IU/mL for 0.5 mL sample; 30 IU/mL for 0.2 mL sample. HCV (genotyping): 500 IU/mL for 0.5 mL prep. HIV-1 (VL): 40 cp/mL for 0.6 mL sample; 150 cp/mL for 0.2 mL sample; 839 cp/mL for DBS. HIV-1 (qualitative, EID): 110 cp/mL for plasma samples; 2500 cp/mL for DBS. MTB: sensitivity in culture positive samples 93%; sensitivity in smear negative culture positive samples 81%.
Specificity (CE)	Assay dependent. For key disease areas: HCV (VL): 100% HCV (genotyping): 100% HIV-1 (VL): plasma 100%, DBS ≥99.5% HIV-1 (qualitative): 100% MTB: 97%
Multiplex	Yes; maxCycle assays allow two assays in a single run; maxCycle for Abbott RealTime HIV-1/HCV (CE marked); maxCycle for Abbott RealTime Cytomegalovirus/Ebola virus (CE marked).
Storage temperature of the device(s)/reagents	System: 1–60 °C Reagents: amplification, control and calibrations kits ≤-10 °C (some amplification kits -15 to -25 °C); sample preparation kits 15–30 °C.
Shelf life of the device(s)/reagents	System: N/A Reagents: amplification, control and calibration kits 18 months upon manufacture; sample preparation kits 12 months
Type of sample required	Assay dependent: E.g. HCV and HBV serum or plasma; HIV-1 plasma or DBS; MTB and MTB RIF/INH resistance sputum or bronchial alveolar lavage or NALC sediment of sputum or bronchial alveolar lavage; CMV and Ebola virus whole blood or plasma; Zika serum, plasma, whole blood or urine
Volume of sample required	Assay and sample type dependent: 0.2–1 mL
Turnaround time	Assay dependent: 4.5–6.3 hours for 24 samples and 6.2–9.5 hours for 96 samples (extraction and amplification)
Dimensions (W x H x D)	m2000sp: 145 cm x 138 cm x 79.5 cm m2000rt: 34 cm x 49 cm x 45 cm

Abbott	
m2000 System – m2000sp (extraction) and m2000rt (amplification/detection)	
Power requirements	m2000sp: 1200 VA m2000rt: 860 VA
Connectivity	AbbottLink and mView are optional features that allow remote diagnostics and performance monitoring, respectively, available using a secured Internet connection
Marketing price per instrument/test	Contact the local Abbott Molecular representative for prices
Complexity/training requirements	Two days; instructor-led training for the system, including one assay; one day per assay thereafter
Supporting instrumentation/ sample preparation required	mPlus (Amplification Reagent Extended Use) is the capability of reusing the amplification reagent one more times or more often (depending on the assay), allowing the reuse of the 24-test pack in order to run batch sizes smaller than 24 for higher efficiency. mPlus gives labs flexibility and added efficiency that allows for customized workflow, and faster results. Supporting instrument required is minimal; automated extraction and amplification. m24sp instrument is for mid-volume extraction, but not all assays are available on this system. M2000sp is for mid- to high-volume throughput; m24sp for low- to mid-volume throughput.
Image of device(s) m2000sp and m2000rt	

Abbott (information not verified by company)	
PRISMnEXT	
Marketing status	On the market
Type of technology	Immunoassay; CIA
POC	No
Infections the device(s) can test for and regulatory approval status	Anti-HBc, anti-HCV, HBsAg (Qualitative Conf.), HBsAg (qualitative), Chagas disease, anti-HIV-1/HIV-2, HIV Ag/Ab Combo
Sensitivity	
Specificity (CE)	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Serum, plasma
Volume of sample required	
Turnaround time	
Throughput*	High
Dimensions (W x H x D)	1.73 m x 2.33 m x .84 m
Power requirements	Single-phase 200–240 VAC ± 10%
Connectivity	
Marketing status	On the market
Type of technology	Immunoassay; CIA
POC	No
Infections the device(s) can test for and regulatory approval status	Anti-HBc, anti-HCV, HBsAg (Qualitative Conf.), HBsAg (qualitative), Chagas disease, anti-HIV-1/HIV-2, HIV Ag/Ab Combo
Sensitivity	
Specificity (CE)	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Serum, plasma

Abbott (information not verified by company)	
PRISMnEXT	
Volume of sample required	
Turnaround time	
Throughput*	High
Dimensions (W x H x D)	1.73 m x 2.33 m x .84 m
Power requirements	Single-phase 200–240 VAC ± 10%
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	VGA-compatible colour monitor with keyboard
Image of device(s)	

Abbott (information not verified by company)	
Iridica System	
Marketing status	On the market (CE marked)
Type of technology	NAT; PCR and mass spectrometry
POC	No
Infections the device(s) can test for and regulatory approval status	Assays that cover 780 bacteria and Candida, 4 resistance markers, 200+ fungi, 13 viral reporting groups – all assays currently on the market (CE marked)
Sensitivity	
Specificity	
Multiplex	Yes; available with IRIDICA BAC BSI Assay, IRIDICA BAC SFT Assay, IRIDICA BAC LRT Assay, IRIDICA FUNGAL Assay, IRIDICA VIRAL IC Assay
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Whole blood, plasma
Volume of sample required	
Turnaround time	360 minutes
Throughput*	High
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Abbott (information not verified by company)	
AxSYM/AxSYM Plus	
Marketing status	On the market
Type of technology	Immunoassay; microparticle enzyme immunoassay (MEIA)
POC	No
Infections the device(s) can test for and regulatory approval status	HIV, HCV, HBV, CMV, toxoplasmosis, FluA/B, MDR and others
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	Medium to high (up to 80–120 samples/hour)
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Abbott (information not verified by company)	
AxSYM/AxSYM Plus	
Marketing status	On the market
Type of technology	Immunoassay; chemiluminescent microparticle immunoassay (CMIA)
POC	No
Infections the device(s) can test for and regulatory approval status	On the market: HIV1, HIV2, HAV, HBsAg, HBcAg, HCV, toxoplasmosis, rubella, CMV, Chagas, human T-cell lymphotropic virus
	In development: TP
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Whole blood, plasma, serum, urine
Volume of sample required	10–150 µL
Turnaround time	
Throughput*	Medium to high
Dimensions (W x H x D)	Ranges from 124.5 cm x 149.9 cm x 76.2 cm (smallest system) to 121.9 cm x 322.6 cm x 124.5 cm (largest system)
Power requirements	AC
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Akonni Biosystems (information not verified by company)	
TruTip® Automated Workstation and TruDx2000® Platform (semi-automated)/TruDx3000® Platform (fully automated)	
Marketing status	TruDx2000® Platform: on the market TruDx3000® Platform: in development
Type of technology	Immunoassay and NAT
POC	No
Infections the device(s) can test for and regulatory approval status	MDR-TB (RIF/INH), MRSA All are RUO
Sensitivity	
Specificity	
Multiplex	Yes; Akonni's microarrays carry anywhere from 5 to 200 3D gel-drops per array
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	15 minutes for immunoassays; 1–3 hours for NATs
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	TruDx2000® is a semi-automated Platform that requires sample preparation on the TruTip® Automated Workstation TruDx3000® will be fully integrated combining both sample preparation and analysis
Image of device(s)	

Alere	
AlereTM q Analyzer	
Marketing status	On the market (CE marked, WHO PQ for Alere q HIV-1/2 Detect assay)
Type of technology	NAT; qPCR
POC	Yes
Infections the device(s) can test for and regulatory approval status	On the market: Alere q HIV-1/2 Detect – HIV-1/HIV-2 (qualitative screening assay) (WHO PQ, CE marked)
Sensitivity	In development: Alere q HIV-1/2 VL Plasma (quantitative VL assay), Alere q Filovirus (Ebola virus) (launch dates TBC)
Specificity	Alere™ q HIV-1/2 Detect:
Multiplex	HIV-1 Group M (IIIB Strain): 2491 cp/mL (2046 cp/mL, 3319 cp/mL) and 4160 IU/mL (3417 IU/mL, 5543 IU/mL)
Storage temperature of the device(s)/reagents	Alere™ q analyzer to be stored at 2–50 °C Alere™ q HIV-1/2 Detect cartridges should be stored at an ambient temperature 4–30 °C
Shelf life of the device(s)/reagents	Alere™ q HIV-1/2 Detect cartridges 9 months
Type of sample required	Alere™ q HIV-1/2 Detect whole blood (fingerstick, heelstick or venepuncture) and plasma
Volume of sample required	25 µL of whole blood or plasma
Turnaround time	Alere™ q HIV-1/2 Detect 52 minutes
Throughput*	Low: single cartridge use/8 tests per day per instrument
Dimensions (W x H x D)	Alere™ q analyzer 20 cm x 22 cm x 31 cm
Power requirements	Mains or battery powered
Connectivity	Yes; as standard. Results can be printed immediately, but results are also stored in an onboard archive and can be viewed and printed at a later date, exported to a USB memory stick or exported to a remote server via the use of an optional USB connectivity package that makes use of GSM network infrastructure.
Marketing price per instrument/test	Available upon request
Complexity/training requirements	Non-complex. Minimal training required. The actual hands-on time for the device is expected to be less than 3 minutes (i.e. sample collection, loading of the cartridge onto the analyzer and entering the operator and sample IDs on the analyzer).
Supporting instrumentation/ sample preparation required	Alere™ q analyzer is factory calibrated and does not require any further calibrations. No sample preparation required.
Image of device(s)	

Alere	
AlereTM q Analyzer	
Marketing status	On the market (WHO PQ, CE marked)
Type of technology	Immunoassay; lateral flow RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV-1 (antibody), HIV-2 (antibody), TP WHO PQ, CE marked
Sensitivity	HIV-1: 99.75% HIV-2: 100% TP: 90%
Specificity	HIV-1: 100% HIV-2: 100% TP: 99.9%
Multiplex	Yes; tests for HIV-1, HIV-2 and TP
Storage temperature of the device(s)/reagents	1–30 °C
Shelf life of the device(s)/reagents	24 months
Type of sample required	Serum, plasma or whole blood (fingerpick)
Volume of sample required	10 µl for serum and plasma, 20 µl for whole blood
Turnaround time	20 minutes
Throughput*	Low; one test takes 20 minutes
Dimensions (W x H x D)	177 mm x 110 mm x 75 mm (25 tests)
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	Available upon request
Complexity/training requirements	Minimal; 10 µl of serum/plasma is added to the test cassette, followed by three drops of assay diluent; results are read 15–20 minutes later
Supporting instrumentation/ sample preparation required	Minimal; capillary pipette/lancet/alcohol swab can also be included with the product (optional choice). Gloves/timer/pipettes required.
Image of device(s)	

Analytik Jena	
qTOWER3/qTOWER3 auto	
Marketing status	On the market
Type of technology	NAT; qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	CE-IVD: HBV, HCV, HDV (VL monitoring). RUO (VL monitoring): HIV-1, CMV, Epstein-Barr virus, parvovirus B19. RUO (confirmation): HSV-1, MTB, norovirus, BF H5N1.
Sensitivity	Assay dependent: HBV: 25 IU/mL HCV: 68 IU/mL HDV: 6 IU/mL
Specificity	Assay dependent
Multiplex	Yes; 6-fold multiplexing
Storage temperature of the device(s)/reagents	qTOWER3/qTOWER3 auto: room temperature RoboGene® assays/reagents: -20 °C
Shelf life of the device(s)/reagents	qTOWER3/qTOWER3 auto: - RoboGene® assays/reagents: minimum 6 months
Type of sample required	Assay dependent: plasma, serum, sputum
Volume of sample required	400 µL
Turnaround time	Assay/device dependent: 120 minutes
Throughput*	Medium: 96
Dimensions (W x H x D)	qTOWER3: 27.5 cm x 58.5 cm x 27.5 cm qTOWER3 auto: 27.5 cm x 46 cm x 31 cm
Power requirements	qTOWER3: Max. 850 W, 100–240 V qTOWER3 auto: Max. 850 W, 100–240 V
Connectivity	PC connection: USB, RS232 Tablet: USB for data transfer, barcode reader
Marketing price per instrument/test	qTOWER3: base unit: €19 450–21 950 Colour module: €2550 FRET module: €3100 Colour module protein: €3100 qTOWER^3 can be equipped with up to 6 modules qTOWER3 auto: base unit: €19 450–21 950 Colour module: €2550 FRET module: €3100 Colour module protein: €3100 qTOWER^3 can be equipped with up to 6 modules
Complexity/training requirements	No

Alere	
AlereTM q Analyzer	
Supporting instrumentation/ sample preparation required	Analytik Jena also supplies InnuPure® devices for fully automated extraction of nucleic acids qTOWER3 auto is suited for connection quantitative real-time PCR with robotic systems
Image of device(s)	
	

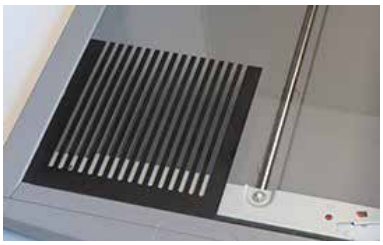
Aquila Diagnostic Systems (information not verified by company)	
Accutas	
Marketing status	On the market
Type of technology	NAT; qPCR
POC	Yes
Infections the device(s) can test for and regulatory approval status	RUO: malaria
	In development: HSV-1, HSV-2, ureaplasma, Mycoplasma hominis
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Artron Laboratories (information not verified by company)	
Detect 3	
Marketing status	On the market; CE marked
Type of technology	Immunochromatography; RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV, HCV, HBV
Sensitivity	>99%
Specificity	>99%
Multiplex	Yes
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Plasma or serum
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Atlas Link (Beijing) Technology	
One Step HIV/ HBsAg/ HCV Serum Test Panel	
Marketing status	On the market
Type of technology	Immunoassay; immunochromatography
POC	Level 1 (POC)
Infections the device(s) can test for and regulatory approval status	HBsAg, HIV-1 antibody, HIV-2 antibody and HCV antibody CE marked
Sensitivity	HIV-1: 99.86% HIV-2: 99.86% HCV: 99.18% HBsAg: 99.19%
Specificity	HIV-1: 99.89% HIV-2: 99.89% HCV: 99.47% HBsAg: 99.54%
Multiplex	Yes; tests for HIV-1, HIV-2, HCV and HBsAg using one sample
Storage temperature of the device(s)/reagents	2–30 °C
Shelf life of the device(s)/reagents	24 months
Type of sample required	Serum
Volume of sample required	Few drops
Turnaround time	10 minutes
Throughput*	Low
Dimensions (W x H x D)	7.5 cm x 2 cm x 0.5 cm
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	HIV-1/2: US$ 0.3 HCV: US$ 0.25 HBsAg: US$ 0.13
Complexity/training requirements	N/A
Supporting instrumentation/ sample preparation required	Tube
Image	

AutoGenomics	
INFINITI® PLUS & INFINITI® High Throughput System (HTS)	
Marketing status	On the market
Type of technology	NAT; target signal amplification – microarray based
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked: HPV, Candida, bacterial vaginosis, mycoplasma, ureaplasma, respiratory viruses – FluA/B, parainfluenza, adenovirus, enterovirus, rhinovirus, coronavirus, etc.
	RUO: MTB, MDR-TB, NTM, HCV genotyping, Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Streptococcus, Helicobacter pylori
Sensitivity	Assay dependent: HCV Genotyping: limit of detection during assay development: 31 copies per test. MDR-TB: limit of detection during assay development: 10 copies per test. NTM: limit of detection during assay development: 10 copies per test.
Specificity	Assay dependent. Cross-reactivity analysis performed against various microorganisms shows no cross-reactivity.
Multiplex	Yes; capable of detecting various analytes simultaneously; capable of testing multiple (1, 2, 4, 6 or 8) samples simultaneously
Storage temperature of the device(s)/reagents	Systems: 0–60 °C Reagents: BioFilmChip® Microarrays: 2–8 °C IntelLPAc®: 2–8 °C Primer Extension Mix: 2–8 °C Amplification Mix: -30 to -15 °C Buffers: 15–30 °C
Shelf life of the device(s)/reagents	Systems: 7 years BioFilmChip® Microarrays: 24 months IntelLPAc®: 18 months Primer Extension Mix: 18 months Amplification Mix: 18 months Buffers: 12 months
Type of sample required	HCV genotyping: extracted RNA from plasma and serum MDR-TB: extracted DNA from sputum NTM: extracted DNA from sputum and culture
Volume of sample required	Assay dependent. Ranges from 4.0–9.0 µL of extracted RNA.
Turnaround time	Assay dependent and varies with the platform used. On the INFINITI® PLUS – 48 samples in ~5.5 hours to 7 hours post-extraction. On INFINITI® High Throughput System (HTS) – 96 samples in 6 hours and 45 minutes post-extraction
Throughput*	INFINITI® PLUS – up to 48 samples in 1 batch INFINITI® HTS – up to 96 or 864 samples in 1 batch

<table>
<tr><th colspan="5">AutoGenomics</th></tr>
<tr><th colspan="5">INFINITI® PLUS & INFINITI® High Throughput System (HTS)</th></tr>
<tr><td rowspan="2">Dimensions (W x H x D)</td><td rowspan="2">INFINITI® PLUS
Length 44” (111.76 cm)
Depth 25” (63.5 cm)
Height 25” (63.5 cm)</td><td colspan="3">INFINITI® HTS</td></tr>
<tr><td>INFINITI® INCUBATOR
Width 25.125”
Depth (door closed) 12.75”
Depth (door opened) 28”
Height 19.50”</td><td>INFINITI® PROCESSOR
Width 38.25”
Depth 27”
Height (door closed) 17.50”
Height (door opened) 33”</td><td>INFINITI® ACE
Width 19”
Height 16”</td></tr>
<tr><td rowspan="2">Power requirements</td><td rowspan="2">INFINITI® PLUS
Current: 12 Amp
Voltage: 100–240 VAC
Frequency: 50–60 Hz</td><td colspan="3">INFINITI® HTS</td></tr>
<tr><td>INFINITI® INCUBATOR
Current: 7 Amp
Voltage: 100–240 VAC
Frequency: 50–60 Hz</td><td>INFINITI® PROCESSOR
Current: 7 Amp
Voltage: 100–240 VAC
Frequency: 50–60 Hz</td><td>INFINITI® ACE
Current: 4 Amp
Voltage: 100–240 VAC
Frequency: 50–60 Hz</td></tr>
<tr><td>Connectivity</td><td colspan="4">Network capable with wireless keyboard and infrared mouse
Internet/LIS compatible</td></tr>
<tr><td>Marketing price per instrument/test</td><td colspan="4">System list price: US$ 227 447
Price of assays variable</td></tr>
<tr><td>Complexity/training requirements</td><td colspan="4">High complexity</td></tr>
<tr><td>Supporting instrumentation/ sample preparation required</td><td colspan="4">Extraction System and Thermal Cycler</td></tr>
<tr><td>Image of device(s)</td><td colspan="4">INFINITI® PLUS
 
INFINITI® I
  </td></tr>
</table>

Autoimmun Diagnostika GmbH	
AID Reader and Scanning System	
Marketing status	On the market (CE marked)
Type of technology	Used to analyse immunoblot and LPAs (PCR amplification and DNA reverse hybridization)
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked: HPV, HSV-1, HSV-2, Chlamydia trachomatis, Chlamydophila pneumoniae, Neisseria gonorrhoeae, TP, CMV, Yersinia pseudotuberculosis, Helicobacter pylori, Campylobacter, FluA/B, Bordetella pertussis, viral community acquired pneumonia pathogens, bacterial community acquired pneumonia pathogens, MDR genes
Sensitivity	Dependent upon the strip/assay
Specificity	Dependent upon the strip/assay
Multiplex	Yes; AID STD Kit, AID Community Acquired Pneumonia Bacteria Kit, AID Community Acquired Pneumonia Virus Kit, AID MRSA Combi Kit
Storage temperature of the device(s)/reagents	Room temperature
Shelf life of the device(s)/reagents	N/A
Type of sample required	The sample required is dependent upon the infection being tested for; samples that can be used for some of the assays include bronchoalveolar lavage (BAL), sputum or pharyngeal swab, and nasal swabs
Volume of sample required	N/A
Turnaround time	Dependent upon the technology being used. Results from immunoblots are available within 2 hours. Results from LPAs are available within 4 hours.
Throughput*	For each process, up to 16 strips can be scanned and one process takes less than 1 minute (scan and interpretation), meaning >100 strips per hour, including interpretation and loading the scanner.
Dimensions (W x H x D)	3.7 cm x 4 cm x 2.7 cm
Power requirements	Connected to PC by USB (5V/500 mA)
Connectivity	USB
Marketing price per instrument/test	€1200 per instrument (including software)
Complexity/training requirements	High; for LPAs, DNA extraction, PCR amplification and DNA hybridization must be carried out before being analysed on the AID Scanner. For Immunoblot assays, a Western Blot procedure must be carried out before samples can be analysed on the AID Scanner.
Supporting instrumentation/ sample preparation required	Instrumentation for Western Blot/DNA extraction/PCR amplification/DNA hybridization required
Image of device(s)	

Axela (information not verified by company)	
dotLab® mX System	
Marketing status	dotLab® mX System: on the marketxxx Next generation diffractive optics unit: in development
Type of technology	Immunoassay; diffractive optics technology
POC	No
Infections the device(s) can test for and regulatory approval status	
Sensitivity	
Specificity	
Multiplex	Yes; up to 3-plex multiplex with panelPlusTM Technology
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	15–45 minutes
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s): dotLab® mX System: Next generation diffractive optics unit:	 

Axela (information not verified by company)	
Ziplex® System	
Marketing status	Ziplex® System: on the market
Type of technology	NAT or immunoassay; microarray
POC	No
Infections the device(s) can test for and regulatory approval status	
Sensitivity	
Specificity	
Multiplex	Yes; each test chip can accommodate <150 targets
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	For gene expression analysis, 8 samples can be run in 3 hours. For proteins, assay times for 8 samples is often less than one hour.
Throughput*	Gene expression assays: 24 tests per day (each test chip can accommodate <150 targets). Protein assays: up to 64 tests per day (each test chip can accommodate <150 targets).
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Axxin (not verified by company)	
AX-2X	
Marketing status	
Type of technology	Rapid testing instrument designed to provide quantitative or qualitative results for visible colorimetric or fluorescent immunoassays
POC	
Infections the device(s) can test for and regulatory approval status	
	RUO
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	Local area network (LAN), WiFi
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

BD (information not verified by company)	
BD MAXTM System	
Marketing status	On the market (CE marked, US FDA approved)
Type of technology	NAT; qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	MRSA, SA, Clostridium difficile, Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis
	In development: MTB, MTB/RIF, MTB/INH
Sensitivity	
Specificity	
Multiplex	Yes; BD MAXTM Chlamydia trachomatis/Neisseria gonorrhoeae/Trichomonas vaginalis
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	CLIA moderately complex and easy to use; less than 1 minute of hands-on time per sample
Supporting instrumentation/ sample preparation required	Automated extraction and thermocycling in a single platform
Image of device(s)	

Beckman Coulter	
DxN VERIS Molecular Diagnostics System	
Marketing status	On the market – not available in the United States (CE marked; currently under WHO PQ, submission accepted)
Type of technology	RT-PCR; mMagnetic particle separation (propriety)
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked: HIV-1 (VL), HCV (VL), HBV (VL), CMV (VL)
Sensitivity	Assay dependent HIV-1: 60 IU/mL HCV: 12 IU/mL
Specificity	Assay dependent HIV-1: 99.8% HCV: 100%
Multiplex	No
Storage temperature of the device(s)/reagents	Device and general consumables: room temperature. Reagents 4 C°. Calibration adjusters -20 C°. QC -20 or -70 C° for long-term storage (>6 months).
Shelf life of the device(s)/reagents	Assays: stable for 30 days once opened; device: N/A
Type of sample required	Plasma (HBV can also be detected in serum)
Volume of sample required	Assay dependent (250–1000 µl). HIV-1 assay available 0.175 mL and 1.0 mL sample volumes.
Turnaround time	Daily maintenance and setup: ≤10 minutes. First results from 70 minutes for HBV and CMV, 90 minutes for HIV-1, 115 minutes for HCV. Walk-away time: ≥2 hours (replenish tips and samples).
Throughput*	~150 results in 8 hours for DNA assays ~100 results in 8 hours for RNA assays
Dimensions (W x H x D)	Line voltage 200–240 VAC, 50/60 Hz, 16 A Class1
Power requirements	Line voltage 200–240 VAC, 50/60 Hz, 16 A Class1
Connectivity	Yes; LIS connectivity
Marketing price per instrument/test	N/A (regional prices vary)
Complexity/training requirements	Low complexity. Very easy to use, fully automated after primary tube loading. Ready-to-use reagents with onboard storage. Training half a day; familiarization 2 days.
Supporting instrumentation/ sample preparation required	Single platform. Fully automated platform. Primary tube loading, secondary tube option available.
Image of device(s)	

bioLytical	
INSTI Multiplex HIV-1/HIV-2/Syphilis Antibody Test	
Marketing status	On the market (CE marked)
Type of technology	Immunoassay; immunofiltration
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV-1 (antibody), HIV-2 (antibody), TP (CE marked)
Sensitivity	HIV-1: 99.6% HIV-2: 100% TP: >95% agreement with TP-PA
Specificity	HIV-1: 99.3% HIV-2: not differentiated from HIV-1 TP: 99.9%
Multiplex	Yes; HIV-1, HIV-2, TP
Storage temperature of the device(s)/reagents	Room temperature (15–30 °C)
Shelf life of the device(s)/reagents	12 months
Type of sample required	Whole blood (fingerstick or venous blood), serum or plasma
Volume of sample required	50 µL
Turnaround time	1 minute
Throughput*	Medium (one test takes 1 minute)
Dimensions (W x H x D)	Single foil pouch, 7” x 5.5”
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	N/A
Complexity/training requirements	Minimal: uses same platform and procedure as the INSTI HIV-1/HIV-2. Antibody test is CLIA waived.
Supporting instrumentation/ sample preparation required	No sample preparation required for venous/whole blood/fingerstick blood; centrifugation required for plasma or serum collection. Timer required.
Image of device(s)	

Bio-Mérieux (information not verified by company)	
NucliSENS® easyMAG® and NucliSENS® easyQ®	
Marketing status	On the market
Type of technology	NAT; NASBA
POC	No
Infections the device(s) can test for and regulatory approval status	HIV-1 (WHO PQ), HPV (CE-IVD)
Sensitivity	
Specificity	
Multiplex	No
Storage temperature of the device(s)/reagents	easyMAG®: easyQ®: 15–30 °C HIV-1 assay: 2–8 °C HPV assay: TBC
Shelf life of the device(s)/reagents	HIV-1 assay: 18 months HPV assay: TBC
Type of sample required	
Volume of sample required	
Turnaround time	Extraction to results in 2 hours for 48 samples.
Throughput*	Low
Dimensions (W x H x D)	42 cm x 22 cm x 42 cm
Power requirements	200 VA max, 32 VA stand-by
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	Requires prior RNA/DNA extraction, but this can this be automated on the NucliSENS® easyMag® or miniMAG® systems. NucliSENtral™, which is an integrated software system, can also be used to link NucliSENS® easyMAG® and NucliSENS® EasyQ® with LIS.
Image of device(s)	

Bio-Mérieux (information not verified by company)	
VIDAS®/VIDAS-3®/miniVIDAS®	
Marketing status	On the market (VIDAS® 3 is CE marked, United States FDA approved and China FDA approved)
Type of technology	Immunoassay; enzyme linked fluorescent assay (ELFA)
POC	No
Infections the device(s) can test for and regulatory approval status	HAV, HIV-1, HIV-2, CMV, Epstein-Barr virus, Helicobacter pylori, Clostridium difficile, HBV, toxoplasmosis, measles, mumps, rubella, varicella-zoster virus, B.R.A.H.M.S PCT assay (able to distinguish between bacterial infections and sepsis)
Sensitivity	
Specificity	
Multiplex	No
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	VIDAS® 3: 17–90 minutes miniVIDAS: 17–90 minutes
Throughput*	VIDAS®: up to 30 tests per hour VIDAS® 3: up to 36 tests per hour miniVIDAS®: up to 36 tests per hour
Dimensions (W x H x D)	miniVIDAS®: 45 cm x 57.5 cm x 55 cm
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	miniVIDAS® comes with built-in computer, keyboard and printer
Image of device(s)	

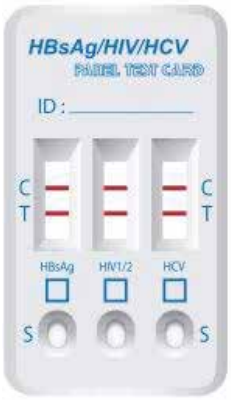
BIONEER	
ExiStation™ Universal Molecular Diagnostic System (ExiPrep™ 16 Dx/ExiPrep™ 48 Dx (with or without ExiLT™ 48 BT/ST) in combination with Exicycler™ 96, or Fully automated ExiStation™ HT (with or without ExiLT™ 48 BT/ST))	
Marketing status	On the market: ExiPrep™ 16 Dx (nucleic acid extraction): CE marked, US FDA approved, WHO PQ. Exicycler™ 96 Dx (5-colour qPCR system): CE marked, WHO PQ. ExiStation™ HT (integrated standalone platform for nucleic acid extraction and qPCR): CE marked. ExiPrep™ 48 Dx (nucleic acid extraction): CE marked
	In development: ExiPrep™ 48 Dx (nucleic acid extraction): CE marking expected Q1 2017. ExiLT™ 48 BT (automated blood sample handler): CE marking expected Q1 2017 ExiLT™ 48 ST (automated sputum, urine, faeces sample handler): CE marking expected Q1 2017. (ExiLT™ 48 BT and ExiLT™ 48 ST dock with ExiPrep™ 48 Dx and Exicycler™ 96 Dx and automate the whole process of clinical sample tube loading and nucleic acid extraction and purification. Only user hands-on process is to seal PCR reaction tube and to load onto the PCR rack – together the system is called the ExiStation™ 48A, expected launch Q2 2017). ExiLT™ 48 BT and ExiLT™ 48 ST can also be used in combination with the ExiStation™ HT System.
Type of technology	NAT; qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked: MTB, Chlamydia trachomatis, Neisseria gonorrhoeae, HPV, HSV-1, HSV-2, enterovirus, Trichomonas vaginalis, human herpesvirus 6, FluA/B, ureaplasma, Mycoplasma genitalium, Mycoplasma hominis, Chlamydophila pneumoniae, dengue virus, Ebola virus, Epstein-Barr virus, Zika virus multiplex (and others). Zika virus (dengue virus, chikungunya virus) multiplex assay also WHO PQ and undergoing US FDA submission.
	RUO: HCV (VL), HBV (VL), HIV-1 (VL)
Sensitivity	Assay dependent: HIV-1: 33.1 IU/mL (EDTA-plasma) MTB: 89.1 cp/mL HCV: 10.7 IU/mL (EDTA-plasma)
Specificity	Assay dependent: HIV-1: 100% MTB: N/A HCV: 99.12%
Multiplex	Yes. AccuPower® STI8A-Plex, AccuPower® Zika virus (dengue virus, chikungunya virus, and others) – all CE marked. The whole ExiStation™ platform is also WHO PQ for AccuPower® Zika virus (dengue virus, chikungunya virus), this assay is undergoing US FDA submission. AccuPower® TB and XDR (FLQ/streptomycin/ethambutol resistance, MTB) – in development. As well as having multiplex assays available, the ExiPrep™ System can automatically aliquot prepared sample into two separate reaction tubes for individual qPCR/RT-PCR analysis by Exicycler™ 96.

BIONEER	
ExiStation™ Universal Molecular Diagnostic System (ExiPrep™ 16 Dx/ExiPrep™ 48 Dx (with or without ExiLT™ 48 BT/ST) in combination with Exicycler™ 96, or Fully automated ExiStation™ HT (with or without ExiLT™ 48 BT/ST))	
Storage temperature of the device(s)/reagents	Instruments: 15–30 °C ExiPrep™ Extraction Kits: 1530°C AccuPower® DNA/RNA Kits: -15 to -25 °C
Shelf life of the device(s)/reagents	Instruments: N/A ExiPrep™ Extraction Kits: 1 year AccuPower® DNA/RNA Kits: 1 year
Type of sample required	Assay dependant: DBS, plasma, serum, nasal swab, urine, etc.
Volume of sample required	Assay dependant: DBS, plasma, serum, nasal swab, urine, etc.
Turnaround time	ExiStation™ 16: 3 hours plus 30 minutes hands-on time ExiStation™ 48: 2 hours 20 minutes plus 1 hour hands-on time ExiStation™ HT: 1st batch 3 hours, subsequent samples in 96 batch 1.5hours
Throughput*	Low to medium depending on the set-up: ExiPrep™ 16 Dx: 16 samples/90 minutes: 10.7 samples/hour ExiStation™: 48 samples/90 minutes: 32 samples/hour Overall: 48 samples/180 minutes: 16 samples/hour ExiPrep™ 48 Dx: 48 samples/140 minutes: 20.6 samples/hour ExiStation™ HT: first batch 96 samples/3 hours (32 samples/hour) Second batch 96 samples/1.5 hours (64.0 samples/hour)
Dimensions (W x H x D)	ExiPrep™ 16 Dx: 320 mm x 500 mm x 535 mm ExiPrep™ 48 Dx: 760 mm x 725 mm x 620 mm Exicycler™ 96: 355 mm x 540 mm x 470 mm ExiStation™ HT: 2182 mm x 1955 mm x 970 mm ExiLT™ 48 BT: 510 mm x 750 mm x 620 mm ExiLT™ 48 ST: TBD
Power requirements	ExiPrep™ 16 Dx: 100–240 VAC via adopter ExiPrep™ 48 Dx: 100–240 VAC Exicycler™ 96: 100–240VAC ExiStation™ HT: 110–120 VAC or 220–240 VAC with voltage selection switch on the back. ExiLT™ 48 BT or ST: 100–240 VAC
Connectivity	TCP/IP 2. USB protocol
Marketing price per instrument/test	ExiStation™ with one ExiPrep™ 16 Dx US$ 50 000 ExiStation™ with two ExiPrep™ 16 Dx US$ 66 000 ExiStation™ with three ExiPrep™ 16 Dx US$ 80 000 Exicycler™ 96 US$ 32 000 ExiPrep™ 48 Dx US$ 48 000 ExiStation™ HT US$ 390 000 ExiLT™ 48 BT or ST US$ 15 000 Assays US$ 10–25 (dependent on the assay)
Complexity/training requirements	Technicians with minimal skills can easily learn to operate ExiStation™ after two full days of education and training

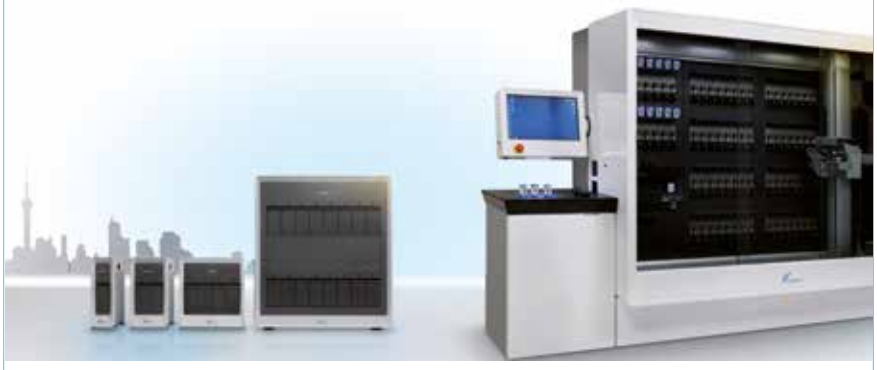
BIONEER	
ExiStation™ Universal Molecular Diagnostic System (ExiPrep™ 16 Dx/ExiPrep™ 48 Dx (with or without ExiLT™ 48 BT/ST) in combination with Exicycler™ 96, or Fully automated ExiStation™ HT (with or without ExiLT™ 48 BT/ST))	
Supporting instrumentation/ sample preparation required	All configuration as priced include a notebook with ExiStation™ Management Software pre-installed. ExiPrep™ HT: price includes a PC, monitor and printer. In some cases, special samples such as sputum may require extra treatment prior to extraction.
Image of device(s) From top to bottom ExiPrep™ 16 Dx and Exicycler™ 96 ExiPrep™ 48 Dx and Exicycler™ 96 ExiPrep™ HT	  

BioRad (information not verified by company)	
GnuBio	
Marketing status	On the market
Type of technology	NGS
POC	No
Infections the device(s) can test for and regulatory approval status	
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Biosensia	
RapiPlex Platform	
Marketing status	In late-stage development/pre-commercial (expected late 2017)
Type of technology	Immunoassay
POC	Yes
Infections the device(s) can test for and regulatory approval status	Biosensia is currently developing two products; one for autoimmune disease (screen and monitoring response to therapy); and one for infectious disease. Both products are utilizing proteomic signatures composed of host proteins.
Sensitivity	
Specificity	Product dependent
Multiplex	Yes; simultaneous testing of up to 24 analytes
Storage temperature of the device(s)/reagents	Room temperature
Shelf life of the device(s)/reagents	18+ months
Type of sample required	Sample required is assay dependent: whole blood (fingerstick and venous blood, plasma, serum, urine, saliva)
Volume of sample required	10 µL–>1000 µL depending on type of sample
Turnaround time	5–15 minutes
Throughput*	30 samples per hour (up to 24 measurements per sample) 720 results/hour
Dimensions (W x H x D)	16.5 cm x 24 cm x 30 cm
Power requirements	AC and rechargeable battery (4 hours continuous use)
Connectivity	Wi-Fi, LIMS, GSM
Marketing price per instrument/test	Competitive and unit price driven by volume
Complexity/training requirements	Biosensia aimed for CLIA waived application requirements, minimal user requirements. The platform may function in two modes: 1. Walk-away mode – user adds sample to disposable cartridge and adds cartridge to reader. The time to result is timed by the reader and at end user is altered by screen colour change and sound. The throughput on this mode is limited by the time to result of the specific product. 2. Batch mode – for users trained to process multiple samples at the same time; time all the cartridges outside of the reader and use the reader to collect the data, which gives maximum throughput. No in-field calibration is required. The batch calibration details are encoded onto a 2D barcode on the reverse of each cartridge – these are product and batch specific.
Supporting instrumentation/ sample preparation required	None required, benchtop portable unit with integrated touchscreen. The unit has multiple USB ports for off-the-shelf 1/2D barcode wand scanners to assist with the input of patient and operator details and a serial port for a printer if required.
Image of device(s)	

Boson	
HBsAg/HIV/HCV Panel Test	
Marketing status	On the market (approved in China; China FDA approved)
Type of technology	Immunoassay: immunochromatography (RDT)
POC	Yes
Infections the device(s) can test for and regulatory approval status	HBsAg, HIV-1 antibody, HIV-2 antibody and HCV antibody
Sensitivity	HIV-1: 99.6% HIV-2: 99.6% HCV: 99.8% HBsAg: 99.6%
Specificity	HIV-1: 99.7% HIV-2: 99.7% HCV: 99.6% HBsAg: 99.6%
Multiplex	Yes; tests for HIV-1, HIV-2, HCV and HBsAg using one sample
Storage temperature of the device(s)/reagents	4–30 °C
Shelf life of the device(s)/reagents	18 months
Type of sample required	Whole blood (fingerstick or venous blood), plasma or serum
Volume of sample required	One drop of serum/plasma/whole blood sample + one drop of sample buffer
Turnaround time	20 minutes
Throughput*	Low; one test takes 20 minutes
Dimensions (W x H x D)	5 mm x 3.8 mm x 6.6 mm
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	US$ 0.8
Complexity/training requirements	30 minutes
Supporting instrumentation/ sample preparation required	N/A
Image of device(s)	

Cepheid®	
GeneXpert® Omni, I, II, IV and XVI, Infinity-48, Infinity-80	
Marketing status	GeneXpert® Omni®: in development (planned launch late 2017). All other systems: on the market. RUO – in North America at only a few sites; CE marked; not WHO prequalified but active application; not CLIA waived; not US FDA approved.
Type of technology	NAT; qPCR
POC	Yes; GeneXpert® Systems are available in a range of sizes/configurations to meet workflow requirements
Infections the device(s) can test for and regulatory approval status	CE marked: HIV-1 (qualitative), HIV-1 (VL), HCV, MTB, SA, Ebola virus, Neisseria gonorrhoeae, Chlamydia trachomatis, HPV, VRE, MRSA, MTB/RIF, MDR carbapenems (and others). HIV-1 (qualitative) assay is also WHO PQ.
	US FDA approved: MTB, SA, Ebola virus, Neisseria gonorrhoeae, Chlamydia trachomatis, MRSA, MTB/RIF, MDR carbapenems (and others)
	In development: MTB/RIF Ultra assay (improved sensitivity) (CE marking expected early 2017), XDR-TB assay (to detect mutations for resistance to INH, FLQ and AMGs (release date TBD), Xpert® Finger Stick HIV-1 VL assay (for use at the POC with GeneXpert® Omni®)
Sensitivity	Assay dependent
Specificity	Assay dependent
Multiplex	Yes; Xpert® Carba-R, Xpert® MRSA/SA, Xpert® Xpress Flu/respiratory syncytial virus, Xpert® MTB/RIF, Xpert® Chlamydia trachomatis/Neisseria gonorrhoeae (all CE marked and US FDA approved)
Storage temperature of the device(s)/reagents	Systems: 15–30 °C (Omni: 2–40 °C) Reagents: 2–28 °C
Shelf life of the device(s)/reagents	Reagents: 12 months Device (estimated to be): 60 months
Type of sample required	Systems accept blood, DBS, serum, plasma, faecal, urine, sputum, nasal, tissue. Type of sample required is assay dependent.
Volume of sample required	Varies depending on test and sample type
Turnaround time	30–90 minutes per sample on average
Throughput*	GeneXpert® Omni, I, II, IV: low GeneXpert® XVI: medium GeneXpert® Infinity-48, Infinity-80: high
Dimensions (W x H x D)	GeneXpert® Omni: 3” x 9.1” x 4.2” GeneXpert® I: 4” x 12” x 11.7” GeneXpert® II: 6.35” x 12” x 11.7” GeneXpert® IV: 11” x 12” x 11.7” GeneXpert® XVI: 22.75” x 25.8” x 1 3.25” GeneXpert® Infinity-48: 85” x 78.5” x 35” GeneXpert® Infinity-80: 108” x 78.5” x 35”
Power requirements	GeneXpert® Omni®: built-in integrated (up to 3 hours operation) and supplemental rechargeable batteries (up to 8 hours operation). GeneXpert® I, II, IV, XVI rated voltage: 100–~240 V, 50–60 Hz. GeneXpert® Infinity-48, Infinity-80 line voltage: 200–240 VAC, 20A.

Cepheid®	
GeneXpert® Omni, I, II, IV and XVI, Infinity-48, Infinity-80	
Connectivity	GeneXpert® Omni® module, mobile device interface and Cepheid C360 support a broad set of communications protocols to enable connectivity: cellular (e.g. SMS, GSM), local area networks (e.g. Wi-Fi), middleware (e.g. LIS connectivity), Bluetooth (e.g. device to device, mobile to printer), secure cloud-based connectivity (e.g. Cepheid C360) integrates timely data streams for greater productivity and performance
Marketing price per instrument/test	System and test dependent. High-burden disease country prices are available, with GeneXpert IV module with laptop priced at US$17,500 (US$ 11 530–426 400 and cartridges ranging from US$ 10–17 on average. Omni®: TBD
Complexity/training requirements	Minimal: GeneXpert® Systems automate and integrate sample preparation, nucleic acid amplification and detection of the target sequence in simple or complex samples. Layperson can be trained in less than half a day.
Supporting instrumentation/ sample preparation required	Minimal. GeneXpert® I, II, IV, XVI require a laptop/computer, barcode scanner and printer. Infinity Systems require a printer.
Image GeneXpert® Systems:	
GeneXpert® Omni:	

Chembio Diagnostic Systems	
DPP® HIV-Syphilis Assay	
Marketing status	On the market (CE marked)
Type of technology	Immunoassay; RDT (DPP® technology)
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV-1, HIV-2, TP
Sensitivity	See package insert
Specificity	See package insert
Multiplex	Yes; HIV-1, HIV-2, TP
Storage temperature of the device(s)/reagents	Room temperature
Shelf life of the device(s)/reagents	24 months; 14 months to the end-user
Type of sample required	Whole blood (venepuncture or fingerstick), serum or plasma
Volume of sample required	10 µL
Turnaround time	15 minutes
Throughput*	Low; one test takes 15 minute.
Dimensions (W x H x D)	24 cm x 9.5 cm x 15.5 cm
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	Contact manufacturer
Complexity/training requirements	Minimal
Supporting instrumentation/ sample preparation required	Not required; see package insert
Image of device(s)	

ChipCare	
PAx Platform	
Marketing status	In development – initial commercial launch 2018
Type of technology	Immunoassays, NATs and cell-based assays
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV (CD4 test), 2018 HIV-1 (antibody), HIV-2 (antibody), TP (antibody) 2019 HIV-1 (EID), HIV-2 (EID), 2019 HIV-1 (VL), HIV-2 (VL), 2020 HCV, 2020
Sensitivity	N/A
Specificity	N/A
Multiplex	Yes
Storage temperature of the device(s)/reagents	Room temperature
Shelf life of the device(s)/reagents	Reagents: 12+ months
Type of sample required	Assay dependant
Volume of sample required	Assay dependant: >10 µL
Turnaround time	Assay dependent: >15 minutes+
Throughput*	Low
Dimensions (W x H x D)	14 cm x 28.5 cm x 12 cm
Power requirements	PAx has an 8-hour battery life and can be recharged via solar power, among other means
Connectivity	3G
Marketing price per instrument/test	Assay dependant
Complexity/training requirements	Low; half-day training
Supporting instrumentation/ sample preparation required	NATs require amplification module
Image of device(s)	

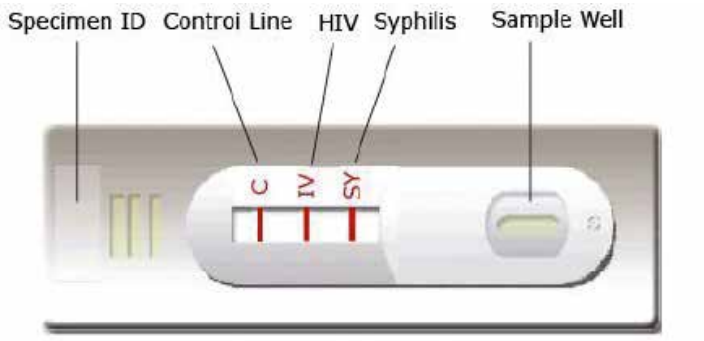
Columbia University	
Smartphone Dongle Device	
Marketing status	In development
Type of technology	Immunoassay; EIA
POC	Yes
Infections the device(s) can test for and regulatory approval status	RUO: HIV-1, HIV-2, TP, NTM
Sensitivity	92–100% (depending upon the infection being tested for)
Specificity	79–92% (depending upon the infection being tested for)
Multiplex	Yes
Storage temperature of the device(s)/reagents	Cassettes can be stored at room temperature or in a cold chamber. Reagent cartridges require a cold chamber.
Shelf life of the device(s)/reagents	Shelf life of cassettes and reagent cartridges in a cold chamber has not yet been tested. The cassettes can be stored at room temperature for 7 months.
Type of sample required	Whole blood (fingerstick or venous blood), plasma or serum
Volume of sample required	2 µL
Turnaround time	15 minutes
Throughput*	Low; one test takes 15 minutes
Dimensions (W x H x D)	5 cm x 7cm x 7.5 cm
Power requirements	Powered by a smartphone, uses 1.6 mW or 0.22 mWh per test
Connectivity	Device is connected to smartphone via an audio jack; smartphone contains all standard connectivity options (Bluetooth, Wi-Fi, SMS)
Marketing price per instrument/test	Not yet determined (manufacturing costs are US$ 34 per device and US$ 1.44 per test)
Complexity/training requirements	Minimal – training of laboratory technicians with no ELISA experience takes 30 minutes
Supporting instrumentation/ sample preparation required	Smartphone. Minimal sample preparation is required; sample is mixed with a diluent and placed into the cassette, the cassette is then inserted into the dongle.
Image of device(s)	

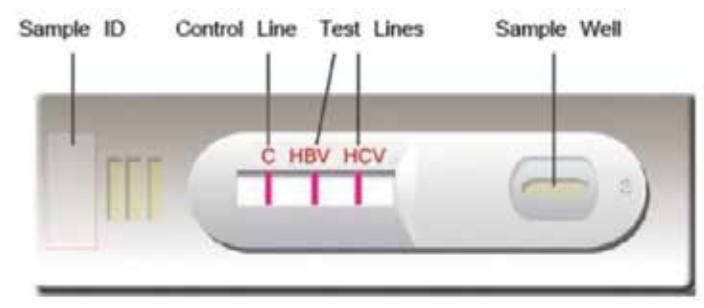
Core Diagnostics (information not verified by company)	
Core Combo HIV-HBsAg-HCV	
Marketing status	On the market
Type of technology	Immunoassay; RDT (lateral flow)
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV-1, HIV-2, HBV, HCV
Sensitivity	
Specificity	
Multiplex	Yes; HIV-1, HIV-2, HBV, HCV
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Whole blood (venepuncture or fingerstick), serum or plasma
Volume of sample required	
Turnaround time	15 minutes
Throughput*	Low; one test takes 15 minutes
Dimensions (W x H x D)	
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	
Complexity/training requirements	Minimal
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Coris BioConcept	
TRAPIST v6	
Marketing status	On the market (RUO) – preparation for CE marking
Type of technology	NAT; PCR amplification and detection by oligochromatography
POC	No
Infections the device(s) can test for and regulatory approval status	Preparation for CE marking: Sepsis Gram-negative bacteria and resistance markers (A. baumannii, C. freundii, Enterobacter spp., E. coli, K. oxytoca, K. pneumoniae, N. meningitidis, P. mirabilis, P. aeruginosa, S. marcescens, CTX-M groups, OXA-23, OXA-24, OXA-58, OXA-48, IMP, KPC, NDM, VIM) Sepsis Gram-positive bacteria and resistance markers (Staphylococcus spp., S. aureus, S. epidermidis, Streptococcus spp., S. agalactiae, S. pneumoniae, S. pyogenes, E. faecalis, E. faecium, L. monocytogenes, mecA, mecC, vanA, vanB)
	In development: assay for TB and AMR: MTB, MTB/RIF (being developed as part of the nanotherapeutics for antibiotic-resistant emerging bacterial pathogens (NAREB) project
Sensitivity	TBD
Specificity	TBD
Multiplex	Yes: Sepsis Gram-negative panel: 21-plex Sepsis Gram-positive panel: 15-plex
Storage temperature of the device(s)/reagents	Systems: room temperature Reagents: -20 °C and room temperature
Shelf life of the device(s)/reagents	Reagents: at least 6 months Device (estimated to be): at least 6 months
Type of sample required	Extracted DNA or RNA samples
Volume of sample required	≤5 µL
Turnaround time	1 hour
Throughput*	Low
Dimensions (W x H x D)	Master (interface) module: 24 cm x 43 cm x 38 cm Chip device (testing) module: 20 cm x 22 cm x 31.5 cm; up to 6 Chip modules can be connected on 1 Master module
Power requirements	Voltage: 85–~264 VAC Frequency: 47–~63 Hz
Connectivity	LIS, USB
Marketing price per instrument/test	Transfer prices: €15 000/instrument (1 master + 1 module) €50/test
Complexity/training requirements	Requires sample preparation. After this step, consists of two pipetting steps (PCR mix with DNA sample and buffer) and then fully automated.

Coris BioConcept	
TRAPIST v6	
Supporting instrumentation/ sample preparation required	Accessories: external barcode reader and printer. Sample preparation: sample lysis and DNA extraction.
Image of device(s)	

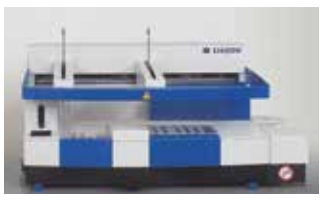
Coyote Bioscience	
Mini8 qPCR/One-step MD-Box-Lab	
Marketing status	On the market (CE marked)
Type of technology	NAT; qPCR
POC	Yes
Infections the device(s) can test for and regulatory approval status	RUO: HIV, respiratory syncytial virus, FluA, FluB, Ebola virus, yellow fever virus, Rift Valley fever virus, Vibrio cholera, adenovirus, MERS, HBV, HCV, dengue virus, Epstein-Barr virus, Salmonella
	Under Chinese FDA approval: Zika virus, norovirus
Sensitivity	98%
Specificity	96%
Multiplex	No
Storage temperature of the device(s)/reagents	Room temperature
Shelf life of the device(s)/reagents	Mini8 qPCR/One-step MD-Box-Lab: 8 years
Type of sample required	Blood, serum, plasma
Volume of sample required	Blood: 50 µL Serum: 2 µL Plasma: 2 µL
Turnaround time	Mini8 qPCR/One-step MD-Box-Lab: 60–120 minutes
Throughput*	Mini8 qPCR/One-step MD-Box-Lab: 8 samples/hour
Dimensions (W x H x D)	205 mm x 190 mm x 98 mm
Power requirements	Mini8 qPCR/One-step MD-Box-Lab: 12V DC, 10A or different alternating current
Connectivity	Mini8 qPCR/One-step MD-Box-Lab: USB2.0
Marketing price per instrument/test	Mini8 qPCR: US$ 6900/unit One-step MD-Box-Lab: US$ 10 000/unit
Complexity/training requirements	One hour training to know all
Supporting instrumentation/ sample preparation required	Laptop/computer WIN7, WIN8.1, WIN10 System
Image of device(s)	 

CTK Biotech	
HIV/Syphilis Ab Combo Rapid Test	
Marketing status	On the market (RUO)
Type of technology	Immunoassay; RDT (lateral flow)
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV-1, HIV-2, TP
Sensitivity	HIV-1+2: 99% TP: 98%
Specificity	HIV-1+2: 99.2% TP: 100%
Multiplex	Yes; HIV-1, HIV-2, TP
Storage temperature of the device(s)/reagents	2–30 °C
Shelf life of the device(s)/reagents	18 months
Type of sample required	Whole blood (venepuncture or fingerstick), serum or plasma
Volume of sample required	20 µL
Turnaround time	15 minutes
Throughput*	Low; one test takes 15 minutes
Dimensions (W x H x D)	20 mm x 72 mm x 3 mm
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	Contact supplier
Complexity/training requirements	Minimal
Supporting instrumentation/ sample preparation required	None
Image of device(s)	

CTK Biotech	
OnSite™ HBSAg/HCV Ab Rapid Test	
Marketing status	On the market (RUO)
Type of technology	Immunoassay; RDT (lateral flow)
POC	Yes
Infections the device(s) can test for and regulatory approval status	HBV, HCV
Sensitivity	HCV Ab: 100% HBsAg: 100%
Specificity	HCV Ab: 99.1% HBsAg: 100%
Multiplex	Yes; HBV, HCV
Storage temperature of the device(s)/reagents	2–30 °C
Shelf life of the device(s)/reagents	24 months
Type of sample required	Whole blood (venepuncture or fingerstick), serum or plasma
Volume of sample required	30–50 µL
Turnaround time	15 minutes
Throughput*	Low; one test takes 15 minutes
Dimensions (W x H x D)	20 mm x 72 mm x 3 mm
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	Contact supplier
Complexity/training requirements	Minimal
Supporting instrumentation/ sample preparation required	None required
Image of device(s)	

Daktari Diagnostics (information not verified by company)	
Daktari Virology	
Marketing status	In development
Type of technology	NAT; biosensor technology: microfluidics and electrochemical sensing
POC	Yes
Infections the device(s) can test for and regulatory approval status	In development: HIV-1, HCV
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Whole blood (fingerstick or venous collection)
Volume of sample required	
Turnaround time	30 minutes
Throughput*	Low; 1 sample takes 30 minutes
Dimensions (W x H x D)	
Power requirements	Battery powered (portable)
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Diagnostics for All (not confirmed by company)	
Rapid Nucleic Acid test kit	
Marketing status	In development
Type of technology	Nucleic acid amplification-based paper microfluidic device
POC	POC
Infections the device(s) can test for and regulatory approval status	HIV, HCV, E. Coli, Ebola, onchoceriasis, brucellosis and others
	In development
Sensitivity	In development
Specificity	In development
Multiplex	Not currently
Storage temperature of the device(s)/reagents	In development
Shelf life of the device(s)/reagents	In development
Type of sample required	Whole blood (fingerstick)
Volume of sample required	Unknown
Turnaround time	Up to one hour
Throughput*	Low
Dimensions (W x H x D)	Unknown
Power requirements	Unknown
Connectivity	N/A
Marketing price per instrument/test	Unknown
Complexity/training requirements	Minimal
Supporting instrumentation/ sample preparation required	Unknown
Image of device(s)	

DiaSorin	
CLIA LIASON® system	
Marketing status	On the market
Type of technology	Immunoassay; chemiluminescent immunoassay with paramagnetic micro-particle solid phase. Random access or batch immunoassay system with continuous loading of samples, reagents and consumables. Fixed needle, 15 reagents on board, 144 samples. STAT. LAS version available.
POC	No
Infections the device(s) can test for and regulatory approval status	System: CE, US FDA approved. Assays: CE-IVD (all the listed assays); US FDA; Therapeutic Goods Administration (depending on the assay).
	Serum and plasma: HBsAg, HBsAg confirmatory, anti-HBs, anti-HBc, HBc IgM, anti-HBe, HBeAg, anti-HAV, HAV IgM, Epstein-Barr virus IgM, VCA IgG, Borrelia IgM and IgG, Chlamydia trachomatis IgG and IgA, TP, varicella-zoster virus IgG and IgM, Mycoplasma pneumoniae IgG and IgM, measles IgG and IgM, mumps IgM and IgG, Bordetella pertussis toxin IgG and IgA, Helicobacter pylori IgG, Toxo IgM and IgG and Avidity, rubella IgG and IgM, CMV IgG and IgM and Avidity, HSV-1/2 IgG, HSV-2 IgG, HSV-1/2 IgM, HSV-1 IgG, parvovirus B19 IgG and IgM (and others).
Sensitivity	Depending on the specific assay
Specificity	Depending on the specific assay
Multiplex	No
Storage temperature of the device(s)/reagents	5–45 °C/2–8° C
Shelf life of the device(s)/reagents	Depending on the specific assay
Type of sample required	Serum, plasma, urine, cerebral spinal fluid and stool (as listed above)
Volume of sample required	Depending on the specific assay (range 10–200 µL)
Turnaround time	Depending on the specific assay and the routine; starting from 17 minutes
Throughput*	Medium; average throughput 100–140 tests/hour, up to 180 tests/hour
Dimensions (W x H x D)	136 cm x 63 cm x 66 cm (benchtop)
Power requirements	Voltage range: 100–240 V; 4–1.7 A Frequency: 50/60 Hz
Connectivity	Yes (LIS, LIMS)
Marketing price per instrument/test	N/A (confidential/sensitive data). Available from DiaSorin.
Complexity/training requirements	Training required
Supporting instrumentation/ sample preparation required	IBM-compatible PC, colour monitor touchscreen, printer. Sample preparation required only for assays to be performed on stool.
Image of device(s)	

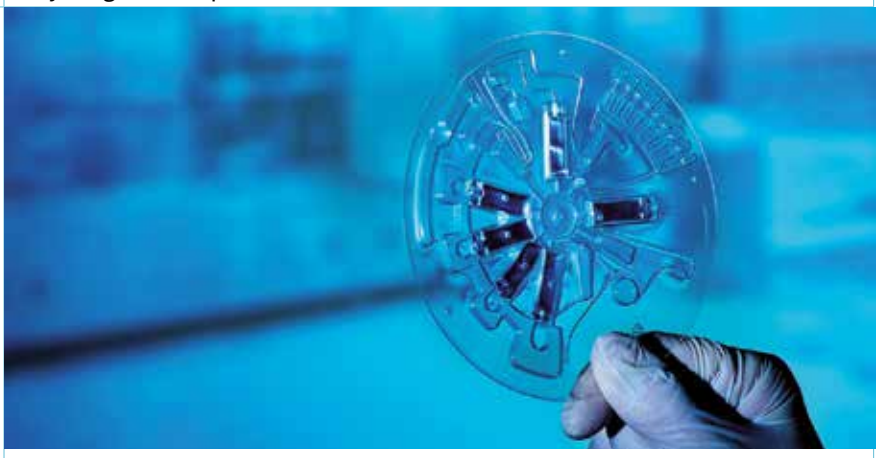
DiaSorin	
CLIA LIAISON® XL system	
Marketing status	On the market
Type of technology	Immunoassay; chemiluminescent immunoassay with paramagnetic micro-particle solid phase. Random access or batch immunoassay system with continuous loading of samples, reagents and consumables. Disposable tips, 25 reagents onboard, 120 samples. RFID technology. STAT. LAS version also available.
POC	No
Infections the device(s) can test for and regulatory approval status	System: CE, US FDA Assays: CE-IVD (all the listed assays); US FDA; Therapeutic Goods Administration (depending on the assay)
	Serum and Plasma: HBsAg, HBsAg confirmatory, anti-HBs, anti-HBc, HBc IgM, anti-HBe, HBeAg, anti-HAV, HAV IgM, anti-HCV, HIV Ag/Ab, Chagas, Epstein-Barr virus IgM, Borrelia IgM and IgG, Chlamydia trachomatis IgG and IgA, TP, varicella-zoster virus IgG and IgM, Mycoplasma pneumoniae IgG and IgM, measles IgG and IgM, mumps IgM and IgG, Bordetella pertussis toxin IgG and IgA, Helicobacter pylori IgG, Toxo IgM and IgG and Avidity, rubella IgG and IgM, CMV IgG and IgM and Avidity, HSV-1/2 IgG, HSV-2 IgG, HSV-1/2 IgM, HSV-1 IgG, parvovirus B19 IgG and IgM (and others). Stool: Clostridium difficile, Helicobacter pylori, rotavirus, adenovirus, Campylobacter.
Sensitivity	Depending on the specific assay
Specificity	Depending on the specific assay
Multiplex	No
Storage temperature of the device(s)/reagents	5–45 °C/2–8 °C
Shelf life of the device(s)/reagents	Depending on the specific assay
Type of sample required	Serum, plasma, urine, cerebral spinal fluid and stool (as listed above)
Volume of sample required	Depending on the specific assay (range 10–200 uL)
Turnaround time	Depending on the specific assay and the routine; starting from 17 minutes
Throughput*	High; up to 180 tests/hour
Dimensions (W x H x D)	150 cm x 150 cm x 90 cm (standalone)
Power requirements	Voltage range: 90–240v Frequency: 50–60 Hz
Connectivity	Yes (LIS, LIMS)
Marketing price per instrument/test	N/A (confidential/sensitive data) Available from DiaSorin
Complexity/training requirements	Training required

DiaSorin	
CLIA LIAISON® XL system	
Supporting instrumentation/ sample preparation required	IBM-compatible PC, 17” diagonal LCD touch sensitive screen, barcode scanners Sample preparation required only for assays to be performed on stool
Image of device(s)	

DiaSorin	
ETI-Max 3000	
Marketing status	On the market
Type of technology	Immunoassay; automated microplate-based ELISAs, 4 plates and up to 7 plates, random access and batch mode, up to 240 primary tubes, disposable tips. Possibility to do archive of samples
POC	No
Infections the device(s) can test for and regulatory approval status	Anti-HIV, HIV Ag/Ab, anti-HCV, HCV Ag/Ab, anti-HBs, anti-HBc, HBc IgM, anti-HBe, HBeAg, anti-HAV, HAV IgM, TP, Chagas and more (>150 tests available)
	System: CE marked, US FDA Assays: CE-IVD (all the listed assays); US FDA; Therapeutic Goods Administration (depending on the assay)
Sensitivity	Depending on the specific assay
Specificity	Depending on the specific assay
Multiplex	No
Storage temperature of the device(s)/reagents	5–40 °C/2–8 °C
Shelf life of the device(s)/reagents	Depending on the specific assay
Type of sample required	Serum, plasma
Volume of sample required	Depending on the specific assay, starting from 10 µL
Turnaround time	Depending on the specific assay and the routine; starting from 60 minutes
Throughput*	Medium
Dimensions (W x H x D)	120 cm x 92 cm x 122 cm (W x D x H) (benchtop)
Power requirements	Voltage range: 115 V–230 V AC Current range: 4 A (115 V)–2 A (230 V) Frequency range: 50–60 Hz Mains fuse: T 4 A
Connectivity	Yes (LIS, LIMS)
Marketing price per instrument/test	N/A (confidential/sensitive data) Available from DiaSorin
Complexity/training requirements	Training required
Supporting instrumentation/ sample preparation required	PC, barcode scanner No sample preparation required
Image of device(s)	

DiaSorin	
Tecan Freedom EVOlyzer® 2-150/8	
Marketing status	On the market
Type of technology	Immunoassay; automated microplate-based ELISAs. Up to 12 plates, disposable tips, 8-way manifold.
POC	No
Infections the device(s) can test for and regulatory approval status	Anti-HIV, HIV Ag/Ab, anti-HCV, HCV Ag/Ab, anti-HBs, anti-HBc, TP, Chagas (and others)
	System: CE marked Assays: CE-IVD (all the listed assays); Therapeutic Goods Administration (depending on the assay)
Sensitivity	Depending on the specific assay
Specificity	Depending on the specific assay
Multiplex	No
Storage temperature of the device(s)/reagents	15–32 °C/2–8° C
Shelf life of the device(s)/reagents	Depending on the specific assay
Type of sample required	Serum, plasma
Volume of sample required	Depending on the specific assay, starting from 10 µL
Turnaround time	Depending on the specific assay and the routine; starting from 60 minutes
Throughput*	High
Dimensions (W x H x D)	120 cm x 92 cm x 122 cm (W x D x H) (benchtop)
Power requirements	1890 mm x 910 mm x 800 mm (benchtop)
Connectivity	Yes (LIS, LIMS)
Marketing price per instrument/test	N/A (confidential/sensitive data) Available from DiaSorin
Complexity/training requirements	Training required
Supporting instrumentation/ sample preparation required	PC, barcode scanner No sample preparation required
Image of device(s)	

DiscoGnosis	
LabDisk System	
Marketing status	Under development: laboratory tested prototype
Type of technology	NAT; disc-shaped lab-on-a-chip microfluidic platform (LabDisk and corresponding processing device) that integrates all (bio)chemical components for fully automated molecular-based (DNA, RNA) identification of pathogens. Isothermal amplification technology uses (LAMP), allowing fast and specific detection
Level of care	POC use in: hospital (in-patient), peripheral lab, clinic/health post (out-patient)
Infections the device(s) can test for and regulatory approval status	Malaria (all species); Salmonella typhi, paratyphi; Streptococcus; dengue virus (all serotypes); chikungunya virus
	• CE-IVD/US FDA clearance will be sought and quality management will be established in all involved components (LabDisk, Player and assay manufacturing facilities) as soon as the related funding is secured (private/public/investor) • WHO PQ will be sought
Sensitivity	No sufficient samples have been tested at the moment in order to provide data for clinical sensitivity
Specificity	No sufficient samples have been tested at the moment in order to provide data for clinical specificity
Multiplex	Up to 12 targets simultaneously detected from one sample
Storage temperature of the device(s)/reagents	Room temperature (no cold chain needed)
Shelf life of the device(s)/reagents	Accelerated shelf life studies at >90% humidity indicate 1.6 year stability at 22 °C storage
Type of sample required	Blood, serum
Volume of sample required	200 µL
Turnaround time	90–120 minutes
Throughput*	Low (1 sample/run)
Dimensions (W x H x D)	18 cm x 15 cm x 28 cm
Power requirements	Currently: 220 V (can be compatible with car battery once an adaptor is used). Development of alternative power sources is planned (battery/solar panel driven – concept is under review in submitted proposals).
Connectivity	• Data storage capacity and transmission of results currently at proof of principle. Further concept including a standalone/laptop-free player is currently under review in submitted proposals. • Plan to develop algorithms that can support patient management based on test results and other information (e.g. clinical symptoms, vitals, history). Concept is currently under review in submitted proposals.
Marketing price per instrument/test	N/A

DiscoGnosis	
LabDisk System	
Complexity/training requirements	Device intended to be used by low-skilled health workers, major skills required are: sample collection and transfer by pipette to the disc. Approximately one half day of training required to operate the device.
Supporting instrumentation/ sample preparation required	LabDisk Player required for disc processing (including motor, temperature and detection modules). No ex situ sample preparation required. After sample inlet, all steps are done in situ (lysis, extraction, purification, detection of DNA and RNA). All necessary reagents are pre-stored on the LabDisk.
Image of device(s)	 LabDisk. Source: Hahn-Schickard, Bernd Müller Fotografie.
Image of device(s)	 LabDisk processing device. Source: Hahn-Schickard, Bernd Müller Fotografie.

Diagnostics for the Real World (DRW)	
Samba I/II	
Marketing status	On the market
Type of technology	SAMBA (simple amplification-based assay) is a single-use rapid nucleic acid amplification-based test
POC	SAMBA I: near-POC settings, including district-level hospitals and level IV health-care centres SAMBA II: true POC settings, including lower levels of health-care centres
Infections the device(s) can test for and regulatory approval status**	SAMBA I and SAMBA II HIV-1 Semi-Q assay for VL monitoring SAMBA I and SAMBA II HIV-1 Qual assay for EID
	CE-IVD (approved) WHO PQ (on going)
Sensitivity	From clinical evaluations: SAMBA I Semi Q (concordance): 97.6% SAMBA II Semi Q (concordance): 98.1% SAMBA I Qual (sensitivity): 98.5% SAMBA II Qual (sensitivity): 100%
Specificity	From clinical evaluations: SAMBA I Semi Q (concordance): 97.6% SAMBA II Semi Q (concordance): 98.1% SAMBA I Qual (specificity):99.8% SAMBA II Qual (specificity): 100%
Multiplex	Yes; the same platform can be used for multiple diseases. SAMBA HIV-1 Semi Q assay (whole blood): product launch Q4 2017 SAMBA FluA/B assay: prototype test developed SAMBA CT/NG assay: prototype test developed SAMBA Hep B assay: R&D phase SAMBA Hep C assay: R&D phase
Storage temperature of the device(s)/reagents	2–37 °C for long-term storage; -10 to 55 °C shipping stability (for 2 weeks) No cold chain transport required
Shelf life of the device(s)/reagents	SAMBA I Semi Q assay: 9 months (ongoing) SAMBA II Semi Q assay: 6 months (ongoing) SAMBA I Qual assay: 9 months (ongoing) SAMBA II Qual assay: 9 months (ongoing)
Type of sample required	SAMBA I and II Semi Q assay: plasma SAMBA I and II Qual assay: whole blood
Volume of sample required	SAMBA I and II Semi Q assay: plasma, 300 µL SAMBA I and II Qual assay: whole blood, 150 µL
Turnaround time	SAMBA I and II Semi Q assay: 75–90 minutes SAMBA I and II Qual assay: 105–120 minutes
Throughput*	SAMBA I system: 16–48 samples per day (depending on instrument configuration) SAMBA II system: 4 – 20 samples per day (depending on instrument configuration)
Dimensions (W x H x D)	SAMBA II: 20 cm x 39 cm x 34 cm SAMBA I: SAMBAprep = 67 cm x 50 cm x 64 cm; SAMBAamp = 41 cm x 14 cm x 32 cm

Diagnostics for the Real World (DRW)	
Samba I/II	
Power requirements	**SAMBA I:** SAMBAprep: standard worldwide supply power (100–250v 50–60 Hz, 3A) transformed to 24V, 7.5A DC SAMBAamp: standard worldwide supply power (100–250v 50–60 Hz, 1.5A) transformed to 24V, 4A DC **SAMBA II:** standard worldwide supply power (100–250v 50–60 Hz) transformed to 24V, 3A DC
Connectivity	SAMBA I: not available SAMBA II: Via SMS and exportable to PC (cloud-based dashboard under development)
Marketing price per instrument/test	Contact company for details
Complexity/training requirements	Both SAMBA I and SAMBA II are low-complexity systems requiring minimal training
Supporting instrumentation/ sample preparation required	**SAMBA I:** SAMPAprep is an automated system that performs sample extraction; SAMBAamp performs amplification and detection. There are three simple pipetting steps required to be performed by the user. Results are read manually by the user. A centrifuge is required for the plasma-based Semi Q assay. **SAMBA II:** Fully automated "sample in – result out" system. The assay module performs all steps – sample extraction, amplification and detection. Results are read and interpreted automatically by the integrated visual detection system. A centrifuge is required for the plasma-based Semi Q assay.
Image of device(s)	

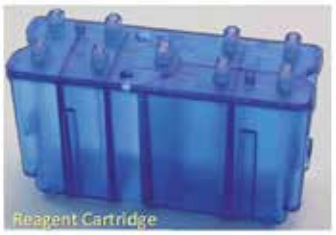
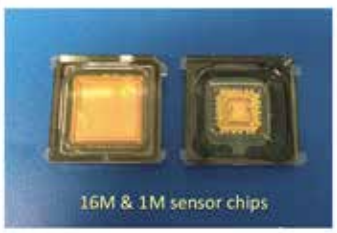
Eiken Chemical (information not verified by company)	
RealTime Turbidimeter LA-500	
Marketing status	On the market
Type of technology	LAMP
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked: Salmonella, verotoxin, E. coli, Listeria moncytogenes, Campylobacter, Legionella, Cryptosporidium, Giardia
Sensitivity	
Specificity	
Multiplex	Yes; maximum 16 samples
Storage temperature of the device(s)/reagents	Reagents and kits: -20° C
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	Maximum 2 hours
Throughput*	Medium to high, depending on the setup
Dimensions (W x H x D)	Control unit: 190 mm x 106 mm x 230 mm Amplification unit: 150 mm x 275 mm x 150 mm
Power requirements	AC 100–240 V, 50/60Hz
Connectivity	USB
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

eNose	
AeonoseTM	
Marketing status	In development – xalidation studies in progress (product CE marked)
Type of technology	Metal-oxide sensors
POC	Level 1 (POC)
Infections the device(s) can test for and regulatory approval status	TB (validation studies in progress)
	In development: H. Pylori (pilot study to be completed)
Sensitivity	TBD
Specificity	TBD
Multiplex	No
Storage temperature of the device(s)/reagents	-40 °C to 70 °C
Shelf life of the device(s)/reagents	Disposables: 5 years
Type of sample required	Breath
Volume of sample required	N/A
Turnaround time	15 minutes
Throughput*	Low
Dimensions (W x H x D)	245 x 180 x 90
Power requirements	Device contains a rechargeable battery
Connectivity	Bluetooth 4.0
Marketing price per instrument/test	TBD
Complexity/training requirements	Easy to use/approximately 2 hours of training required
Supporting instrumentation/ sample preparation required	iPad/NA
Image of device(s)	

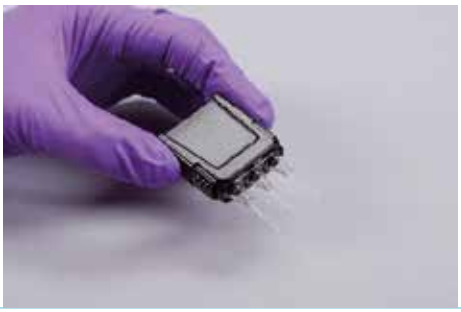
Fio Corporation	
Deki Reader V100/Deki Reader V200	
Marketing status	Deki Reader V100: CE marked in the European Union; on the market in Africa and Latin America Deki Reader V200: in development (launch late 2017)
Type of technology	The Deki Reader captures a digital image of RDT results and applies a software algorithm that automatically determines the presence or absence of a control line and any test line(s) by comparing the intensity of the lines to preset cut-off values. The device displays an automated interpretation of the test results consistent with the RDT manufacturer's package insert – positive, negative or invalid. The Deki Reader's software provides step-by-step guidance and a timer to aid with the correct use of RDTs and then detects any errors that might have occurred during the testing procedure (including errors related to attempting to reuse tests, attempting to analyse a test for the wrong patient, adding too much or too little sample or buffer solution or applying sample or buffer solution to the wrong well, attempting to analyse test results too early or too late, etc.). Test results can be transmitted to a cloud database.
POC	Yes
Infections the device(s) can test for and regulatory approval status	CE marked: SD Bioline malaria Ag P.f; SD Bioline malaria Ag P.f/P.v; SD Bioline malaria Ag Pan; CareStart malaria HRP2 (Pf); first response malaria Ag. (HRP-2); dengue NS1 Ag; dengue IgG/IgM
	RUO: Alere Determine HIV 1/2; First Response HIV 1-2 O Card Test; Uni-Gold HIV
Sensitivity	Deki Reader performance has been evaluated in reference to human visual read using five different malaria RDTs. Positive percent concordance for Deki Reader is 99.6% (n=1676) and negative percent concordance is 98.9% (n= 5877). Deki Reader uses sophisticated algorithms to detect typical errors users make while processing an RDT, e.g. adding too much whole blood. If the Deki Reader detects one of these errors, then it will show an "Error Detected" message on the results screen and tell the user to repeat the test.
Specificity	
Multiplex	Reader can analyse RDTs with multiple strips and multiple test lines
Storage temperature of the device(s)/reagents	Recommended storage conditions are -20 °C to 45 °C. Recommended operating conditions are 5–40 °C.
Shelf life of the device(s)/reagents	Reusable Functional Check (FC) Cassettes are provided with the Deki Reader to perform a regular quality control check to ensure the device is operating within specifications
Type of sample required	Any RDT in cassette or card format. Fio configures and validates each RDT on the Deki Reader test menu.
Volume of sample required	As per RDT manufacturers' instructions
Turnaround time	N/A (dependent upon the processing time of the RDT being used with the Deki Reader; the device interprets RDT results immediately upon image capture)
Throughput*	Low
Dimensions (W x H x D)	V100: 225 mm x 128 mm x 104 mm

Fio Corporation	
Deki Reader V100/Deki Reader V200	
Power requirements	Deki Reader V100 incorporates a 3.7 V 8700 mA/Hr rechargeable lithium-ion battery with built-in protection. Battery is recharged using universal AC/DC adapter with interchangeable plugs (100–240 V, 50–60Hz, 5.0 V/2.0 A).
Connectivity	Deki Readers can be integrated with other systems via wireless connectivity (3G network or Wi-Fi). Fio also offers service packages with its Fionet data system – a cloud-based information system that provides online access to real-time reports and analytics generated from device data; e.g. the Fionet web portal can be used to allow authorized remote stakeholders to oversee patient test results, health worker performance data, analytics on epidemiology, commodity use or customized reports on any other metrics.
Marketing price per instrument/test	Fio offers a variety of monthly subscription options for use of Deki Readers with Fionet service. Pricing scales to number of devices, duration of contract. Contact Fio for more details.
Complexity/training requirements	Low complexity; training on the use of the Deki Reader is available upon request.
Supporting instrumentation/ sample preparation required	RDTs are not included with the Deki Reader.
Image of device(s)	 V100  V200

FujireBio Diagnostics (not confirmed by company)	
Auto LiPA 48	
Marketing status	On the market
Type of technology	LPA
Level of Care	Level 3 and 4
Infections the device(s) can test for and regulatory approval status	HCV, HIV, HPV, HTLV, syphilis
	CE marked
Sensitivity	Assay dependent; e.g. INNO-LIA HCV score: 100%
Specificity	Assay dependent; e.g. INNO-LIA HCV score: 94.5% blood donors. 93.7% clinical samples.
Multiplex	Yes
Storage temperature of the device(s)/reagents	Assay dependent; e.g. INNO-LIA HCV score: 2–8 °C
Shelf life of the device(s)/reagents	12 months (INNO-LIA HCV score)
Type of sample required	Human serum or plasma
Volume of sample required	Assay dependent; e.g. INNO-LIA HCV score: 10 µL for 16 hour incubation, 20 µL for 2–3 hour incubation
Turnaround time	2–3 hours
Throughput*	Low
Dimensions (W x H x D)	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	Contact manufacturer
Complexity/training requirements	TBC
Supporting instrumentation/ sample preparation required	TBC
Image of device(s) Top to bottom	

Genapsys	
GenapSys Gene Electronic Nano-Integrated Ultra-Sensitive (GENIUS) technology	
Marketing status	Pilot introduction – 2018
Type of technology	NGS; labelled as RUO
POC	N/A
Infections the device(s) can test for and regulatory approval status	In development
Sensitivity	10 ng to 200 ng
Specificity	Unknown
Multiplex	≤8 samples
Storage temperature of the device(s)/reagents	Device: room temperature Reagent cartridge and enzymes: frozen Other reagents: room temperature
Shelf life of the device(s)/reagents	Device: ≤30 000 runs Reagents: 18 months from shipment
Type of sample required	Human, bacteria, viral purified DNA
Volume of sample required	
Turnaround time	2 hours/run
Throughput*	Unknown
Dimensions (W x H x D)	9” x 6” x 7”; 8 lbs
Power requirements	100–240V; 12A–25A
Connectivity	USB, Ethernet, Wifi
Marketing price per instrument/test	Device: ≤US$ 25 000 Reagents: ≤US$ 300/run
Complexity/training requirements	Low complexity; video training or phone support
Supporting instrumentation/ sample preparation required	Standard Library Prep Kits from various manufacturers
Image of device(s)	  

Genedrive plc. (an Epistem company)	
Genedrive®	
Marketing status	On the market
Type of technology	NAT; detection of DNA or RNA targets by fluorescent end-point PCR
POC	No
Infections the device(s) can test for and regulatory approval status	MTB, MTB/RIF, HCV (qualitative and pan-genotypic): CE marked
Sensitivity	Genedrive® HCV: validation studies show high sensitivity in line with FIND target product profile requirements
Specificity	Genedrive® HCV: validation studies show high specificity in line with FIND target product profile requirements
Multiplex	Current Genedrive® tests are singleplex; but Genedrive® technology allows for multiplexing with a maximum 9–12 targets
Storage temperature of the device(s)/reagents	Genedrive® Platform 5–50 oC Genedrive® MTB/RIF: 2–28 oC Genedrive® HCV: 2–28 oC
Shelf life of the device(s)/reagents	Genedrive® MTB/RIF: 18 months Genedrive® HCV: 12-18 months (expect 6 months at launch)
Type of sample required	Genedrive® MTB/RIF: fresh sputum Genedrive® HCV: fresh or frozen EDTA plasma
Volume of sample required	Genedrive® MTB/RIF: 20–50 µL Genedrive® HCV: 25 µL
Turnaround time	Genedrive® MTB/RIF: 75 minutes per test Genedrive® HCV: 90 minutes per test
Throughput*	Low; single-sample throughput
Dimensions (W x H x D)	Genedrive® Platform: 12 cm x 18 cm x 10 cm
Power requirements	Genedrive® Platform Standard Mains PSU: 100–240 VAC 1.2A 50/60 Hz input to 12 VDC/8.33A output. Uninterruptable power supply: 11.1 VDC 7400mAh (nominal) rechargeable battery sufficient for 2–3 test executions per charge cycle (test type/duration dependent). No requirement for an external charging station.
Connectivity	Each Genedrive® ID test programme is loaded onto the instrument using RFID technology. Genedrive® supports the use of an external thermal printer to print test results. Future expansion of connectivity features for Genedrive® may include Blue-tooth connectivity to external IT/mobile devices.
Marketing price per instrument/test	N/A
Complexity/training requirements	Minimal user training and single-button operation (press/hold executions)

Genedrive plc. (an Epistem company)	
Genedrive®	
Supporting instrumentation/ sample preparation required	Genedrive® Platform is required for use with all Genedrive® tests. No other supporting instrumentation or sample preparation is required once plasma/serum has been processed.
Image of device(s)	Genedrive® Platform with test cartridge 
	Genedrive® test cartridge 
	Genedrive® MTB/RIF ID Kit components 
	Genedrive® HCV ID Kit components 

Genia (information not verified by company)	
Marketing status	
Type of technology	NGS
POC	
Infections the device(s) can test for and regulatory approval status	
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

GenMark Diagnostics (information not verified by company)	
XT-8/ePlex System	
Marketing status	XT-8: on the market ePlex System: on the market
Type of technology	NAT; biosensor (electrochemical detection technology)
POC	XT-8: No ePlex System: Yes
Infections the device(s) can test for and regulatory approval status	XT-8: US FDA-approved; Respiratory Viral Panel (14 respiratory virus types)
	XT-8: in development; HCVg Direct test (HCV genotyping)
	ePlex: CE marked and US FDA approved; Respiratory Pathogen Panel (20 viral targets and 3 bacterial targets)
	ePlex: in development; blood culture Gram-positive panel, blood culture Gram-negative panel, blood culture identification fungal pathogen panel, gastrointestinal pathogen panel, HCV genotyping panel
Sensitivity	
Specificity	
Multiplex	Yes
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	ePlex: 60–90 minutes
Throughput*	ePlex: 1–4 towers can be integrated into the modular system to address testing capacity requirements; 48–196 samples can be processed in an 8-hour shift, depending on the number of towers
Dimensions (W x H x D)	XT-8 (single analyzer system): 40 cm x 46 cm x 41 cm ePlex (one-tower system): 53 cm x 58 cm x 47 cm
Power requirements	XT-8: 100–240 Vac, 50/60 Hz, 600W ePlex: 100–240 Vac, 50/60 Hz, 265W
Connectivity	ePlex: bi-directional LIS interface
Marketing price per instrument/test	
Complexity/training requirements	XT-8: requires prior RNA extraction ePlex: minimal; less than 2 minutes of hands-on time

GenMark Diagnostics (information not verified by company)	
XT-8/ePlex System	
Supporting instrumentation/ sample preparation required	
Image of device(s): XT-8 ePlex System	 

Hain Lifescience (information not verified by company)	
FluoroType® Technology Platform	
Marketing status	On the market
Type of technology	NAT; DNA isolation followed by PCR amplification. Amplicons are detected via fluorescence-labelled probes.
POC	No
Infections the device(s) can test for and regulatory approval status	MTB
	CE marked: Chlamydia trachomatis, Neisseria gonorrhoeae, Borrelia, Clostridium difficile, HSV, MRSA.
Sensitivity	
Specificity	
Multiplex	Yes; 24–96 tests
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Chlamydia trachomatis/Neisseria gonorrhoeae: cervical swabs, urine, ejaculation, whole blood Borrelia: synovial fluid, cerebrospinal fluid, blood Clostridium difficile: stool HSV, MRSA: Swab specimen
Volume of sample required	15–100 µL
Turnaround time	
Throughput*	
Dimensions (W x H x D)	FluoroCycler® 12: 7.2 x 9.4 x 9.4
Power requirements	100–240 VAC, 50/60 Hz
Connectivity	USB port
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	DNA isolation (using FluoroLyse) and extraction (using GenoXtract®), and amplification and detection (using FluoroCycler® 12, 96), computer
Image of device(s)	

Hologic	
Panther® system	
Marketing status	On the market (CE marked, US FDA approved)
Type of technology	NAT; target capture; target amplification by transcription-mediated amplification (TMA); and detection of the amplification products (amplicon) by fluorescent-labelled probes (torches)
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked and US FDA approved: HIV-1, HCV, HBV, Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, HPV, HSV-1, HSV-2, Mycoplasma genitalium, Zika (Zika assay has Emergency Use Authorization)
	In development: Clostridium difficile, MRSA, FluA, FluB, respiratory syncytial virus, parainfluenza, adenovirus, rotavirus, MPV, CMV
Sensitivity	Assay dependent
Specificity	Assay dependent
Multiplex	Yes; Chlamydia trachomatis/Neisseria gonorrhoeae, FluA/FluB/respiratory syncytial virus, adenovirus/MPV/rotavirus
Storage temperature of the device(s)/reagents	Systems: room temperature
Shelf life of the device(s)/reagents	N/A
Type of sample required	Type of sample required is assay dependent. Samples include vaginal and male urethral swab specimens, vaginal swabs, urine, plasma and serum.
Volume of sample required	500 µL
Turnaround time	161 minutes to first results
Throughput*	Low; up to 320 samples processed in 8 hours
Dimensions (W x H x D)	122 cm x 175 cm x 81.5 cm
Power requirements	AC 100–230 +/- 10% vac, 50–60 Hz, single-phase
Connectivity	N/A
Marketing price per instrument/test	Pricing will be variable and dependent upon a variety of elements including instrument purchase, reagent rental and test volume
Complexity/training requirements	3 days
Supporting instrumentation/ sample preparation required	Fully automated sample-to-answer instrument, the Panther® system automates all aspects of nucleic acid testing on a single, integrated platform
Image of device(s)	

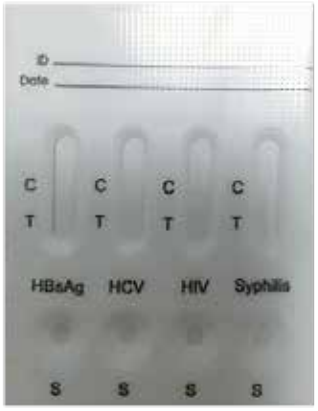
Human Diagnostics Worldwide	
HumaLoop M	
Marketing status	On the market (CE marked)
Type of technology	NAT; sample lysis by heating and LAMP, visual detection of fluorescence
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked: malaria Pan, malaria Pan/Pf
	In development: Leishmania, P. vivax malaria (pipeline)
Sensitivity	Assay dependent; usually >95%
Specificity	Assay dependent; usually >95%
Multiplex	No
Storage temperature of the device(s)/reagents	Device: 5–40 °C
Shelf life of the device(s)/reagents	Device: 5 years
Type of sample required	Assay dependent
Volume of sample required	Assay dependent
Turnaround time	~60 minutes depending on the number of samples
Throughput*	Low
Dimensions (W x H x D)	39 cm x 37.5 cm x 35 cm
Power requirements	AC
Connectivity	No
Marketing price per instrument/test	FIND negotiated prices available to eligible countries
Complexity/training requirements	Low complexity; training required
Supporting instrumentation/ sample preparation required	N/A
Image of device(s)	

Human Diagnostics Worldwide	
HumaTurb System (C + A)	
Marketing status	On the market (CE marked)
Type of technology	NAT; sample lysis by heating and LAMP, visual detection of fluorescence
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked: MTB, malaria Pan, malaria Pan/Pf
	In development: Leishmania (estimated launch date 2017), P. vivax Malaria (pipeline)
Sensitivity	Assay dependent; usually >95%
Specificity	Assay dependent; usually >95%
Multiplex	No, but different parameters can be detected during one run (but in separate reaction tubes)
Storage temperature of the device(s)/reagents	Device: 5–50 °C transportation/storage; operating temperature 15–30 °C Reagents/assays: dependent on parameter, but for most assays room temperature
Shelf life of the device(s)/reagents	Device: 5 years Reagents/assays: assay dependent but in general ≥12 months from production
Type of sample required	Assay dependent (sputum, blood, etc.)
Volume of sample required	Assay dependent (e.g. MTB – 60 µL, malaria – 30 µL)
Turnaround time	~60 minutes depending on the number of samples
Throughput*	Low to medium; 16 tests –14 patient samples plus 2 controls (1 positive, 1 negative) per HumaTurb A (amplification unit); up to six units of HumaTurb A can be connected to one HumaTurb C (control unit); in total maximum 96 tests can be performed at the same time; each HumaTurbA unit can be controlled separately
Dimensions (W x H x D)	HumaTurb C (control unit): 19 cm x 10.6 cm x 23 cm HumaTurb A (amplification unit): 15 cm x 12.1 cm x 27.5 cm
Power requirements	AC
Connectivity	LIS, USB
Marketing price per instrument/test	FIND negotiated prices available to eligible countries
Complexity/training requirements	Moderate complexity, 2.5 days training required for end users (covers background information, usage of instrument, workflow)

Human Diagnostics Worldwide	
HumaTurb System (C + A)	
Supporting instrumentation/ sample preparation required	Depending on assay, different extraction methods can be used (e.g. manual extraction via Loopamp™ PURE DNA Extraction), DNA isolation required; heating block/device (e.g. HumaHeat) for sample lysis for some assays needed
Image of device(s)	

Illumina (information not verified by company)	
MiSeq, HiSeq, NextSeq	
Marketing status	On the market
Type of technology	NGS
POC	No
Infections the device(s) can test for and regulatory approval status	
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

InSilixa	
HYDRA-1K CMOS Biochip Platform	
Marketing status	In development (expected launch Q4 2018 – IVD)
Type of technology	Immunoassay/NAT; biosensor technology: CMOS biochips
POC	Yes
Infections the device(s) can test for and regulatory approval status	Upper respiratory viral and bacterial infections – RUO MDR-TB – RUO Hospital-acquired infections – RUO HPV genotype identification and VL quantification – RUO HIVDR and VL quantification – RUO
	TBD/>95%
	TBD/>98%
Multiplex	The biochip has 1024 (32 x 32) pixels that can individually detect the binding of complementary DNAs from a standard multiplex PCR (or RT-PCR) of different infectious agents. Currently using a 4x redundancy (256), but with optimization will likely support 3x (341).
Storage temperature of the device(s)/reagents	Reagents: 9 months Device: N/A
Shelf life of the device(s)/reagents	Reagents: 9 months Device: N/A
Type of sample required	Nasopharyngeal swab, liquefied sputum, endotracheal aspirate, saliva and blood
Volume of sample required	Up to 1 mL depending on assay
Turnaround time	<1hour
Throughput	Low; 8 assays per hour
Dimensions (W x H x D)	26” x 12” x 18”
Power requirements	100–240 VAC ±10% 50–60Hz
Connectivity	USB, Wi-Fi
Marketing price per instrument/test	TBD
Complexity/training requirements	CLIA waivable
Supporting instrumentation/ sample preparation required	None: sample-to-answer system
Product image	 

JAL Innovation	
iCARE HBsAg/HCV/HIV/Syphilis Combo Rapid Test Cassette	
Marketing status	On the market
Type of technology	Immunoassay; immunochromatography (RDT)
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV-1 (antibody), HIV-2 (antibody), HCV (confirmatory), TP, HBsAg
Sensitivity	>99.9%
Specificity	99.7–99.8%
Multiplex	Yes; tests for HIV-1, HIV-2, HCV, TP and HBsAg
Storage temperature of the device(s)/reagents	Room temperature or cold chamber
Shelf life of the device(s)/reagents	24 months
Type of sample required	Whole blood (fingerstick or venous blood), plasma or serum
Volume of sample required	50 µL
Turnaround time	10 minutes
Throughput	Low; one test takes 10 minutes
Dimensions (W x H x D)	0.5 cm x 6 cm x 9 cm
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	US$ 3
Complexity/training requirements	Minimal
Supporting instrumentation/ sample preparation required	Minimal (timer required)
Product image	

LG Life Sciences (information not verified by company)	
AdvanSure™ GenoLine Station	
Marketing status	On the market
Type of technology	NAT; LPA
POC	No
Infections the device(s) can test for and regulatory approval status	Mycobacterium Genoblot Assay (up to 21 species of Mycobacterium), MDR-TB (INH/RIF), HPV (genotyping)
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	150 minutes
Throughput	48 strips/run
Dimensions (W x H x D)	915 mm x 555 mm x 465 mm
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	Prior DNA extraction required (all reagents for this are included in the kits)
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Hongshi Tech/Sansure (information not verified by company)	
SLAN®/SLAN®-96P	
Marketing status	On the market
Type of technology	NAT; qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	TB, NTM, Chlamydia trachomatis, Neisseria gonorrhoeae, Clostridium difficile, parainfluenza, coronavirus, respiratory syncytial virus, FluA/B, adenovirus, HBV, HCV, HPV (genotyping)
Sensitivity	1 copy
Specificity	
Multiplex	Yes; TB/NTM, Chlamydia trachomatis/Neisseria gonorrhoeae, RV assay (14 infectious respiratory virus types)
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Assay dependent
Volume of sample required	15–100 µL
Turnaround time	SLAN®: 48 wells/50 minutes
Throughput	SLAN®: medium – 48 wells/50 minutes SLAN®-96P: high – 96 wells/50minutes
Dimensions (W x H x D)	520 mm x 250 mm x 380 mm, 18 kg
Power requirements	220V, 50Hz, 850VA
Connectivity	RS232 USB
Marketing price per instrument/test	Contact supplier
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	DNA/RNA extraction required Requires computer (1BG RAM, 40BG HD, CPU 1.5GHz)
Image of device(s)	

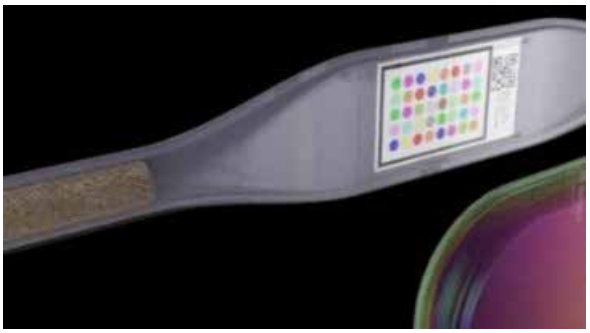
Maternova Inc. (information not verified by company)	
HIV/HBsAg/HCV Combination Rapid Test	
Marketing status	On the market; CE marked
Type of technology	Immunochromatography; RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV/HBsAg/HCV
Sensitivity	
Specificity	
Multiplex	Yes
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

McGill University	
Paper-based electrochemical platform	
Marketing status	Pipeline (expected in ~5 years)
Type of technology	Immunoassay; chromatographic immunoassay
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV-1, HCV (RUO)
Sensitivity	The limits of detection of the platform for HIV-1 and HCV are 0.3 ng/µl and 0.75 ng/µl, respectively
Specificity	Currently unknown
Multiplex	Yes
Storage temperature of the device(s)/reagents	2–30 °C
Shelf life of the device(s)/reagents	12 months
Type of sample required	Blood/serum/plasma
Volume of sample required	3 µL per test
Turnaround time	20 minutes
Throughput*	Low (8 samples analysed in 20 minutes)
Dimensions (W x H x D)	8 cm x 12 cm x 3 cm
Power requirements	Battery
Connectivity	Bluetooth, USB
Marketing price per instrument/test	US$ 200 per instrument; US$ 0.5 per test.
Complexity/training requirements	Low; only training on solution pipetting is required
Supporting instrumentation/ sample preparation required	None
Image of device(s)	

MedMira	
MULTIPLO Rapid TP/HIV Antibody Test	
Marketing status	On the market (RUO, submitted for CE mark in December 2016)
Type of technology	Immunochromatography; rapid vertical flow assay (RDT)
POC	Yes
Infections the device(s) can test for and regulatory approval status	Rapid TP/HIV: HIV-1, HIV-2, TP (RUO, submitted for CE mark in December 2016)
Sensitivity	HIV-1: 99.8% HIV-2: 100% TP: 100%
Specificity	HIV-1: 99.7% HIV-2: 100% TP: 100%
Multiplex	Yes
Storage temperature of the device(s)/reagents	Room temperature or cold chamber if room temperature exceeds 30 °C (2–30 °C)
Shelf life of the device(s)/reagents	18–20 months
Type of sample required	Whole blood (fingerstick and venous blood), serum, plasma
Volume of sample required	1 drop, 40 µl
Turnaround time	Immediate
Throughput*	Medium
Dimensions (W x H x D)	12 cm x 17 cm x 1.8 cm – POC test pouch
Power requirements	None
Connectivity	None
Marketing price per instrument/test	Pricing ranges depending on local market conditions and order volumes
Complexity/training requirements	No special training required and the same procedure applies across any testing application on this platform
Supporting instrumentation/ sample preparation required	No additional equipment is required to run and read the fingerstick and whole blood samples, a centrifuge is needed if using serum or plasma
Image of device(s)	

MedMira	
MULTIPLO HBC/HIV/HCV Antibody Test	
Marketing status	On the market (RUO)
Type of technology	Immunochromatography; rapid vertical flow assay (RDT)
POC	Yes
Infections the device(s) can test for and regulatory approval status	Multiplo: HIV-1/HIV-2, HBV, HCV (RUO)
Sensitivity	HCV: 99.1% HBc: 96.2% HIV-1: 99.8% HIV-2: 100%
Specificity	HCV: 99.7% HBc: 100% HIV-1: 99.7% HIV-2: 100%
Multiplex	Yes
Storage temperature of the device(s)/reagents	Room temperature or cold chamber if room temperature exceeds 30° C (2–30°C)
Shelf life of the device(s)/reagents	18–20 months
Type of sample required	Whole blood (fingerstick and venous blood), serum, plasma
Volume of sample required	1 drop, 40 µl
Turnaround time	Immediate
Throughput*	Medium
Dimensions (W x H x D)	12 cm x 17 cm x 1.8 cm – POC test pouch
Power requirements	None
Connectivity	None
Marketing price per instrument/test	Pricing for Multiplo HBc/HIV/HCV ranges depending on local market conditions and order volumes
Complexity/training requirements	No special training required and the same procedure applies across any testing application on this platform
Supporting instrumentation/ sample preparation required	No additional equipment is required to run and read the fingerstick and whole blood samples, a centrifuge is needed if using serum or plasma
Image of device(s)	

Menssana Research, Inc. (information not verified by company)	
BCA	
Marketing status	On the market
Type of technology	VOC
POC	No
Infections the device(s) can test for and regulatory approval status	MTB, viral influenza (in development)
Sensitivity	
Specificity	
Multiplex	No
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Breathing for 2 minutes
Volume of sample required	N/A
Turnaround time	180 minutes
Throughput*	Low
Dimensions (W x H x D)	
Power requirements	
Connectivity	Breathlink™ platform
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	Lab analysis services available
Image of device(s)	

Metabolomx (information not verified by company)	
Metabolomx Sensor	
Marketing status	In development
Type of technology	VOC
POC	Yes
Infections the device(s) can test for and regulatory approval status	TB, respiratory infections
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Sample required will be dependent upon the assay; for TB, gas from urine will be used
Volume of sample required	N/A
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Molbio Diagnostics Pvt. Ltd	
Trueprep™ Auto sample preparation device /Truelab™ Uno Dx Real Time Micro PCR Analyser	
Marketing status	Older generation devices: on the market (CE marked) New generation devices: in development CE marking application in progress)
Type of technology	NAT; qPCR
POC	Yes
Infections the device(s) can test for and regulatory approval status	On the market: HBV, MTB, Salmonella, dengue virus, chikungunya virus, H1N1, MTB-RIF, malaria Pf/Pv
	In development: HIV-1, HIV-2, HCV, Trichomonas vaginalis, Chlamydia trachomatis, Neisseria gonorrhoeae, HPV, Zika virus, Klebsiella, MRSA, meningitis, FluA/B
Sensitivity	Assay dependent. Preliminary data for HCV: overall average sensitivity: 100% (94–100%).
Specificity	Assay dependent. Preliminary data for HCV: overall average specificity: 100% (85–100%).
Multiplex	Yes; device can potentially detect multiple targets at the same time. Potential multiplex options – chikungunya virus/dengue virus/Zika virus; HBV/HCV/HIV; Trichomonas vaginalis/Chlamydia trachomatis/Neisseria gonorrhoeae
Storage temperature of the device(s)/reagents	Device: room temperature Assays/reagents: room temperature
Shelf life of the device(s)/reagents	MicroPCR chips, sample prep kits and reagents are stable for 2 years at room temperature
Type of sample required	Whole blood (fingerstick or venous blood), plasma or serum for HCV; Auto-prep can also process sputum, stool and swabs
Volume of sample required	Trueprep™ Auto requires 0.25/0.5 mL of whole blood/plasma/serum and Truelab™ Uno Dx requires 6 µL of purified DNA
Turnaround time	Sample-to-result in 1 hour (~20 minutes for sample prep on Trueprep™ Auto and 35–40 minutes for RT/qPCR on Truelab™ Uno DX)
Throughput*	Low-throughput (<50 samples/hour)
Dimensions (W x H x D)	Trueprep™ Auto sample prep device: 215 mm x 115 mm x 235 mm Truelab™ Uno Dx: 248 mm x 112 mm x 185 mm
Power requirements	Rechargeable lithium ion battery pack – sufficient backup for 1 day of testing; input to AC/DC adaptor: single-phase 100–240V; 50/60Hz; 1500 mA; output from AC/DC adaptor: 10 V; 4500mA; 45VA
Connectivity	Bluetooth, GSM and Wi-Fi
Marketing price per instrument/test	Trueprep™ Auto and Truelab™ Uno Dx combo: US$ 12 000. Per test: US$ 18
Complexity/training requirements	Minimal training, less than 1 day

Molbio Diagnostics Pvt. Ltd	
Trueprep™ Auto sample preparation device /Truelab™ Uno Dx Real Time Micro PCR Analyser	
Supporting instrumentation/ sample preparation required	No computer required – all data entry and analysis is done on the devices. The new generation Trueprep™ Auto sample prep device is a fully automated, portable, battery-operated sample preparation device that can process a wide range of clinical specimens and extract purified RNA/DNA. Processing is done on disposable cartridges that process the sample, bind the nucleic acids on a proprietary matrix and the cartridge stores all bio-waste in an enclosed dump area. The entire process is fully contained and biosafe. Purified RNA/DNA that can then be analysed on microchips run on the Truelab™ Uno Dx (Molbio's new microPCR device) that has enhanced hardware and software capability and allows for greater multiplexing. The device retains all other desirable features such as portability, battery operation, connectivity as the previous Truelab™ Uno device.
Image of device(s) Trueprep™ Auto Sample Prep Device: Truelab™ Uno Dx microPCR Device:	 

Nanobiosym (information not verified by company)	
Gene-RADAR®	
Marketing status	In development
Type of technology	NAT
POC	Yes
Infections the device(s) can test for and regulatory approval status	
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Nipro	
Genoscholar NTM+MDRTB II	
Marketing status	On the market
Type of technology	NAT; LPA
POC	No
Infections the device(s) can test for and regulatory approval status	TB, NTM, MDR-TB (WHO PQ, CE marked)
Sensitivity	RIF:92.4 %, INH:89.9 %
Specificity	RIF:97.5 %, INH:99.4 %
Multiplex	Yes
Storage temperature of the device(s)/reagents	Reagent: 2–10 °C
Shelf life of the device(s)/reagents	Reagent: 12 months
Type of sample required	Sputum, cultured strain
Volume of sample required	5–10 µL from extracted DNA
Turnaround time	5 hours
Throughput*	Low
Dimensions (W x H x D)	488 mm x 443 mm x 395 mm (MULTIBLOT NS-4800)
Power requirements	85–264 V, 5A (at maximum)
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	High complexity
Supporting instrumentation/ sample preparation required	i-Phone application for reading the strip is available. NALC-NaOH treatment and DNA extraction is needed.
Image of device(s)	 

OPKO (information not verified by company)	
Claros® 1 Analyzer	
Marketing status	On the market
Type of technology	Immunoassay; sandwich immunoassays in microfluidics
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV, HBV, TP
Sensitivity	
Specificity	
Multiplex	Yes
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Whole blood sample, serum, urine, semen, saliva, amniotic fluid, spinal fluid, tears, sweat
Volume of sample required	N/A
Turnaround time	10 minutes
Throughput*	Low
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	Lab analysis services available
Image of device(s)	  

Oxford Nanopore	
minION, PromethION, SmidgION	
Marketing status	MinION, GridION: on the market, RUO PromethION, VolTRAX: early access SmidgION, Flongle/MinION Dx: in development As Nanopore sequencing is not approved for diagnostic use at this time, some of the information below cannot be provided.
Type of technology	DNA and RNA sequencing
POC	Nanopore technology is uniquely miniaturizable so the MinION (size of a stapler) and SmidgION (in development, mobile phone sequencer) are designed to be used in any environment. The larger less moveable instruments, GridION and PromethION, are designed for high-sample number, high-throughput scenarios. MinION Dx, also in development, will be a version of the handheld MinION that is designed for frequent, single-use experiments.
Infections the device(s) can test for and regulatory approval status	Nanopore sequencing has been used in a research context in a wide variety of infectious diseases, where DNA or RNA analysis can confirm identity/characterize pathogens, e.g. MTB, FluA, FluB, E. coli, ZIKV, Epstein-Barr virus, STDs, fungal disease. It has also been used in research context to characterize AMR in pathogens, in real time. Further translational work is under way.
Sensitivity	N/A
Specificity	N/A
Multiplex	N/A
Storage temperature of the device(s)/reagents	N/A
Shelf life of the device(s)/reagents	N/A
Type of sample required	Nanopore sequencers will sequence DNA or RNA from any organism, with some basic library preparation procedures. Automated library preparation technologies are being developed, e.g. VolTRAX. RUO at this time.
Volume of sample required	N/A
Turnaround time	Dependent on the information required. Nanopore sequence data streams in real time, so DNA/RNA sequence data starts to become available as soon as the sequencing starts. RUO at this time.
Throughput*	N/A
Dimensions (W x H x D)	PromethION: GridION: MinION: SmidgION:
Power requirements	PromethION: standard power cable GridION: standard power cable MinION: USB powered (laptop/PC) SmidgION: powered by a smartphone
Connectivity	PromethION: network GridION: network MinION/MinION Dx: USB SmidgION: smartphone (in development)

Oxford Nanopore		
minION, PromethION, SmidgION		
Marketing price per instrument/test	N/A	
Complexity/training requirements	Oxford Nanopore is exploring developments of the technology that may be applied for diagnostic use in the future, where the devices are plug-and-play and the workflow is achievable by any user.	
Supporting instrumentation/ sample preparation required	Devices require a laptop/computer/smartphone and prior sample preparation. However, VolTRAX is being developed to perform library preparation automatically, so that a user can get a biological sample ready for analysis, hands free.	
Image of device(s)		
		

PacBio (information not verified by company)	
Sequel/RS2	
Marketing status	On the market
Type of technology	NGS
POC	No
Infections the device(s) can test for and regulatory approval status	
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Primerdesign	
Genesig® q16	
Marketing status	On the market (RUO)
Type of technology	NAT: qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	RUO: HIV-1, HIV-2, HCV, MTB, MRSA, HAV, HBV, HPV, HSV, adenovirus, Clostridium difficile, E. coli, dengue virus, chikungunya virus, ZIKA, CMV, Chlamydophila pneumoniae, Chlamydia trachomatis, Neisseria gonorrhoeae, FluA, FluB, Ebola virus, Epstein-Barr virus, human herpesvirus 6 (and others)
Sensitivity	N/A (no clinical studies have yet been performed)
Specificity	N/A (no clinical studies have yet been performed)
Multiplex	No multiplex assays available, but up to 3 tests can be run at once
Storage temperature of the device(s)/reagents	System: room temperature Reagents: freezer
Shelf life of the device(s)/reagents	Reagents: 18 months lyophilized, 6 months once reconstituted Device: N/A
Type of sample required	Systems accepts blood, serum, plasma, faecal, urine, sputum, nasal, tissue, etc.
Volume of sample required	10 µl
Turnaround time	90–120 minutes
Throughput*	Low; <50 samples/hour
Dimensions (W x H x D)	12 cm x 16 cm x 12 cm
Power requirements	AC power supply
Connectivity	Local area network (LAN) cable/USB
Marketing price per instrument/test	£5/reaction £4995/device
Complexity/training requirements	Basic lab training, simple step-by-step operations (requires prior RNA/DNA extraction)
Supporting instrumentation/ sample preparation required	Computer required; reagents for prior RNA/DNA extraction required
Image of device(s)	

QIAGEN	
QIAsymphony® SP/AS and Rotor-Gene® Q instruments	
Marketing status	On the market
Type of technology	RT-qPCR
Level of Care	Lab: Level II/III/IV
Infections the device(s) can test for and regulatory approval status	HIV, HCV, TB, malaria, HSV, varicella-zoster virus, HPV, BK Virus, CMV, Epstein-Barr virus, HBV, parvovirus, Severe Acute Respiratory Syndrome
	CE marked
Sensitivity	HIV: 66.9 IU/mL HCV: 21 IU/mL TB: 0.23 cp/µL
Specificity	HIV: TBC HCV: 99.4% TB: TBC
Multiplex	No
Storage temperature of the device(s)/reagents	-20° C
Shelf life of the device(s)/reagents	1200 µL
Type of sample required	Whole blood (fingerstick and venous blood), serum, plasma
Volume of sample required	HIV: plasma HCV: plasma TB: human sputum, bronchoalveolar lavage (BAL), bronchial secretion, cerebral spinal fluid, stomach fluid, or peritoneal punction Malaria: blood
Turnaround time	5–20 minutes
Throughput*	Medium to high
Dimensions (W x H x D)	TBC
Power requirements	TBC
Connectivity	TBC
Marketing price per instrument/test	artus® HCV RG RT-PCR (24) £641 to (96) £2431; HCV QS-RGQ: (24) £669 to (72) £1971
Complexity/training requirements	Manual
Supporting instrumentation/ sample preparation required	For use with QIAsymphony® SP/AS and Rotor-Gene® Q Instruments
Image of device(s) Top: Rotor-Gene® Q Bottom: QIAsymphony® SP/AS	 

QIAGEN (information not verified by company)	
GeneReader	
Marketing status	On the market
Type of technology	NGS
POC	No
Infections the device(s) can test for and regulatory approval status	
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

QuantuMDx	
Q-POC	
Marketing status	In development (launch estimated 2018)
Type of technology	NAT; onboard sample preparation, qPCR and/or PCR and hybridization
POC	Yes
Infections the device(s) can test for and regulatory approval status	In development: TB, MDR-TB, malaria, Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, HPV
Sensitivity	TBD
Specificity	TBD
Multiplex	Yes; STI panel test, HPV subtyping (in development)
Storage temperature of the device(s)/reagents	5–50 °C
Shelf life of the device(s)/reagents	Reagents: 12–18 months Device: N/A
Type of sample required	
Volume of sample required	
Turnaround time	15–25 minutes depending on the assay (this does not include preprocessing of the sputum sample for MTB assay)
Throughput*	Low; one sample takes 15–25 minutes. Device can be stacked allowing for higher-throughput.
Dimensions (W x H x D)	TBD
Power requirements	Batteries; can be also run using AC and solar energy
Connectivity	GSM, Wi-Fi 33, 3G
Marketing price per instrument/test	£1500–2000 (dependent upon the assays and the market; targeting low costs of goods for deployment in LMICs)
Complexity/training requirements	Low complexity from a user perspective, with minimal training required. Aiming to be CLIA waived
Supporting instrumentation/ sample preparation required	Assay dependent. Aiming for minimal peripheral equipment and consumables. TB requires QMDx's sputum processing technology.
Image of device(s)	

Qualpro Diagnostics	
Combiquic HIV/HCV	
Marketing status	On the market
Type of technology	Immunoassay; rapid immunoconcentration assay for simultaneous detection of HIV1/2 and HCV (RDT)
POC	Yes
Infections the device(s) can test for and regulatory approval status	HIV, HCV (not US FDA approved or CE marked)
Sensitivity	HIV1/2: 100% HCV: 100%
Specificity	HIV1/2: 100% HCV: 99.6%
Multiplex	50 tests
Storage temperature of the device(s)/reagents	Unopened kit: 2–8 °C for 12 months
Shelf life of the device(s)/reagents	12 months
Type of sample required	Serum, plasma
Volume of sample required	25 µl
Turnaround time	5 minutes
Throughput*	Low
Dimensions (W x H x D)	33.5 cm x 7 cm x 11 cm
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	N/A
Complexity/training requirements	Minimal
Supporting instrumentation/ sample preparation required	No instrumentation required
Image of device(s)	

Rapid Biosensor Systems Ltd (information not verified by company)	
Breathalyzer	
Marketing status	In development
Type of technology	VOC
POC	
Infections the device(s) can test for and regulatory approval status	Currently being developed for TB, but the platform can also be adapted to detect for other diseases, and the company plans to develop a test for bacterial pneumonia
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	Results available in 2 minutes
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	None
Marketing price per instrument/test	
Complexity/training requirements	Minimal; sample is taken with TB sample cough tube, and then placed in the reader to process
Supporting instrumentation/ sample preparation required	
Image of device(s)	

ReLIA Diagnostics (specifications not verified)	
ReLIA Multi-Functional Immunoassay Instrument, HIV-HCV Dual Test	
Marketing status	On the market
Type of technology	Colloidal gold-based immunoassay
Level of care	Level 1
Infections the device(s) can test for and regulatory approval status	HIV-HCV Dual Test, HCV, HBsAg-TP Dual Test
	RUO
Sensitivity	HIV: 99.74% HCV: 99.19% HBSAg TP
Specificity	HIV: 99.56% HCV: 98.96% HBSAg TP
Multiplex	Yes (2/3 assays)
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	18 months
Type of sample required	Whole blood, plasma, serum
Volume of sample required	
Turnaround time	<20 minutes
Throughput*	Low
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s) Top to bottom	 

Roche Molecular Diagnostics (information not verified by company)	
Cobas® 6800/8800	
Marketing status	On the market
Type of technology	NAT; qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked and US FDA approved: HIV-1, HIV-2, HBV, HCV, parvovirus B19, HAV, West Nile virus, Zika virus
	CE marked: HEV, CMV, Chlamydia trachomatis/Neisseria gonorrhoeae
	In development: chikungunya virus/dengue virus, HIV-1/2 Qual, MTB, RIF/INH, HPV, Trichomonas vaginalis/Mycoplasma genitalium
Sensitivity	Assay dependent
Specificity	Assay dependent
Multiplex	Yes; cobas® DPX (parvovirus B19, HAV), Cobas® MPX (HIV, HCV, HBV), chikungunya virus/dengue virus (in development), Chlamydia trachomatis/Neisseria gonorrhoeae
Storage temperature of the device(s)/reagents	Device: 15–28°C
Shelf life of the device(s)/reagents	
Type of sample required	Assay dependent
Volume of sample required	Assay dependent
Turnaround time	Up to 96 test results are available in less than 3.5 hours, with additional 96 results available every 90 minutes thereafter for cobas® 6800; and every 30 minutes thereafter for cobas® 8800
Throughput*	Cobas® 6800: 384 tests per 8-hour shift Cobas® 8800: 960 tests per 8-hour shift
Dimensions (W x H x D)	Cobas® 6800: 292 cm x 216 cm x 129 cm Cobas® 8800: 429 cm x 216 cm x 129 cm
Power requirements	200–240 VAC ±10%, 50/60 Hz ±5%, maximum power; cobas® 6800: 3500 VA, cobas® 8800: 8200 VA
Connectivity	LIS connectivity
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	Integrated system for sample preparation, extraction and analysis
Image of device(s)	

Roche Molecular Diagnostics (information not verified by company)	
Cobas® 4800 (cobas® x 480 instrument and cobas® z 480 analyzer)	
Marketing status	On the market
Type of technology	NAT; qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	HIV-1, HCV, HCV (genotyping), Chlamydia trachomatis/Neisseria gonorrhoeae, HPV (genotyping), HSV-1, HSV-2, SA, MRSA, HBV
Sensitivity	
Specificity	
Multiplex	Yes; Chlamydia trachomatis/Neisseria gonorrhoeae
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	Up to 384 samples per 8-hour shift
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	Fully automated sample preparation, nucleic acid extraction and analysis can be carried out with the cobas® x 480 instrument (sample preparation) and cobas® z 480 analyzer (qPCR)
Image of device(s)	

Roche Molecular Diagnostics (information not verified by company)	
Cobas® s 201 system	
Marketing status	On the market
Type of technology	NAT; qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked/US FDA approved: HIV-1, HIV-2, HCV, HBV, parvovirus B19, HAV, West Nile virus
Sensitivity	
Specificity	
Multiplex	Yes; cobas® DPX test (parvovirus B19, HAV), cobas® MPX test (HIV-1, HIV-2, HCV, HBV)
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Roche Molecular Diagnostics (information not verified by company)	
Cobas® AmpliPrep® instrument and cobas® TaqMan® analyzers	
Marketing status	On the market
Type of technology	NAT; qPCR
POC	Level 3 and 4
Infections the device(s) can test for and regulatory approval status	HIV-1 (qualitative, EID), HIV-1 (quantitative), CMV, HBV, HCV (qualitative), HCV (quantitative); HIV assays are WHO PQ
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	147 patient samples within 8 hours
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	COBAS® AmpliPrep® Instrument for automated specimen processing and the COBAS® TaqMan®Analyzer or the COBAS® TaqMan® 48 Analyzer for automated amplification and detection
Image of device(s) Cobas® AmpliPrep® Instrument: Cobas® TaqMan® 48 Analyser:	 

Sacace Biotechnologies	
SaMag-12/24 and SaCycler-96	
Marketing status	On the market (CE marked)
Type of technology	NAT; qPCR
POC	No
Infections the device(s) can test for and regulatory approval status	CE marked: HCV (confirmatory), HIV-1 (VL), HIV-2 (VL), HIV abacavir sensitivity, MTB, HAV, HBV, HPV, Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, TP, CMV, HSV-1, HSV-2, Ebola virus, Epstein-Barr virus, bacterial vaginosis, human herpesvirus 6, parvovirus B19, FluA/B, respiratory syncytial virus (and others)
	RUO: HCV (genotyping), HIV-1 (EID), HIV-2 (EID), MDR (and others)
Sensitivity	Assay dependent; e.g. HCV Real-TM Quant Dx: 13 IU/mL (sample input 1000uL), 30 µL when using SaMag extraction) HCV Genotype Plus Real-TM sensitivity: 1000 IU/mL
Specificity	Assay dependant; r.g. HCV Real-TM Quant Dx Specificity: 100%. HCV Genotype Plus Real-TM specificity: 100%.
Multiplex	Yes; system has 5 channels for multiplexing, allowing up to 5 targets to be tested for in a single well. Multiplex assays available include HCV/HBV/HIV-1/HIV-2 (RUO), STD multiplex PCR kits (various combinations, some RUO, some CE marked).
Storage temperature of the device(s)/reagents	HCV Dx (lyophilized reagents) are stored at 2–8 °C, shipped at room temperature. Other liquid format reagent kits (e.g. HCV genotype) stored at -20 °C and shipped at 2–8 °C.
Shelf life of the device(s)/reagents	Liquid reagent kits 6–9 months. Lyophilized reagents 12 months. Extraction kit reagents: 12 months.
Type of sample required	Plasma (recommended) and serum.
Volume of sample required	Up to 400 µL of plasma/serum when using SaMag extraction kit. Up to 1000 µL of plasma when using manual extraction kit (Sacace MagnoVirus extraction kit).
Turnaround time	3.5–4 hours
Throughput	Low (<50 samples/hour), but at full theoretical capacity (with 2 SaMag-24 extraction systems plus 1 SaCycler-96 PCR instrument) ~280 tests per day (8-hour shift) can be performed with the HCV Real-TM Quant Dx kit
Dimensions (W x H x D)	Sa Cycler-96: 210 mm x 540 mm x 540 mm
Power requirements	10A, 250V power cable
Connectivity	USB
Marketing price per instrument/test	US$ 18 645 (for the version that comes with a notebook computer, but only works with Sacace test kits) or ~US$ 21 750 (for the version that does not include a notebook computer, but can also be used with non-Sacace test kits)

Sacace Biotechnologies	
SaMag-12/24 and SaCycler-96	
Complexity/training requirements	Requires prior DNA/RNA extraction, but extraction can be automated using the SaMag-12 or SaMag-24 Systems. PCR setup can be automated when using SaMag instrument; the SaMag instrument will elute DNA/RNA directly in the HCV Dx PCR tube with lyophilized reagents, the user must close the PCR tube cap and transfer directly into the SaCycler-96 instrument to perform PCR (this applies only to HCV Dx lyophilized kit).
Supporting instrumentation/ sample preparation required	SaCycler-96 Real Time PCR instrument requires a PC notebook with Microsoft Windows. Other instrumentation required are normal for molecular biology labs (micropipettes, filter tips, spin centrifuge).
Image of Device SaMag-12 (SaMag-24 has two modules) Sa Cycler-96	 

Scanogen (information not verified by company)	
Biosensor Technology	
Marketing status	In development
Type of technology	NAT; biosensor
POC	Yes
Infections the device(s) can test for and regulatory approval status	Infectious diseases are one of the areas Scanogen is focussing on. An assay for TB has been reported.
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Seegene	
Allplex™/Anyplex™/Seeplex™ Assays	
Marketing status	AllplexTM assays (multiplex PCR and multi-Ct value analysis): on the market Anyplex™ II assays (multiplex PCR and melt curve analysis): on the market Anyplex™ assays (multiple PCR and Ct value analysis): on the market
Type of technology	NAAT; high multiplex real-time PCR
POC	No
Infections the device(s) can test for and regulatory approval status	**Allplex™ assays** (CE marked): respiratory pathogens (16 viruses, 7 bacteria detections and 3 FluA subtyping), gastrointestinal pathogens (25 gastrointestinal pathogens), STI pathogens (28 pathogens causing STIs)
	Allplex™ assays (CE marked): respiratory virus (16 respiratory viruses), respiratory bacteria (5 bacteria), STI pathogens (7 STI pathogens), HPV (genotyping 28 HPVs), MTB/MDR/XDR (MTB, 25 MDR mutations, and 13 XDR mutations)
	Allplex™ assays (CE marked): FluA/B (FluA/B subtyping), MERS-CoV (MERS CoV detection), CT/NG, MTB/NTM/MDR (MTB and NTM differentiation with 25 MDR mutations), MTB/NTM, VanR (VanA, VanB, VanC detection; not CE marked)
Sensitivity	Assay dependent (e.g. Anyplex™ II MTB/MDR/XDR detection: 20 copies/reaction of all targets)
Specificity	Assay dependent (cross-reactivity of all assays is assessed; Anyplex™ II MTB/MDR/XDR detection: 100% specificity)
Multiplex	Yes
Storage temperature of the device(s)/reagents	Below -20 °C
Shelf life of the device(s)/reagents	Assay dependent
Type of sample required	Assay dependent (indicated in manual)
Volume of sample required	Assay dependent (indicated in manual)
Turnaround time	Assay dependent (e.g. turnaround time of TB products are 3–4.5 hours)
Throughput*	Assay and instrument dependent (<96 samples)
Dimensions (W x H x D)	**Automated extraction and PCR setup:** Microlab NIMBUS IVD (Hamilton): 1041 mm x 800 mm x 673 (mm) Microlab STARlet IVD (Hamilton): 1124 mm x 903 mm x 795 (mm)
	Real-time PCR: CFX96™ (Bio-Rad): 330 mm x 360 mm x 460 mm
Power requirements	**Automated extraction and PCR setup:** Microlab NIMBUS IVD (Hamilton): 100–240 VAC, 50–60 Hz, 5A Microlab STARlet IVD (Hamilton): 600 VA (depending on configuration)
	Real-time PCR: CFX96™ (Bio-Rad): 100–240 VAC, 50-60Hz, 5A
Connectivity	Microlab NIMBUS IVD: local area network (LAN) Microlab STARlet IVD: USB cable CFX96™: USB cable – system includes integrated Ethernet and wireless connectivity for data import and export
Marketing price per instrument/test	N/A

<table>
<tr><th colspan="4">Seegene</th></tr>
<tr><th colspan="4">Allplex™/Anyplex™/Seeplex™ Assays</th></tr>
<tr><td>Complexity/training requirements</td><td colspan="3">Preparation of reagents for amplification and extraction is moderately complex</td></tr>
<tr><td>Supporting instrumentation/ sample preparation required</td><td colspan="3">No instruments supplied/automated extraction and sample preparation is allowed depending on assay types</td></tr>
<tr><td rowspan="2">Image of device(s)</td><td colspan="2">Automated extraction and PCR set up:</td><td>Real-time PCR:</td></tr>
<tr><td>Microlab NIMBUS IVD (Hamilton):
  </td><td>Microlab STARlet IVD (Hamilton):
  </td><td>CFX96™ (Bio-Rad):
  </td></tr>
<tr><td colspan="3">Anyplex™ II MTB/XDR Detection:
  </td></tr>
</table>

Siemens Healthcare	
BEP® 2000 Advance System/BEP® III System	
Marketing status	On the market
Type of technology	Automated microtiter plates (MTP) (ELISA processing)
POC	No
Infections the device(s) can test for and regulatory approval status	More than 100 validated Siemens CE marked assays on BEP® system for viruses: HIV, hepatitis, bacteria like TP, borreliosis, fungi, worms, parasites, etc. HIV-1/2, HBV, HAV, HCV, HSV-1/2, CMV, Epstein-Barr virus, dengue virus, Chlamydia trachomatis, chikungunya virus. HBsAg assay and HIV Integral 4 immunoassay (tests for HIV Abs and p24 Ag) are WHO PQ. HCV assay is currently under WHO PQ assessment.
	CE marked; registration in other countries as well –contact Siemens for detailed information
Sensitivity	Assay specific – contact Siemens for detailed information
Specificity	Assay specific – contact Siemens for detailed information
Multiplex	BEP® 2000 Advance System: yes; up to 4 MTPs, up to 12 tests/plate frame (Enzygnost® and Novagnost® Assays), 100 tubes. BEP® III System: yes; 10 MTPs in parallel.
Storage temperature of the device(s)/reagents	Data provided in IFU for 2–8 °C and 15–25 °C
Shelf life of the device(s)/reagents	Assay specific – typically between 12 and 24 months; contact Siemens for detailed information
Type of sample required	Assay specific – serum and/or plasma
Volume of sample required	Assay specific – typical 100 µl
Turnaround time	Assay specific – between 1 and 2 hours
Throughput*	BEP® 2000 Advance System: 4 plates per run: BEP® III System: 10 plates per run
Dimensions (W x H x D)	BEP® 2000 Advance System: 44.8” x 39.4” x 61.4” BEP® III System: 13.8” x 9.8” x 23.6”
Power requirements	BEP® 2000 Advances System: 100–260 V Ac, 47–63 Hz, typically maximum 500 VA BEP® III System: operating unit: 100–240 V Ac, 50/60 Hz, supply unit: 110V 90 –125 V (50/60 Hz), 230V: 205–245 V (50/60 Hz)
Connectivity	Yes
Marketing price per instrument/test	Contact the local Siemens organization
Complexity/training requirements	Siemens offers training in European training centres. Customer specific training in individual countries are available on request.
Supporting instrumentation/ sample preparation required	Siemens offers support either in the country or from global organization
Image of device(s)	 

Siemens Healthcare	
Atellica MDX 160 Molecular System	
Marketing status	On the market (CE marked)
Type of technology	NAT; kPCR
POC	No
Infections the device(s) can test for and regulatory approval status	HIV-1 (WHO PQ), HCV, HBV, Chlamydia trachomatis, Neisseria gonorrhoeae, Zika virus, kPCR PLX assays (CMV, Epstein-Barr virus, HSV-1/2, varicella-zoster virus, HHV-6, BK virus, JC virus, adenovirus, parvovirus B19)
Sensitivity	Assay specific
Specificity	Assay specific
Multiplex	Yes; 5 channels for up to 5 targets
Storage temperature of the device(s)/reagents	Room temperature
Shelf life of the device(s)/reagents	
Type of sample required	Plasma, serum, urine, whole blood, stool, etc.
Volume of sample required	Up to 500 µL (HIV-1, HBV, HCV, kPCR PLX assays, Zika virus), 250 µL (Chlamydia trachomatis, Neisseria gonorrhoeae); not including dead volume requirements which are sample tube type dependent
Turnaround time	96 tests in about 6 hours
Throughput*	Low; 96 tests per run
Dimensions (W x H x D)	SP module: 0.903 m x 1.124 m x 1.006 m (depth includes autoload tray) (no plumbing or drainage required) AD module: 0.534 m x 0.368 m x 0.457 m
Power requirements	SP and AD: 100–120 V alternating current at 50 or 60 Hertz ± 5% or 200–240 V alternating current at 50 or 60 Hertz ± 5%
Connectivity	Bi-directional LIS
Marketing price per instrument/test	Country and volume dependent
Complexity/training requirements	Minimal complexity for molecular diagnostic laboratories; free training provided for new customers
Supporting instrumentation/ sample preparation required	VERSANT® kPCR Molecular System includes both sample prep and amplification-detection modules; VERSANT® Sample Preparation 1.0 Reagents kit required for extraction; automated PCR plate set-up included
Image of device(s)	

Spartan	
Spartan Cube	
Marketing status	Commercially available
Type of technology	NAT
POC	Yes
Infections the device(s) can test for and regulatory approval status	The Spartan Cube is being developed for infectious disease diagnostics, pharmacogenetic diagnostics, and food and water safety testing
Sensitivity	5–10 organisms
Specificity	95-100%
Multiplex	Yes
Storage temperature of the device(s)/reagents	Room temperature and fridge stable
Shelf life of the device(s)/reagents	>6 months
Type of sample required	Buccal swab
Volume of sample required	<2 µL
Turnaround time	Sample-to-result in as few as 30 minutes
Throughput*	Low
Dimensions (W x H x D)	4 inches cubed
Power requirements	Electrical compatibility: 100–240 V, 50–60 Hz
Connectivity	Connect wirelessly with a tablet or laptop
Marketing price per instrument/test	Undisclosed
Complexity/training requirements	Minimal; Spartan's technology fully integrates DNA collection, extraction and analysis
Supporting instrumentation/ sample preparation required	None
Image of device(s)	

Spectrum (information not verified by company)	
HBsAg/HCV Ab Rapid Test	
Marketing status	On the market
Type of technology	Later flow chromatographic immunoassay
POC	Yes
Infections the device(s) can test for and regulatory approval status	HBV, HCV
Sensitivity	98.7%
Specificity	99.6%
Multiplex	No
Storage temperature of the device(s)/reagents	Test: 2–30 °C Reagents: 2–8 °C
Shelf life of the device(s)/reagents	
Type of sample required	Human serum, plasma, whole blood
Volume of sample required	1 drop of blood (40–50 µl or 30–45 µl of serum)
Turnaround time	15 minutes
Throughput*	Low
Dimensions (W x H x D)	
Power requirements	N/A
Connectivity	N/A
Marketing price per instrument/test	
Complexity/training requirements	Minimal
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Tangen Biosciences (information not verified by company)	
TangenDx Instrument	
Marketing status	In development
Type of technology	NAT
POC	
Infections the device(s) can test for and regulatory approval status	TB and other infectious diseases
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

ThermoFisher (information not verified by company)	
Ion S5/Ion PGM, Ion Proton	
Marketing status	On the market
Type of technology	NGS
POC	No
Infections the device(s) can test for and regulatory approval status	
Sensitivity	
Specificity	
Multiplex	
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Tosoh Bioscience	
TRCReady®-80	
Marketing status	On the market
Type of technology	NAT; TRC method (transcription-Reverse transcription concerted reaction)
POC	No
Infections the device(s) can test for and regulatory approval status	On the market; MTB kit (CE marked), MAC kit (Japanese FDA approved), norovirus kit (RUO assay in Japan)
	In development: Chlamydia trachomatis/Neisseria gonorrhoeae (planning to launch in 2017 in Japan, 2018 in the European Union), Mycoplasma pneumoniae (in development)
Sensitivity	The minimum detectable concentration was determined as 300 copies of standard RNA per test (one MTB contains thousands to tens of thousands of rRNA copies)
Specificity	
Multiplex	Device can detect two different infections, using a single sample
Storage temperature of the device(s)/reagents	Device: 15–30 °C Detection reagents: 2–8 °C
Shelf life of the device(s)/reagents	Device: N/A Reagents: 12 months
Type of sample required	MTB and MAC: clinical specimens (pulmonary and extra-pulmonary) or in a suspension of cultured cells
Volume of sample required	Sample required is assay dependent: MTB and MAC – specimens (200–500 micro L)
Turnaround time	40 minutes
Throughput*	Low; <50 samples/hour (8 samples in 40 minutes)
Dimensions (W x H x D)	350 mm x 600 mm x 600 mm
Power requirements	AC100–240V 50/60Hz 180VA
Connectivity	Two instruments can be connected to one control PC
Marketing price per instrument/test	Upon request
Complexity/training requirements	Easy to use, only 2 hours training required
Supporting instrumentation/ sample preparation required	Sample prep required for MTB test (heating 10 minutes for lysis step). Equipment: pipette (dispensing 2–10 micro L and 200–500 micro L)/pipette tips/vortex mixer/centrifuge (RCF ranging from 2000 to 10 000 x g).
Image of device(s)	

Two Pore Guys	
(MoM)	
Marketing status	In development
Type of technology	Silicon Nanopore
Level Care	POC
Infections the device(s) can test for and regulatory approval status	Assays to be developed by third parties
	RUO (in development)
Sensitivity	Single-molecule detection
Specificity	Specified by third-party reagents
Multiplex	N/A (reagents are dehydrated)
Storage temperature of the device(s)/reagents	N/A (reagents are dehydrated)
Shelf life of the device(s)/reagents	Not determined
Type of sample required	Any
Volume of sample required	Down to 5 µL
Turnaround time	30 seconds to 10 minutes (analytes to nucleic acids)
Throughput*	Single sample
Dimensions (W x H x D)	3” x 7”
Power requirements	Internal batter
Connectivity	Wired and wireless
Marketing price per instrument/test	US$ 499/device
Complexity/training requirements	Depends on test
Supporting instrumentation/ sample preparation required	Sample prep integrated into device
Image of device(s)	

UAB Euro Genomas (information not verified by company)	
HBsAg and HCV Combo Test	
Marketing status	On the market; CE marked
Type of technology	Immunochromatography; RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HBsAg and HCV
Sensitivity	
Specificity	
Multiplex	Yes
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Plasma or serum
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

UAB Euro Genomas (information not verified by company)	
HBsAg/HCV/HIV/Syphilis Combo Test	
Marketing status	On the market; CE marked
Type of technology	Immunochromatography; RDT
POC	Yes
Infections the device(s) can test for and regulatory approval status	HBsAg/HCV/HIV/syphilis
Sensitivity	
Specificity	
Multiplex	Yes
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	
Supporting instrumentation/ sample preparation required	
Image of device(s)	

Ustar Biotechnologies (not confirmed by manufacturer)	
Cross priming amplification (CPA), EasyNAT™ TB-CPA	
Marketing status	On the market
Regulatory approval status	TB: CE marked
Type of technology	Cross Priming Amplification based (isothermal amplification – lateral flow)
Level of care	Level 1, 2, 3 and 4
Infections the device(s) can test for and regulatory approval status	TB Other tests are available for toxoplasmosis and chlamydia
Sensitivity	TB: 84.1%
Specificity	TB: 97.8%
Multiplex	Yes
Storage temperature of the device(s)/reagents	-20 °C (Box 2), 2–30 °C (Box 1)
Shelf life of the device(s)/reagents	12 months
Type of sample required	Whole blood (fingerstick)
Volume of sample required	100 µL
Turnaround time	1–2 hours
Throughput	Low; (<50 samples/hour), 4 samples at once
Dimensions (W x H x D)	380 mm x 280 mm x 350 mm
Power requirements	AC, rechargeable batteries available
Connectivity	WiFi
Marketing price per instrument/test	TBC
Complexity/training requirements	TBC
Supporting instrumentation/ sample preparation required	Micropipette and disposable tips; heating block, water bath or any isothermal devices; centrifuge; vortex; timer; 5–10 mL centrifuge tubes; 1.5 mL centrifuge tubes, with safe-lock feature; normal saline
Image of device and cartridge	

Ustar Biotechnologies	
RT-CPA HCV/TB/HIV Viral Load Test	
Marketing status	Pipeline (expected 2019)
Regulatory approval status	RUO – yes. CLIA waived – no. WHO prequalified – no. CE marked – no. US FDA approved – no.
Type of technology	Cross Priming Amplification based, integrated molecular test
Level of care	Level 1, 2, 3 and 4
Infections the device(s) can test for and regulatory approval status	HCV, TB, HIV (all in development)
Sensitivity	N/A
Specificity	N/A
Multiplex	Yes
Storage temperature of the device(s)/reagents	Room temperature
Shelf life of the device(s)/reagents	2 years
Type of sample required	Whole blood (fingerstick)
Volume of sample required	100 µL
Turnaround time	1 hour
Throughput	Low; (<50 samples/hour), 4 samples at once
Dimensions (W x H x D)	380 mm x 280 mm x 350 mm
Power requirements	AC, rechargeable batteries available
Connectivity	WiFi
Marketing price per instrument/test	US$ 5000/US$ 5
Complexity/training requirements	Minimal – instrument will be fully integrated (RNA extraction and analysis)
Supporting instrumentation/ sample preparation required	Printer
Image of device(s)	 

Vela Diagnostics	
Sentosa SQ301	
Marketing status	On the market
Type of technology	NGS
POC	No
Infections the device(s) can test for and regulatory approval status	HCV genotyping and resistance mutation testing (CE-IVD) HIV genotyping and resistance mutation testing (CE-IVD)
Sensitivity	HCV: better than or equal to 1000 IU/mL for genotypes 1a, 1b, 2, 3 and 4. Better than or equal to 2000 IU/mL for genotypes 5 and 6. HIV: 1000 cp/mL for targeted mutation variant frequency of 20%. HIV: 4000 cp/mL for targeted mutation variant frequency of 5%.
Specificity	HCV: No cross-reactivity with HAV, HBV, HIV, CMV, Epstein-Barr virus, BK virus, dengue virus or genomic DNA. HIV: No cross-reactivity with all organisms tested.
Multiplex	HCV: Genotypes 1a, 1b, 2, 3, 4, 5 and 6 as well as amino acid mutations in NS3, NS5A and NS5B. HIV: HIV-1-M subtypes A, B, C, D, F, G, H, J, K, CRFs as well as drug resistance mutations (DRMs) in protease, real time and integrase genes.
Storage temperature of the device(s)/reagents	HCV: room temperature, refrigerated and frozen HIV: room temperature, refrigerated and frozen.
Shelf life of the device(s)/reagents	HCV: ~12 months plus HIV: ~12 months plus
Type of sample required	HCV: plasma or serum HIV: plasma
Volume of sample required	HCV: 530 µL HIV: 730 µL
Turnaround time	HCV: approximately 24 working hours HIV: approximately 28 working hours
Throughput*	HCV: Low HIV: Low
Dimensions (W x H x D)	SQ 301 = 61 x 53 x 51
Power requirements	
Connectivity	Available connection to LIS/LIMS
Marketing price per instrument/test	Contact Vela Diagnostics for a quotation
Complexity/training requirements	Can be run by a trained medical laboratory assistant and/or biomedical scientist
Supporting instrumentation/ sample preparation required	SX101, ST401, SQ Reporter Server
Image of device(s)	

Veredus Laboratories (information not verified by company)	
VerePLEX™ Biosystem	
Marketing status	On the market
Type of technology	NAT; microarray
POC	No
Infections the device(s) can test for and regulatory approval status	MTB, MDR-TB (RIF/INH), MERS, FluA, FluB, E. coli, BA, Yersinia pestis, Campylobacter, Salmonella (and others)
Sensitivity	Assay dependent: MTB/RIF: 100% MTB/INH: 95.5%
Specificity	Assay dependent: MTB/RIF: 94.6% MTB/INH: 94.6%
Multiplex	Yes; VereFoodbourne™, VereThreat™, VereVet™
Storage temperature of the device(s)/reagents	
Shelf life of the device(s)/reagents	
Type of sample required	Assay dependent; samples include serum, respiratory swabs, faecal swabs
Volume of sample required	
Turnaround time	
Throughput*	
Dimensions (W x H x D)	
Power requirements	
Connectivity	
Marketing price per instrument/test	
Complexity/training requirements	Requires prior DNA/RNA extraction
Supporting instrumentation/ sample preparation required	
Image of device(s)	

YD Diagnostics	
MolecuTech HybREAD480	
Marketing status	On the market (CE marked)
Type of technology	NAT; LPA or reverse blot hybridization
POC	No
Infections the device(s) can test for and regulatory approval status	MTB, MTB/NTM, MTB/MDR, HPV
Sensitivity	Assay dependent: MTB: ≥98%
Specificity	Assay dependent: MTB: ≥98%
Multiplex	No, but multiple samples can be tested at the same time.
Storage temperature of the device(s)/reagents	Systems: -10 to 70 °C (operates at room temperature). Reagents: 4–35 °C (PCR reagents -20°C).
Shelf life of the device(s)/reagents	Reagents: 12 months. Device: N/A.
Type of sample required	Sputum raw, swab, liquid and solid cultured sample.
Volume of sample required	0.5–2 mL
Turnaround time	<2hours/10 tests, 3 hours/48 tests
Throughput*	Low; 384 tests per day
Dimensions (W x H x D)	650 mm x 750 mm x 1100 mm
Power requirements	AC
Connectivity	USB port and Ethernet
Marketing price per instrument/test	N/A
Complexity/training requirements	Laboratory technicians require approximately two days of training
Supporting instrumentation/ sample preparation required	Requires prior DNA extraction and amplification (all reagents for manual DNA extraction, PCR reagents and hybridization reagents are included in the test kits). Computer required.
Image of device(s): MolecuTech HybREAD480® MolecuTech HybREAD480® (working place layout)	 

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