WHO Technical Report Series

1017

First WHO Model List of Essential In Vitro Diagnostics

World Health Organization

The World Health Organization was established in 1948 as a specialized agency of the United Nations serving as the directing and coordinating authority for international health matters and public health. One of WHO's constitutional functions is to provide objective and reliable information and advice in the field of human health, a responsibility that it fulfils in part through its extensive programme of publications

The Organization seeks through its publications to support national health strategies and address the most pressing public health concerns of populations around the world. To respond to the needs of Member States at all levels of development, WHO publishes practical manuals, handbooks and training material for specific categories of health workers; internationally applicable guidelines and standards; reviews and analyses of health policies, programmes and research; and state-of-the-art consensus reports that offer technical advice and recommendations for decision-makers. These books are closely tied to the Organization's priority activities, encompassing disease prevention and control, the development of equitable health systems based on primary health care, and health promotion for individuals and communities. Progress towards better health for all also demands the global dissemination and exchange of information that draws on the knowledge and experience of all WHO's Member countries and the collaboration of world leaders in public health and the biomedical sciences.

To ensure the widest possible availability of authoritative information and guidance on health matters, WHO secures the broad international distribution of its publications and encourages their translation and adaptation. By helping to promote and protect health and prevent and control disease throughout the world, WHO's books contribute to achieving the Organization's principal objective – the attainment by all people of the highest possible level of health.

The WHO *Technical Report Series* makes available the findings of various international groups of experts that provide WHO with the latest scientific and technical advice on a broad range of medical and public health subjects. Members of such expert groups serve without remuneration in their personal capacities rather than as representatives of governments or other bodies; their views do not necessarily reflect the decisions or the stated policy of WHO.

For further information, please contact: WHO Press, World Health Organization, 20 avenue Appia, 1211 Geneva 27, Switzerland (tel. +41 22 791 3264; fax: +41 22 791 4857; email: bookorders@who.int; order on line: www.who.int/bookorders).

WHO Technical Report Series
1017

First WHO Model List of Essential In Vitro Diagnostics

World Health Organization

First WHO Model List of Essential In Vitro Diagnostics
(WHO Technical Report Series, No. 1017)
ISBN 978-92-4-121026-3
ISSN 0512-3054

Suggested citation. First WHO Model List of Essential In Vitro Diagnostics. Geneva: World Health Organization; 2019 (WHO Technical Report Series, No. 1017). Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Printed in Switzerland

Contents

Abbreviations and acronyms

CLIA	chemiluminescence immunoassay
ECL	electrochemiluminescence
EDL	Model List of Essential In Vitro Diagnostics
EIA	enzyme immunoassay
G6PD	glucose-6-phosphate dehydrogenase
GLASS	Global Antimicrobial Resistance Surveillance System
HBV	hepatitis B virus
HCV	hepatitis C virus
IVD	in vitro diagnostic
MSF	Médecins Sans Frontières
RDT	rapid diagnostic test
SAGE	Strategic Advisory Group of Experts
TB	tuberculosis
USCDC	Centers for Disease Control and Prevention (USA)
USFDA	Food and Drug Administration (USA)

1. Introduction

The three strategic priorities of WHO stated in its Thirteenth General Programme of Work 2019–2023 are to advance universal health coverage, address health emergencies and promote healthier populations (*1*). The WHO Model List of Essential Medicines contains the medications considered to be the most effective and safe to meet the most important needs in a health system, thus advancing these strategic priorities. Access to good-quality, affordable in vitro diagnostics (IVDs) that allow health providers to make timely diagnoses and offer the most appropriate treatment is also essential for reaching these goals. The WHO Model List of Essential Medicines published in 2017 (*2*) included a recommendation by the Expert Committee on the Selection of Essential Medicines that WHO prepare a list of essential in vitro diagnostics, which will make an important contribution to universal health coverage.

Like the Model List of Essential Medicines, the Model List of Essential In Vitro Diagnostics ("essential diagnostics list", EDL) is intended to provide evidence-based guidance to countries for creating their own lists of essential in vitro diagnostic tests. National essential medicines lists have been successful in facilitating access to treatment, particularly in low-resourced countries, by prioritizing the most important medicines all countries should make available to their populations. It is expected that national EDLs will provide the same benefits for in vitro diagnostic tests. It should be noted that EDLs may be included in national lists of essential / priority medical devices that are used for public procurement, reimbursement or for universal health coverage (*3*).

The EDL comprises a group of IVDs that are recommended by WHO for use at various levels of a tiered national health care system (*4*). The List is not intended to be prescriptive with respect to the IVDs nor the levels at which they can or should be used. Countries should make their own decisions about which IVDs to select and where they are to be used on the basis of the national or regional burden of the disease, unmet needs, available resources and priorities.

The EDL will provide guidance and serve as a reference to ministries of health, programme managers, users such as laboratory managers, procurement officers and reimbursement systems in Member States, who are establishing or updating national lists of essential IVDs for universal health coverage. It will also inform United Nations agencies and nongovernmental organizations that support the selection, procurement, supply, donations or provision of IVDs. Finally, it will inform and guide the private sector for medical technology on IVD priorities and the IVDs needed to address global health issues.

While the EDL provides a list of tests required at various levels of the health care system, the EDL cannot be useful without an integrated, connected, tiered laboratory system, with adequate human resources, training, laboratory

infrastructure and regulatory and quality-assurance systems (*5*). Its impact also requires adoption and adaptation of the EDL by Member States, establishment of national and regional EDLs and the selection and supply mechanisms necessary to ensure access to the IVDs.

This report presents the first EDL and describes the process by which it was established and proposed next steps.

2. First WHO Model List of Essential In Vitro Diagnostics

2.1 Explanatory notes

2.1.1 Scope of the first EDL

This List is the definitive Model List of Essential In Vitro Diagnostics and replaces two previous versions that were published on the WHO website in May and November 2018.

The EDL consists of:

- general laboratory tests that can be used for routine patient care as well as for the detection and diagnosis of communicable and noncommunicable diseases. These IVDs are grouped by discipline (e.g. clinical chemistry, serology, haematology, microbiology and mycology) and test type (e.g. bilirubin, complete blood count).
- IVDs for the detection, diagnosis and monitoring of WHO priority diseases: HIV infection, tuberculosis (TB), malaria, hepatitis B, hepatitis C, human papillomavirus (HPV) infection and syphilis. These IVDs are grouped by disease area and analyte tested.

The EDL does *not* list specific brands but lists IVDs according to their biological targets. Links are provided to information on specific products in categories of tests listed in the EDL that have been prequalified by WHO or are recommended by a WHO disease programme; these are updated regularly.

2.1.2 Content and format

The first EDL consists of:

- 35 test categories of general IVDs that can be used for the assessment and diagnosis of a wide array of common and important diseases and
- 27 test categories of IVDs for the detection, diagnosis and monitoring of HIV infection, tuberculosis, malaria, hepatitis B and C, syphilis and HPV infection,

for a total of 62 test categories and 107 test formats.
For each test listed in the EDL, the following are described:

- test purpose;
- assay format;
- specimen type;

- facility level (primary level or higher level with laboratory);
- link to WHO guidance, if available; and
- link to a WHO prequalified or recommended test or that specific category, if available.

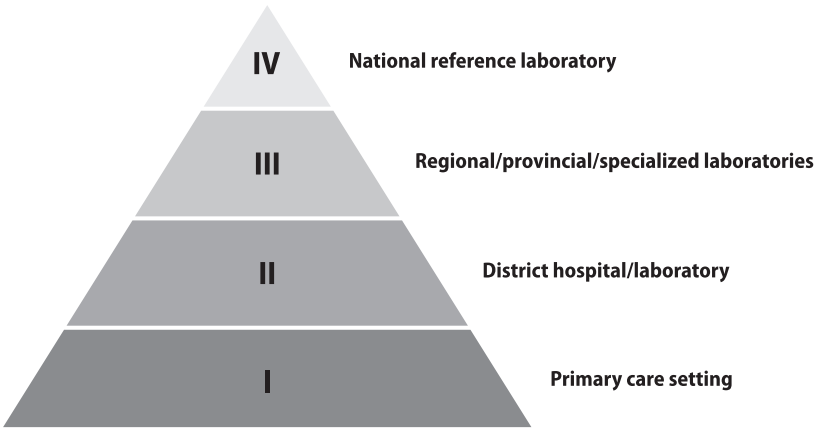
2.1.3 Recommended use of the EDL

For effective use of the EDL and its adaptation for national requirements, Member States should consider factors such as local demographics, burden of disease, disease elimination priorities, availability of treatments, training and experience of personnel, local unmet testing needs and gaps, supply chain, cost of IVDs, reagents and supplies, quality assurance capacity, financial resources, information technology capability and environmental factors. For that purpose, WHO has collated and maintains an IVD-specific webpage[1] linked to the EDL, with information to support selection and use of IVDs, including relevant WHO clinical guidelines, selected systematic reviews, key references, lists of prequalified IVDs and IVDs recommended by WHO disease control departments and resources on quality assurance, basic techniques, procurement and maintenance.

The EDL should not be used in isolation but within the scope of testing services that meet the clinical needs and expectations of each country through their laboratory networks. An example of a tiered health care delivery and laboratory network in a resource-limited country is shown in Fig. 1 (*6*). The base of the pyramid reflects primary care facilities, which serve most patients directly. Next, there is a smaller number of centralized facilities that serve fewer patients directly. National reference laboratories and some provincial laboratories may not serve patients directly or may offer broad specialist consultation and serve as referral centres for quality assurance and training or for complex testing of samples either sent by facilities lower down the system and transported or from patients referred from other facilities. Other factors that determine use of IVDs are access to electricity, reagent-grade water and specialized human resources (*7*).

[1] https://www.who.int/in-vitro-diagnostic/en/

Fig. 1
Example of tiered health facilities for use of IVDs



Source: adapted from reference *6*.

In the first EDL, to simplify its presentation and use, IVDs are listed for two tiers: primary care settings where no or minimal laboratory services are available (level I in Fig. 1) and facilities with laboratories (levels II, III and IV).

2.1.4 Glossary

Essential diagnostics. Diagnostics that satisfy the priority health care needs of the population and are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and accuracy and comparative cost-effectiveness; similar to the definition of an essential medicines.

Health care facility with laboratory support. District, regional, provincial or specialized hospitals or laboratories and national reference laboratories. Trained laboratory technicians, specialist expertise and laboratory infrastructure/equipment are available at the appropriate level. All diagnostic tests available at the primary care level are assumed to be available at higher levels as appropriate.

In vitro diagnostics. A subset of medical devices, defined as devices which, whether used alone or in combination, are intended by the manufacturer for the examination in vitro of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. They include reagents, calibrators, control material and test kits (*8*).

Medical device. Any article, apparatus, instrument, machine, appliance, implant, reagent for in vitro use, software, material or other similar related articles,

intended to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information by means of in vitro examination of specimens derived from the human body; and
- does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means (*8*).

Primary health care facilities. Health centres, doctors' offices, health posts, outreach clinics. Typically, self-testing and rapid diagnostics tests are available, but there are either no laboratories or small laboratories with trained health care personnel but no trained laboratory technicians.

2.2 Model List of Essential In Vitro Diagnostics

The EDL is presented by health care facility level in two tiers:

- I. Primary health care; with section:
  a. for general IVDs,[2] and
  b. for specific diseases
- II. Health care facilities with clinical laboratories, with section:
  a. for general IVDs,[2] and
  b. for specific diseases

I. For primary health care

Includes IVDs for health posts, community health centres, doctors' offices, outreach clinics and ambulatory care. Typically, self-testing and rapid diagnostics

[2] WHO documents used to compile general laboratory tests for the first EDL are listed under "Sources used for general laboratory tests".

tests are available, but there are either no laboratories or only small laboratories with trained health care personnel but no trained laboratory technicians. If laboratory facilities are available in a primary health care facility, please refer to the IVDs described in the next tier. In some cases, samples may be taken where there are no laboratories and processed at the next tier.

I.a General IVDs for primary health care

Use	Diagnostic test	Test purpose	Assay format	Specimen type
Haematology	Haemoglobin (Hb)	Diagnosis and monitoring of anaemia Key clinical marker for severe infections (i.e. malaria, dengue, viral haemorrhagic fevers) Safety monitoring when using certain drugs (e.g. Zidovudine for HIV infection)	Haemoglobinometer	Capillary whole blood Venous whole blood
			Dipstick	Urine
	White blood cell count	Surrogate marker for certain infections, inflammation or certain cancers (e.g. leukaemia)	Haematology analyser	Capillary whole blood Venous whole blood
	Complete blood count (CBC) manual (only as back-up to automated method)	To detect anaemia, infections and leukaemia	Haemocytometer (to measure WBC) and Wright, May-Grünwald or Giemsa stain (for differential detection of parasites, malignant cells)	Capillary whole blood Venous whole blood
			Peripheral blood film examination	Capillary whole blood Venous whole blood

Table I.a *continued*

Use	Diagnostic test	Test purpose	Assay format	Specimen type
Clinical chemistry and immunoassays	Albumin	To detect/monitor kidney disease	Dipstick	Urine
	Bilirubin	To detect/monitor liver disease, liver/pancreas and bile duct disorders, and red cell destruction	Dipstick	Urine
	Glucose	To diagnose and screen for diabetes and intermediate hyperglycaemia, to diagnose hypoglycaemia	Dipstick	Capillary whole blood Urine
			Glucometer	Capillary whole blood
	Haemoglobin A1c (HbA1c)	Diagnosis and monitoring of diabetes mellitus	Handheld and small analyser	Capillary whole blood
	Whole blood lactate	To assess metabolic acidosis, diabetic keto-acidosis, sepsis and dehydration	Electro-analytical method Handheld analyser	Arterial whole blood Venous whole blood
Blood transfusion	Blood typing	To determine blood compatibility for blood transfusions; Rh typing for pregnant women	Antisera for agglutination	Capillary whole blood Venous whole blood
Serology	Human chorionic gonadotropin (hCG)	Pregnancy	Dipstick	Urine

Table I.a *continued*

Use	Diagnostic test	Test purpose	Assay format	Specimen type
Microbiology, mycology and parasitology	Urine dipstick and urine microscopy	Detection of UTIs (dipstick) and identification of red and white blood cells, casts, squamous epithelial cells, bacteria, yeast, *Schistosoma haematobium* and other cellular components (microscopy)	Multi-parameter strips (dipstick) and light microscopy	Urine
	Microscopy	Microbial morphology, presence/absence of white blood cells versus squamous epithelial cells for presumptive identification	Microscopic examination of slides as wet preparations or which have been treated with a variety of organism-specific chemical stains (e.g. Gram stain)	Disease appropriate specimens (e.g. venous whole blood, urine, stool, etc.)

I.b Disease-specific IVDs for primary health care

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Hepatitis B	Hepatitis B surface antigen (HBsAg)	Screening for acute and chronic hepatitis B (HBV) infection: infants > 12 months of age, children, adolescents, adults	RDT	Oral fluid Capillary whole blood	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/public_report/en/)	Guidelines on hepatitis B and C testing (February 2017): http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1
	Hepatitis B e antigen (HBeAg)	Staging to assess the need for HBV treatment in chronic HBV infection	RDT	Capillary whole blood		
Hepatitis C	Hepatitis C virus antibody (anti-HCV Ab)	Screening for HCV infection: infants > 18 months of age, children, adolescents, adults	RDT	Oral fluid Capillary whole blood	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report/en/)	Guidelines on hepatitis B and C testing (February 2017): http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1

Table I.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
HIV infection	HIV 1/2 antibody (anti-HIV Ab)	HIV self-testing	RDT	Oral fluid Capillary whole blood	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/)	Guidelines on HIV self-testing and partner notification (2016) http://apps.who.int/iris/bitstream/handle/10665/251655/9789241549868-eng.pdf?sequence=1
		For the diagnosis of HIV infection: adults, adolescents, children and infants over 18 months of age	RDT	Oral fluid Capillary whole blood		Consolidated guidelines on HIV testing services (July 2015) http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/ WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection, module 10 for testing providers (2017) http://www.who.int/hiv/pub/prep/prep-implementation-tool/en/

Table I.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
HIV infection *continued*	Combined HIV antibody/ p24 antigen (anti-HIV/ p24 Ag)	For the diagnosis of HIV infection: adults, adolescents, children and infants over 18 months of age	RDT	Oral fluid Capillary whole blood	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/)	Consolidated guidelines on HIV testing services (2015) http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/
Malaria	*Plasmodium* spp. antigens; species specific (e.g. HRP2) and/or pan-species specific (e.g. pan-pLDH)	For diagnosis of one or more human malaria species (*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale*)	RDT	Capillary whole blood	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/)	WHO guidelines for the treatment of malaria, third edition (2015) http://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf Malaria rapid diagnostic test performance. Results of WHO product testing of malaria RDTs: Round 7 (2015–2016) http://www.who.int/malaria/publications/atoz/978924151268/en/

Table I.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Malaria *continued*						WHO good practices for selecting and procuring rapid diagnostic tests for malaria (2011) http://apps.who.int/iris/bitstream/handle/10665/44530/9789241501125_eng.pdf?sequence=1
	Plasmodium spp.	For diagnosis of one or more human malaria species (*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale* and *P. knowlesi*) and monitoring response to treatment	Light microscopy (if good quality microscopy available)	Capillary whole blood		WHO guidelines for the treatment of malaria, third edition (2015) http://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf Basic malaria microscopy Part I: Learner's guide (2010) http://apps.who.int/iris/bitstream/handle/10665/44208/9789241547826_eng.pdf?sequence=1

Table I.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products*	WHO supporting documents
Malaria *continued*						Malaria microscopy standard operating procedures (2015) http://www.wpro.who.int/mvp/lab_quality/mm_sop/en/
Tuberculosis	*Mycobacterium tuberculosis*	For diagnosis and treatment monitoring of active TB	Microscopy	Sputum	Implementing tuberculosis diagnostics: Policy framework (2015) http://apps.who.int/iris/bitstream/10665/162712/1/9789241508612_eng.pdf	Compendium of WHO guidelines and associated standards: Ensuring optimum delivery of the cascade of care for patients with tuberculosis (2017) http://apps.who.int/iris/bitstream/handle/10665/259180/9789241512572-eng.pdf?sequence=1 Implementing tuberculosis diagnostics: Policy framework (2015) http://apps.who.int/iris/bitstream/10665/162712/1/9789241508612_eng.pdf

* All TB tests are evaluated and guidelines developed through the WHO Global TB Programme.

Table I.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products*	WHO supporting documents
Tuberculosis *continued*		For diagnosis of active TB	Loop mediated isothermal amplification (LAMP)	Sputum	The use of loop-mediated isothermal amplification (TB-LAMP) for the diagnosis of pulmonary tuberculosis: Policy guidance (2016) http://apps.who.int/iris/bitstream/10665/249154/1/9789241511186-eng.pdf?ua=1	
	Immune response	For diagnosis of latent TB infection	Intradermal tuberculin skin test (TST)	N/A	Latent TB infection: Updated and consolidated guidelines for programmatic management (2018) http://apps.who.int/iris/bitstream/handle/10665/260233/9789241550239-eng.pdf;jsessionid=6D1BB246312B378ACFEBF9BFFAFEB0ED?sequence=1	

* All TB tests are evaluated and guidelines developed through the WHO Global TB Programme.

Table I.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Syphilis	Antibodies to *Treponema pallidum*	For diagnosis or as an aid in the diagnosis of *T. pallidum*	RDT	Capillary whole blood	WHO list of prequalified in vitro diagnostic products (http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/)	WHO laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus (2013) http://apps.who.int/iris/bitstream/handle/10665/85343/9789241505840_eng.pdf?sequence=1
	Combined antibodies to *T. pallidum* and to HIV-1/2	For diagnosis or as an aid in the diagnosis of HIV-1/2 and/or *T. pallidum*	RDT	Capillary whole blood	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/)	WHO Information note on the use of dual HIV/syphilis rapid diagnostic tests (RDT) (2017) http://apps.who.int/iris/bitstream/handle/10665/252849/WHO-RHR-17.01-eng.pdf?sequence=1

II. For health care facilities with clinical laboratories

This list is for district, regional, provincial or specialized hospitals or laboratories and national reference laboratories. Trained laboratory technicians, specialist expertise and laboratory infrastructure and equipment are available at the appropriate level. All diagnostic tests available at the primary care level are assumed to be available at higher levels, as appropriate. The list comprises: section a for general laboratory equipment and section b for tests for specific diseases.

II.a General IVDs for health care facilities with clinical laboratories

Use	Diagnostic test	Test purpose	Assay format	Specimen type
Clinical chemistry and immunoassays	Alanine amino-transferase (ALT)	To assess liver function (often done with aspartate aminotransaminase AST))	Optical and electro-analytical methods	Serum Plasma
	Albumin	To detect or monitor malnutrition, liver or kidney disease	Photometric, turbidimetric and nephelometric testing	Urine Serum Plasma
	Alkaline phosphatase	To detect or monitor malnutrition, Paget's disease or certain malignancies, including liver cancer	Colorimetric testing	Serum Plasma
	Aspartate amino-transferase (AST)	To assess of liver function (often done with alanine aminotransferase (ALT))	Optical and electro-analytical methods	Serum Plasma
	Bilirubin	To detect/monitor liver disease, liver/ pancreas and bile duct disorders, and red cell destruction	Optical and electro-analytical methods	Serum Plasma
	Blood pH and gases	To assess lung function, metabolic or kidney disorders, and monitor oxygen therapy Measurement of blood pH, oxygen and carbon dioxide	Electro-analytical methods, including portable analysers	Arterial whole blood Venous whole blood
	Blood urea nitrogen (BUN)	To assess kidney function and disease	Optical and electro-analytical methods	Serum Plasma

Table II.a *continued*

Use	Diagnostic test	Test purpose	Assay format	Specimen type
Clinical chemistry and immunoassays *continued*	Creatinine	To estimate glomerular filtration rate (eGFR) and urine albumin/creatinine ratio Key clinical marker for management of severe infections (i.e. sepsis, Lassa fever), and antimicrobial regimen adjustment	Optical and electro-analytical methods	Serum Urine
	Electrolytes	To monitor organ damage and electrolyte alterations	Optical and electro-analytical methods	Serum Plasma
	Glucose	To diagnose and screen for diabetes and intermediate hyperglycaemia, to diagnose hypoglycaemia	Automated analyser	Plasma Serum
	Haemoglobin A1c (HbA1c)	Diagnosis and monitoring of diabetes mellitus	ELISA Automated analyser	Capillary whole blood Venous whole blood
	C-reactive protein (CRP)	To detect inflammation as an indicator of various conditions (e.g. cardiovascular disease [CVD] – high sensitivity CRP required - sepsis)	RDT EIA	Venous whole blood Serum Plasma
	Lipid profile	To assess risk of developing CVD and type 2 diabetes by measuring cholesterol, triglycerides and lipoproteins	Colourimetry Spectrophotometry	Plasma Serum

Table II.a *continued*

Use	Diagnostic test	Test purpose	Assay format	Specimen type
Clinical chemistry and immunoassays *continued*	Basic metabolic panel (BMP)	Includes glucose, sodium chloride, carbon dioxide, blood urea nitrogen (BUN), BUN/creatinine ratio, glomerular filtration rate (eGFR) and may include calcium	Photometric and colorimetric testing, ion-selective potentiometry (8-parameter automated clinical chemistry analyser)	Venous whole blood Serum Plasma
	Comprehensive metabolic panel	BMP plus magnesium, protein, albumin, globulin, albumin/globulin ratio, bilirubin (direct or total), alkaline phosphatase, alanine and aspartate aminotransferases (ALT and AST)	As with BMP (14 or more parameter automated clinical chemistry analyser)	Venous whole blood Serum Plasma
	Amylase and lipase	To assess acute pancreatitis	Colourimetric and photometric analysers	Serum Peritoneal fluid (Amylase)
	Troponin T/I	For diagnosis of myocardial infarction	EIA (handheld or large automated instrument)	Venous whole blood Plasma
	Urinalysis	Detection of substances in the urine associated with metabolic disorders, renal dysfunction or urinary tract infections	Automated chemical analyser	Urine

Table II.a *continued*

Use	Diagnostic test	Test purpose	Assay format	Specimen type
Blood transfusion	Blood cross-matching	To determine blood compatibility for blood transfusions; Rh typing for pregnant women	Antisera for agglutination	Venous whole blood
	Transfusion transmitted infections	To screen for e.g. Chagas, human T-lymphotropic virus (HTLV) in the blood supply etc. (see also EDL sections on HIV & syphilis)	EIA (microplate) Manual method	Serum Plasma
			CLIA/ECL (automated instrument)	Serum Plasma
Serology	Human chorionic gonadotropin (hCG)	Pregnancy	Optical method	Serum
Microbiology, mycology and parasitology	Urine dipstick and urine microscopy	Detection of UTIs (dipstick) and identification of red and white blood cells, casts, squamous epithelial cells, bacteria, yeast, Schistosoma haematobium and other cellular components (microscopy)	Multi-parameter strips (dipstick) and light microscopy	Urine
	Microscopy	Microbial morphology, presence or absence of white blood cells versus squamous epithelial cells for presumptive identification	Microscopic examination of slides as wet preparations or which have been treated with organism-specific chemical stains (e.g. Gram stain)	Disease appropriate specimens (e.g. venous whole blood, urine, stool, cerebrospinal fluid, etc.)

Table II.a *continued*

Use	Diagnostic test	Test purpose	Assay format	Specimen type
Microbiology, mycology and parasitology *continued*	Culture	Initial step in detection and identification of bacterial species for selection of appropriate antibiotic regimens	Culture on growth media plates in an incubator followed by recovery of isolates and species identification (traditional manual techniques or automated equipment)	Disease appropriate specimens (e.g. venous whole blood, urine, stool, cerebrospinal fluid etc.)
	Blood culture	For the diagnosis of bacterial and fungal bloodstream infections (sepsis)	Blood culture bottle in an incubator followed by recovery of isolates and species identification (traditional manual techniques or automated equipment)	Venous whole blood
	Antimicrobial susceptibility testing	Final step in selection of appropriate antibiotic regimens after species identification	Antimicrobial susceptibility testing of isolates – may be done manually by disc diffusion technique or automated platforms	Microbial isolates
Haematology	Haematocrit (Ht)	Diagnosis and monitoring of anaemia Volume of red blood cells as a percentage of total blood volume	Micro-haematocrit centrifuge	Capillary or venous whole blood

Table II.a *continued*

Use	Diagnostic test	Test purpose	Assay format	Specimen type
Haematology *continued*	Prothrombin time test and international normalized ratio (PT/INR)	To detect or diagnose a bleeding disorder or excessive clotting disorder (prothrombin time (PT)); monitor performance of anticoagulant medications (International normalised ratio (INR))	Hand-held or automated coagulation analyser	Citrate plasma
	Platelet count	Diagnosis of thrombocytopenia Marker to manage severe infections associated with bleeding and sepsis (i.e. viral haemorrhagic fever, meningococcaemia) and certain haematological disorders	Haemocytometer	Capillary whole blood
			Haematology analyser	Venous whole blood
	Complete blood count (CBC) Automated, differential	Evaluation of patient's overall health and to detect a wide range of disorders, including anaemia, infection and leukaemia	Automated hematology analyser (white blood cell count (WBC), red blood cell count (RBC), platelets, haemoglobin (Hb) and haematocrit (Ht) includes lymphocytes, monocytes and granulocytes (for three-part differential)	Venous whole blood

II.b Disease-specific IVDs for health care facilities with clinical laboratories

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Hepatitis B	Hepatitis B surface antigen (HBsAg)	Screening for acute and chronic hepatitis B virus (HBV) infection: infants > 12 months of age, children, adolescents, adults	RDT	Venous whole blood Plasma Serum	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/public_report/en/)	Guidelines on hepatitis B and C testing (February 2017) http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1
			EIA	Plasma Serum		
			CLIA	Plasma Serum		
	Virological (HBV DNA – quantitative)	Staging to assess the need for treatment in chronic HBV infection and monitoring of response to treatment	Nucleic acid test	Serum Plasma		

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Hepatitis B *continued*	Hepatitis B e antigen (HBeAg)	Staging to assess the need for HBV treatment in chronic HBV infection	EIA	Serum Plasma		
			CLIA	Serum Plasma		
	IgM-specific antibodies to hepatitis B core antigen (IgM anti-HBc)	For the diagnosis of acute HBV infection – used for outbreak investigation	EIA (microplate) Manual method	Serum Plasma		
			CLIA/ECL (automated instrument)	Serum Plasma		
	Antibodies to hepatitis B surface antigen (anti-HBs)	To determine effectiveness of HBV vaccination at patient and at a population level Also used as a marker for recovery from HBV infection	EIA (microplate) Manual method	Serum Plasma		
			CLIA/ECL (automated instrument)	Serum Plasma		

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Hepatitis C	Antibodies to HCV (anti-HCV)	Screening for HCV infection: infants > 18 months of age, children, adolescents, adults	RDT	Venous whole blood Plasma Serum	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report/en/)	Guidelines on hepatitis B and C testing (February 2017) http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1
			EIA (microplate) Manual method	Serum Plasma		
			CLIA/ECL (automated instrument)	Serum Plasma		
	Antibodies to HCV (anti-HCV) and HCV core antigen (HCV cAg)	Screening for past or present HCV infection: infants > 18 months of age, children, adolescents, adults	EIA (microplate) Manual method	Serum Plasma		
			CLIA/ECL (automated instrument)	Serum Plasma		
	HCV core antigen (HCV cAg)	For diagnosis of viraemic HCV	CLIA/ECL (automated instrument)	Serum Plasma		

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Hepatitis C *continued*	HCV RNA (qualitative or quantitative)	For diagnosis of viraemic HCV and monitoring of response to treatment as a test of cure	Nucleic acid test	Serum Plasma		
HIV infection	Antibodies to HIV-1/2 (anti-HIV) test	For the diagnosis of HIV infection: adults, adolescents, children and infants > 18 months of age	RDT	Venous whole blood Plasma Serum	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/)	Guidelines on HIV self-testing and partner notification (2016) http://apps.who.int/iris/bitstream/handle/10665/251655/9789241549868-eng.pdf?sequence=1
			EIA (microplate) Manual method	Serum Plasma		Consolidated guidelines on HIV testing services (July 2015) http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/
			CLIA/ECL (automated instrument)	Serum Plasma		

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
HIV infection *continued*						WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection, module 10 for testing providers (2017) http://www.who.int/hiv/pub/prep/prep-implementation-tool/en/
		For screening for HIV in the blood supply and in blood products.	EIA (microplate) Manual method	Serum Plasma		Screening donated blood for transfusion transmissible infections: Recommendations (2009) http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&isAllowed=y
			CLIA/ECL (automated instrument)	Serum Plasma		
	Combined HIV antibody/p24 antigen (anti-HIV/p24 Ag) test	For the diagnosis of HIV infection: adults, adolescents, children and infants > 18 months of age	RDT	Venous whole blood Plasma Serum	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/)	Consolidated guidelines on HIV testing services (2015) http://apps.who.int/iris/bitstream/handle/10665/179870/9789241508926_eng.pdf?sequence=1

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
HIV infection *continued*			EIA (microplate) Manual method	Serum Plasma		
			CLIA/ECL (automated instrument)	Serum Plasma		
		For screening for HIV in the blood supply and in blood products	EIA (microplate) Manual method	Serum Plasma		Screening donated blood for transfusion transmissible infections: Recommendations (2009) http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&isAllowed=y
			CLIA/ECL (automated instrument)	Serum Plasma		
	Qualitative or quantitative virological test	For diagnosis of HIV infection in infants < 18 months of age	Nucleic acid test	Capillary whole blood Venous whole blood Dried blood spot Serum Plasma	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/public_report/en/)	Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (2016) http://www.who.int/hiv/pub/arv/arv-2016/en/

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
HIV infection *continued*	Quantitative virological test	Monitoring response to antiviral treatment	Nucleic acid test	Dried blood spot Serum Plasma	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/public_report/en/)	
	CD4 cell enumeration (quantitative)	For staging advanced HIV disease	Flow cytometry	Capillary whole blood Venous whole blood	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/public_report/en/)	
	Cryptococcal antigen test	For screening and diagnosis of cryptococcal meningitis in people living with advanced HIV disease	RDT	Cerebrospinal fluid Venous whole blood Serum Plasma		Guidelines for the diagnosis, prevention, and management of cryptococcal disease in HIV-infected adults, adolescents and children (2018) http://apps.who.int/iris/bitstream/handle/10665/260399/9789241550277-eng.pdf?sequence=1
			EIA	Cerebrospinal fluid Serum Plasma		

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Malaria	*Plasmodium* spp. antigens; species specific (e.g. HRP2) and/or pan-species specific (e.g. pan-pLDH)	For diagnosis of one or more human malaria species (*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale*)	RDT	Capillary whole blood Venous whole blood	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/)	WHO guidelines for the treatment of malaria, third edition (2015) http://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf Malaria rapid diagnostic test performance: Results of WHO product testing of malaria RDTs: Round 7 (2015–2016) http://www.who.int/malaria/publications/atoz/978924151268/en/ WHO good practices for selecting and procuring rapid diagnostic tests for malaria (2011) http://apps.who.int/iris/bitstream/handle/10665/44530/9789241501125_eng.pdf?sequence=1

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Malaria *continued*	*Plasmodium* spp.	For diagnosis of one or more human malaria species (*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale* and *P. knowlesi*) and monitoring response to treatment	Light microscopy	Capillary whole blood Venous whole blood		WHO guidelines for the treatment of malaria, third edition (2015) http://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf Basic malaria microscopy Part I: Learner's guide (2010) http://apps.who.int/iris/bitstream/handle/10665/44208/9789241547826_eng.pdf?sequence=1 Malaria microscopy standard operating procedures (2015) http://www.wpro.who.int/mvp/lab_quality/mm_sop/en/

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Malaria *continued*	Glucose-6-phosphate dehydrogenase activity (G6PD)	To determine G6PD activity (normal, intermediate, deficient) and specifically to inform decision to administer 8-aminoquinoline group drugs for radical cure of *P. vivax* For screening newborns for G6PD deficiency	Semi quantitative fluorescent spot test	Venous whole blood	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/)	Beutler E, Blume KG, Kaplan JC, Lohr GW, Ramot B, Valentine WN. International Committee for Standardization in Haematology: Recommended screening test for glucose-6-phosphate dehydrogenase deficiency. Br J Haematol 1979;43:469–477 WHO guidelines for the treatment of malaria, third edition (2015) http://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products*	WHO supporting documents
Tuberculosis	*Mycobacterium tuberculosis* bacteria	For diagnosis and treatment monitoring of active TB	Microscopy	Other specimen types	Implementing tuberculosis diagnostics: Policy framework (2015) http://apps.who.int/iris/bitstream/10665/162712/1/9789241508612_eng.pdf	Compendium of WHO guidelines and associated standards: Ensuring optimum delivery of the cascade of care for patients with tuberculosis (2017) http://apps.who.int/iris/bitstream/handle/10665/259180/9789241512572-eng.pdf?sequence=1 Implementing tuberculosis diagnostics: Policy framework (2015) http://apps.who.int/iris/bitstream/10665/162712/1/9789241508612_eng.pdf
		For diagnosis and treatment monitoring of active TB including drug-resistant TB	Bacterial culture	Sputum or other specimen types		

* All TB tests are evaluated and guidelines developed through the WHO Global TB Programme.

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products*	WHO supporting documents
Tuberculosis *continued*	*M. tuberculosis* DNA	For diagnosis of active TB and simultaneous detection of rifampicin resistance	Cartridge-based nucleic acid test	Sputum or extra-pulmonary tuberculosis specimen types	WHO Meeting report of a technical expert consultation: Non-inferiority analysis of Xpert MTB/RIF Ultra compared to Xpert MTB/RIF (2017) http://apps.who.int/iris/bitstream/handle/10665/254792/WHO-HTM-TB-2017.04-eng.pdf;jsessionid=E02D0994930EDBD9A4BC5BB3D3A28568?sequence=1	
					Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Policy update (2013) http://apps.who.int/iris/bitstream/10665/112472/1/9789241506335_eng.pdf	

* All TB tests are evaluated and guidelines developed through the WHO Global TB Programme.

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products*	WHO supporting documents
Tuberculosis *continued*	*M. tuberculosis* DNA mutations associated with resistance	For detection of resistance for first-line anti-TB medicines	Molecular line probe assay (LPA)	Sputum	The use of molecular line probe assays for the detection of resistance to isoniazid and rifampicin: Policy update (2016) http://apps.who.int/iris/bitstream/10665/250586/1/9789241511261-eng.pdf?ua=1	
	M. tuberculosis DNA mutations associated with resistance	For detection of resistance for second-line anti-TB medicines	Molecular line probe assay (LPA)	Sputum	The use of molecular line probe assays for the detection of resistance to second-line anti-tuberculosis drugs: Policy update (2016) http://apps.who.int/iris/bitstream/handle/10665/246131/9789241510561-eng.pdf?sequence=1	

* All TB tests are evaluated and guidelines developed through the WHO Global TB Programme.

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products*	WHO supporting documents
Tuberculosis *continued*	Drug susceptibility testing in *M. tuberculosis* culture	To detect resistance to first-line and/or second-line anti-TB medicines	Drug susceptibility testing (DST)	Bacterial culture of *M. tuberculosis*	Technical report on critical concentrations for drug susceptibility testing of medicines used in the treatment of drug-resistant tuberculosis (2018) http://www.who.int/tb/publications/2018/WHO_technical_report_concentrations_TB_drug_susceptibility/en/	

* All TB tests are evaluated and guidelines developed through the WHO Global TB Programme.

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products*	WHO supporting documents
Tuberculosis *continued*	Lipoarabino-mannan (LAM) antigen	To aid in the diagnosis of TB in seriously ill HIV-positive inpatients	RDT	Urine	The use of lateral flow urine lipoarabinomannan assay (LF-LAM) for the diagnosis and screening of active tuberculosis in people living with HIV: Policy update (2015) http://apps.who.int/iris/bitstream/handle/10665/193633/9789241509633_eng.pdf;jsessionid=9A9EB886DC17658BF7FDF86758D7A9F9?sequence=1	

* All TB tests are evaluated and guidelines developed through the WHO Global TB Programme.

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products*	WHO supporting documents
Tuberculosis *continued*	Immune response	For diagnosis of latent TB infection	Interferon gamma release assay (IGRA)	Venous whole blood	Latent TB Infection: Updated and consolidated guidelines for programmatic management (2018) http://apps.who.int/iris/bitstream/handle/10665/260233/9789241550239-eng.pdf;jsessionid=6D1BB246312B378ACFEBF9BFFAFEB0ED?sequence=1	

* All TB tests are evaluated and guidelines developed through the WHO Global TB Programme.

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
HPV infection	Human papillomavirus (HPV) nucleic acid	For cervical cancer screening	Nucleic acid test	Cervical cells collected in test specific transport fluid	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/public_report_hpv/en/)	WHO human papillomavirus laboratory manual, first edition (2009) http://apps.who.int/iris/bitstream/handle/10665/70505/WHO_IVB_10.12_eng.pdf?sequence=1
Syphilis	Antibodies to *Treponema pallidum*	For diagnosis or as an aid in the diagnosis of *T. pallidum*	RDT	Venous whole blood Plasma Serum	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/)	WHO laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus (2013) http://apps.who.int/iris/bitstream/handle/10665/85343/9789241505840_eng.pdf?sequence=1
			EIA (Microplate) Manual method	Serum Plasma		
			CLIA/ECL (automated instrument)	Serum Plasma		

Table II.b *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Syphilis *continued*		For screening blood and blood products	EIA (Microplate) Manual method	Serum Plasma		Screening donated blood for transfusion transmissible infections (2009) http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&isAllowed=y
	Combined antibodies to *T. pallidum* and to HIV-1/2 (anti-HIV)	For the diagnosis or as an aid in the diagnosis of HIV-1/2 and/or *T. pallidum*	RDT	Venous whole blood Plasma Serum	http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/	WHO Information note on the use of dual HIV/syphilis rapid diagnostic tests (RDT) (2017) http://apps.who.int/iris/bitstream/handle/10665/252849/WHO-RHR-17.01-eng.pdf?sequence=1

3. Methods used to establish the List

3.1 Strategic Advisory Group of Experts on In Vitro Diagnostics

In March 2017, the WHO Expert Committee on Selection and Use of Essential Medicines recommended that an EDL be developed. In support of that recommendation, WHO created an EDL Secretariat, which drafted the first edition of the EDL in consultation with WHO disease programmes. A strategic technical advisory group of experts (SAGE IVD)[3] was then established to advise WHO on the in vitro diagnostics to be included. The terms of reference of the group were as follows:

1. Serve as a principal advisory group to the WHO Director-General on all aspects of IVDs.[4]
2. For priority, essential and neglected IVDs, where no established advisory mechanisms exist, the SAGE IVD will:
    a. provide technical advice on global policies and strategies, ranging from development, assessment, use of IVDs and their linkages with other health interventions;
    b. advise on the adequacy of progress towards the achievement of IVDs-related goals set in the World Health Assembly resolutions;
    c. recommend policies for long-term and integrated diagnostic capabilities as indispensable element for universal health coverage and global public health security;
    d. suggest guiding principles for how, when and where to use particular IVDs in national, regional and global settings;
    e. review the pipeline of existing and innovative IVDs for noncommunicable diseases, rare diseases and infectious diseases, including for emerging pathogens and existing public health conditions of international concern, and identify major gaps;

[3] All introductory and background material, including the terms of reference of the SAGE IVD, are available on the WHO website (http://www.who.int/medical_devices/diagnostics/back-doc_WHO-model-list-essential-diagnostics-updt.pdf).

[4] Except where policy and technical recommendations on IVD are provided through WHO established advisory mechanisms, such as for HIV, tuberculosis and malaria. For these, SAGE IVD would accept such recommendations without further review and incorporate such advice in its consideration of organization-wide policies.

f. provide high level advice on development and maintenance of appropriate standards for IVDs, including methodologies for evidence review;

g. provide advice to WHO Secretariat for the development of the List of Essential Diagnostics (EDL) and in line with the work of the Expert Committee on Selection and Use of Essential Medicines.

h. provide advice on WHO activities in the area of IVDs, including engagement of WHO in partnerships in the development, access and use of needed IVDs.

The terms of reference were approved by the Director-General of WHO and posted on the WHO website with a call for candidates. The applications were reviewed by the EDL Secretariat and sent for approval to the Director-General. The 19 members of the SAGE IVD were selected with due attention to regional, professional and gender balance. SAGE IVD operated with its current membership until September 2018, and the Group agreed to hold monthly teleconferences until that time to discuss matters related to the EDL. A new SAGE IVD will be convened for each review of the EDL, some members being replaced each time.

3.2 Selection of IVDs for inclusion in the first EDL

The EDL Secretariat prepared a draft list of IVDs in collaboration with WHO departments that had assessed in vitro diagnostic tests for HIV, malaria, tuberculosis and syphilis, defined as categories of tests for identifying specific biological markers. The EDL Secretariat also reviewed WHO guidance, disease-specific clinical and diagnostic guidelines, technical manuals, and the WHO priority medical devices list.[5] They also considered the tests listed by WHO Prequalification of In Vitro Diagnostics and in other WHO IVD assessments.

The draft list was posted for public consultation in March 2018. The comments received from the consultation were analysed by the EDL Secretariat and integrated into a list presented to the SAGE IVD at its first meeting, on 16–20 April 2018 at WHO headquarters in Geneva, Switzerland. The work of the SAGE IVD takes place in the context of WHO's commitment to transparent, evidence-based decision-making. Annex 1 lists the participants at the first meeting of the SAGE IVD, and Annex 2 lists their declarations of interest.

The first SAGE IVD was asked to make recommendations to the EDL Secretariat on:

- principles that should guide preparation of the EDL;

[5] WHO documents reviewed to compile and propose the general laboratory tests for the first EDL are listed under "Sources used for general laboratory test".

- integration of the EDL with existing WHO work on IVDs;
- the draft first EDL proposed by the Secretariat;
- procedures for revising the EDL, including methods for assessing candidate IVDs for inclusion, priorities for inclusion of IVDs in subsequent Lists and procedures for addressing applications for inclusion or deletion; and
- integrating user feedback and adapting the EDL for national lists.

SAGE IVD designated IVDs that should be available in primary health care settings where laboratories are not available and those that should be available in laboratories, hospitals and reference laboratories.

3.3 Principles that should guide preparation of the EDL

The EDL comprises IVDs, a subset of medical devices intended for examination in vitro of specimens taken from the human body. For the purposes of the EDL, "IVD" refers to categories of tests for identifying specific biological markers and not to individual tests. For example, as several tests are available for measuring HIV load, the IVD for "HIV load" refers to a category of tests for measuring this end-point. The word "test" is used interchangeably with "assay" to refer to laboratory assays and rapid diagnostic tests. Further, the word "sample" is used interchangeably with "specimen".

The proposed procedure for preparing the EDL was based on experience in preparing the WHO Model List of Essential Medicines, which suggested that the best approach would be to include tests associated with *WHO priority diseases*, for which there is robust evidence and which are well covered by WHO guidelines for use; these would be complemented by a set of *general laboratory tests described in WHO publications*.[6] The list will be reviewed annually, with the addition or deletion of items as appropriate. On principle, it was proposed that IVDs be added or deleted according to an evidence-based, public health approach, as little evidence may be available for certain types of tests and in certain countries, especially in low- and middle-income countries.

The first SAGE IVD endorsed the aim of the EDL, to offer wide-ranging benefits to health care systems by:

- prioritizing laboratory testing and infrastructure;
- bulk and advance purchasing of IVDs to increase affordability;
- improving laboratory capacity, organization, sample processing and other aspects to improve responses to public health emergencies;

[6] WHO documents reviewed to compile and propose the general lab tests for the first draft EDL are listed in the reference section under WHO sources for general laboratories

- helping IVD designers and manufacturers to develop new or improved IVDs, including through target product profiles; and
- supporting the rational use of medicines in the WHO Model List of Essential Medicines.

The SAGE IVD agreed on the core principle of prioritizing IVDs required for progress towards universal health coverage. The Group also agreed that the EDL should, in principle, include IVDs recommended by or necessary for implementation of WHO guidelines. It noted, however, that some publications are out of date and recommended revision of the WHO technical documents that constitute resources for EDL as a priority.

The SAGE IVD identified four main themes in preparation of the EDL.

1. The scope must be clearly defined.
2. The EDL should indicate the tests and laboratory infrastructure that are appropriate for different levels of health care delivery.
3. The results of clinical studies indicate treatment decisions and not the direct result of test performance and cannot be used as evidence to support the use of IVDs.
4. The EDL should not be read in isolation, because diagnostic tests are part of an entire system of diagnostics delivery, which includes training, laboratory infrastructure, quality assurance and supply chain management.

An executive summary, which included the initial version of the List, was published on the WHO website in May 2018. After identification of several minor errors by SAGE IVD members and the EDL secretariat, a corrected version was posted in November 2018. The List included in this publication, which has further minor corrections, is the definitive first WHO Model List of Essential In Vitro Diagnostics and replaces the two previous versions.

3.4 Draft first EDL proposed by the Secretariat

The SAGE IVD considered the subjects summarized above and a first draft of the EDL.

The SAGE IVD endorsed the procedure that was used to draft the first EDL and concluded that the EDL should have three components.

- A preface describing the scope and objectives and instructions for users, including the appropriate level of the health care system in which tests should be used, how tests were selected for inclusion on the EDL, the relation between EDL and prequalification and any necessary disclaimers.

- A chart of the laboratory tests chosen for inclusion, consisting of IVD tests for physiological evaluation of patients and detection and diagnosis of diseases and IVD tests for the detection, diagnosis and monitoring of WHO priority diseases: HIV infection, TB, malaria, hepatitis B, hepatitis C, syphilis and HPV infection. The list will include links to WHO technical information.
- Procedures for revising the EDL, including methods for assessing candidate IVDs for inclusion, priorities for inclusion of IVDs in subsequent EDLs and procedures for addressing applications for inclusion or deletion

The SAGE IVD discussed how the EDL should be structured, the process to be used in considering applications for addition or deletion of tests, the collection and assessment of evidence about IVDs and assessment of the utility of the EDL for its target audience.

3.4.1 Method for assessing IVDs for inclusion or deletion

The SAGE IVD considered the methods used to assess IVDs in WHO disease programmes and suggestions for optimizing methods for future editions of the EDL. The Group also considered the importance of avoiding methodological requirements that render assessment of applications technically demanding or create inequitable obstacles to submissions from stakeholders with limited resources.

The SAGE IVD agreed that in all cases there should be:

- a systematic summary of evidence, with systematic reviews of test accuracy performed with accepted methods;
- assessment of the strength and limitations of the evidence, including significant aspects for which evidence is lacking; and
- consideration of the generalizability of evidence, particularly to low-resource settings.

The SAGE IVD also agreed that:

- assessment of the clinical accuracy of a test in the setting in which it would be used will generally be required;
- the required accuracy of a tests will be difficult to decide, given that clinical accuracy depends on reference standards, patient populations and testing protocols;
- randomized controlled clinical trials are not necessarily applicable for assessing the performance of IVDs; and

- evidence of impact on disease detection and management may be easier to obtain and more useful than evidence of impact on patient outcomes.

3.4.2 Identification of high-priority IVDs for the EDL

The SAGE IVD considered a proposal for identifying high-priority candidate IVDs by reference to WHO disease priorities. Relevant WHO staff and the SAGE IVD discussed areas of high clinical priority that might guide prioritization of candidate IVDs for inclusion in future editions of the EDL. The areas were:

- antimicrobial resistance
- fungal disease
- influenza
- reproductive health
- neglected tropical diseases
- public health emergencies
- noncommunicable diseases.

Antimicrobial resistance

The Global Antimicrobial Resistance Surveillance System (GLASS) was launched in 2015 for collaboration in surveillance of antimicrobial resistance by standardized collection of data on patients and populations from national surveillance sites. GLASS has drawn up a list of essential IVDs for the identification and testing of eight priority pathogens for antimicrobial susceptibility: *Escherichia coli*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Salmonella* spp., *Shigella* spp. and *Neisseria gonorrhoeae*.

Fungal diseases

Fungi that cause opportunistic infections in patients with HIV/AIDS were discussed, particularly cryptococcal meningitis, *Pneumocystis* pneumonia, disseminated histoplasmosis and aspergillosis complicating pulmonary TB.

Influenza

The gold standard in testing is polymerase chain reaction, for which there are a number of commercial kits. The Centers for Disease Control and Prevention in the USA (USCDC) has an in-house test that is updated regularly; primers and probes are made available only to national reference laboratories and public health laboratories.

Reproductive health

The priority IVDs for reproductive health are point-of-care tests for syphilis, HPV infection and *N. gonorrhoeae*. WHO recommends that all pregnant women be screened for syphilis as part of the universal health coverage package. HPV testing and treatment of pre-cancerous cervical lesions are also part of the package for women, and WHO will launch a campaign on HPV testing in 2018. Point-of-care testing for *N. gonorrhoeae* is considered important to ensure appropriate selection of antibiotic.

Neglected tropical diseases

WHO focuses on three neglected tropical diseases: dengue, visceral leishmaniasis and schistosomiasis and soil-transmitted helminths. These infections present a range of challenges for health care: outbreak management for dengue, elimination and case management for leishmaniasis and mass drug administration for schistosomiasis and soil-transmitted helminths. For each disease, there is either a test for which performance has been assessed or a recent "diagnostic landscape" document.

Public health emergencies

The emergencies addressed by WHO are cholera, Ebola virus disease, Lassa virus disease, Marburg virus disease, meningitis, Middle East respiratory syndrome coronavirus disease, plague, severe acute respiratory syndrome and yellow fever. The responsible technical group did not propose inclusion of IVDs for these diseases in the first EDL. It plans comprehensive mapping of IVDs for 35 diseases of concern and consultation with the United Nations Children's Fund, Médecins Sans Frontières (MSF), USCDC, the International Federation of Red Cross and Red Crescent Societies, the United States Agency for International Development and the Department for International Development in the United Kingdom with a view to submitting candidate tests for the 2019 and 2020 editions of the EDL.

Noncommunicable diseases

The priority is IVDs for cancer that can be widely used in low- and middle-income countries. At present, diagnosis of cancer requires anatomical pathology services, which are often weak or lacking in resource-poor settings. Screening tests for several cancers allow effective, affordable treatment of early-stage disease. These are cancers of the breast, cervix (HPV testing) and colo-rectum (faecal immunochemical tests in stool).

SAGE IVD agreed that the above list of priority conditions, with the addition of sepsis, could usefully guide prioritization of IVDs for inclusion in

the next editions of EDL. With regard to antimicrobial resistance, SAGE IVD agreed that the GLASS list of priority pathogens for surveillance should guide assessment of candidate IVDs for the EDL.

4. Integration of the EDL with other WHO initiatives

The SAGE IVD identified groups within WHO that are conducting work relevant to that of the SAGE IVD and agreed on the importance of coordinating the work.

WHO Expert Committee on Biological Standardization

The WHO Constitution requires the Organization "to develop, establish and promote international standards with respect to biological and pharmaceutical products". For this purpose, WHO has established expert committees, including the Expert Committee on Biological Standardization. The Committee has published a number of written standards on IVDs, invited discussion with the SAGE IVD and noted that it looked forward to discussing the report of the first SAGE IVD meeting at the meeting of the Committee in October 2018.

The SAGE IVD agreed that it should establish regular, formal communication with the Expert Committee on Biological Standardization on matters of common concern.

WHO priority status of HIV, tuberculosis, malaria, viral hepatitis, syphilis and human papillomavirus

It was proposed that the first EDL include tests relevant to WHO priority diseases – HIV infection, tuberculosis, malaria, viral hepatitis B and C, syphilis and HPV infection – for which there are WHO guidelines and technical reports, including recommendations for the IVDs to be used. The SAGE IVD considered:

- the IVDs recommended for each of these diseases and the reasons for the recommendations;
- the evaluation process used to recommend the tests;
- how guidelines for testing and treatment in each disease were developed, including evidence retrieval, assessment and synthesis;
- how the recommendations are formulated; and
- whether "grading of recommendations assessment, development and evaluation" (GRADE) was used, when applicable, to assess the quality of evidence from studies for formulating recommendations.

The SAGE IVD agreed that:

- existing recommendations for IVD use in the proposed WHO priority disease areas would form the basis for inclusion of IVDs in the first edition of the EDL;

- testing for cryptococcal antigen in blood and cerebrospinal fluid would be included in the HIV section; and
- tests included in the EDL should be commercially available.

General laboratory tests

A second area proposed for inclusion in the first EDL was general core and routine laboratory tests for clinical chemistry, haematology, blood transfusion, microbiology (virology, bacteriology, parasitology and mycology) and histopathology. For the first EDL, the tests proposed to the SAGE IVD were selected on the basis of the scientific validity of an analyte, i.e. the association between an analyte and a clinical condition or physiological state; and clinical utility. Many of these tests are required for effective management of patients with the high-priority diseases listed above and have already been described in WHO publications.[7]

The SAGE IVD agreed to include the proposed list of general laboratory tests in the first EDL.

WHO Prequalification of In Vitro Diagnostics

The EDL and the list of the WHO Prequalification of In Vitro Diagnostics are complementary and distinct. The Prequalification lists include high-priority IVDs that have been assessed by WHO and are identified by brand (in contrast to the EDL, which lists categories of IVDs). Currently, the Prequalification lists has a narrower scope than the EDL. The inclusion of a category of tests on the Prequalification list is not a requirement for it to be considered for inclusion on the EDL. In the context of the EDL, the Prequalification lists should be considered a resource, as they list prequalified brands of products that correspond to certain categories of tests in the EDL. Relevant links are provided in the EDL.

The SAGE IVD noted that WHO prequalification plays an important role in increasing access to IVDs of assured quality, safety and performance. The Group affirmed that the EDL and the WHO programme for prequalification are complementary in improving access of Member States to IVDs.

The Prequalification of In Vitro Diagnostics requested guidance from the SAGE IVD with respect to its proposed process for selecting IVDs for review, which comprised the:

- burden of disease associated with the target condition;

[7] WHO documents reviewed to compile and propose the general lab tests for the first draft EDL are listed in the reference section under WHO sources for general laboratories

- health interventions associated with the IVD;
- existence of WHO recommendations for the IVD;
- EDL listing of the IVD;
- current demand for similar tests; and
- expectation of donor funding for supplying the IVD.

The SAGE IVD discussed the criteria and agreed that they were appropriate, with the addition of a public health impact on disease burden and deletion of the availability of donor funding. The Group agreed that prequalification of tests by WHO was neither necessary nor sufficient for their inclusion on the EDL.

5. Procedures for revising the EDL

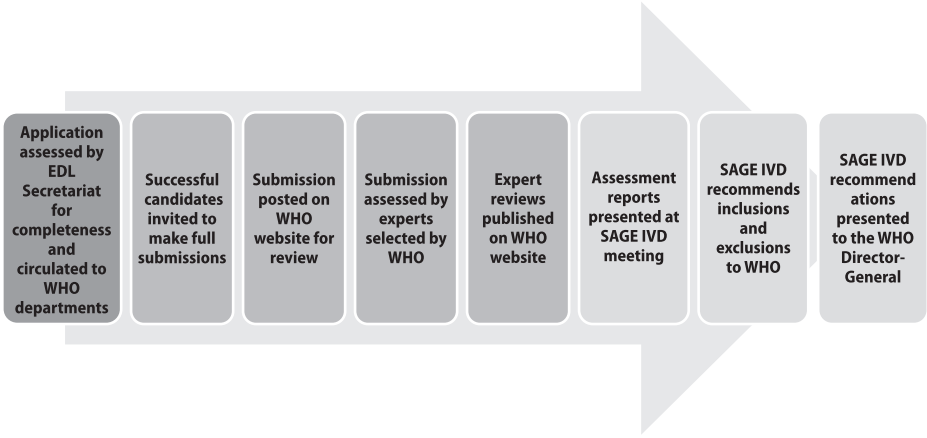
The SAGE IVD considered a draft process from the EDL Secretariat for adding, removing or updating IVDs in future editions of the EDL. The SAGE IVD agreed to form a working group to review and advise the EDL Secretariat on the application form. The EDL Secretariat proposed a timeline for submission and review.

The SAGE IVD agreed that all applications should include:

- information on the applicant:
  - name of and information about the person or organization making the application; and
  - name(s) of and information about the people or institutions consulted on or supporting the application;
- the disease or condition addressed:
  - evidence of the public health importance of the disease or condition;
  - how the candidate IVD contributes to diagnosis or treatment; and
  - how the disease or condition affects the mortality, morbidity, quality of life or economic status of patients;
- description of the IVD:
  - intended use, test utility and method;
  - specimen type and sample volume;
  - performance;
  - how results are provided to the intended user;
  - storage and transport requirements; and
  - biosafety requirements;
- summary of evidence:
  - studies of diagnostic accuracy;
  - evaluations;
  - clinical evidence;
  - non-clinical data: appraisals of quality and ease of use;
- social issues:
  - ethics;

  - human rights; and
  - equity;
- impact on health care system:
  - comparative cost and cost–effectiveness;
  - resource and budget impact on health care systems, including human resources and supplies of consumables; and
  - sustainability;
- proposed text for the EDL.

The proposed process for review of applications for inclusion in the EDL is illustrated in Fig. 2.



The EDL will be updated annually. WHO will issue a call each year for applications to add IVD test categories to the next edition of the EDL, and additions will be made to the List to promote progress towards the goal of universal health coverage.

6. Adaptation of the EDL for national lists

The SAGE IVD considered adaptation of the model EDL for national and institutional EDLs, including factors such as local patterns of prevalent diseases, the availability of diagnostics and treatments, including medicines, health care facilities and personnel, sustainability and affordability. The SAGE IVD asked that feedback from countries be solicited as a priority. It noted that there would be a process of trial, feedback and revision and suggested that WHO work with "pathfinder" countries to make the process more efficient.

It will be important that Member States adopt and adapt the EDL to establish national EDLs. Implementation of the lists will require investment in integrated, connected, tiered laboratory systems, with adequate human resources, training, laboratory infrastructure, and regulatory and quality assurance systems. The local costs of IVDs, supplies and reagents should also be considered.

7. Recommendations

The SAGE IVD made the following recommendations to the WHO Secretariat.

- Recognizing the importance of tests for a wide variety of diseases, the EDL should include a broad list of general laboratory tests, as well as tests for the following initial set of diseases, pursuant to WHO policy and for which there is high-quality guidance: HIV infection, TB, malaria, hepatitis B, hepatitis C, HPV infection and syphilis.
- The EDL Secretariat should consider including tests for the following priority diseases or conditions in future editions of the EDL: antimicrobial resistance, neglected tropical diseases, noncommunicable diseases, outbreaks and emergencies and sepsis.
- The EDL Secretariat should include a detailed preface to the EDL to explain its objectives, limitations and guidance for use. The preface should include: the scope of the EDL, definitions of health service levels, the rationale for the contents and the importance of adapting the list to local or regional settings and conditions.
- The EDL Secretariat should emphasize that, while the EDL provides a list of important tests for use at various levels of the health system, the list will not be useful without an integrated, connected, tiered laboratory system, with adequate human resources, training, laboratory infrastructure and regulatory and quality assurance systems.
- Member States can adapt the EDL and prepare national or regional EDLs; they should also ensure the necessary mechanisms for impact.
- Revise and update the WHO technical documents that constitute resources for the EDL to ensure that they are relevant and current. This task should be a priority, if necessary supported by WHO collaborating centres, other institutions and SAGE IVD.
- Support EDL with a dedicated page on the WHO website containing information on IVDs and laboratories.
- The EDL Secretariat should review the WHO prequalification process, and acknowledge that it plays an important role in increasing access to IVDs of assured quality, safety and performance. SAGE IVD appreciates that EDL and prequalification are complementary in improving access of Member States to IVDs.

On 20 April 2018, an open session was held with SAGE IVD members and representatives of nongovernmental organizations, trade associations and

WHO Member States to discuss the outcomes of the first SAGE IVD meeting. It was agreed that, for future EDLs, an open session will be held before the SAGE IVD meeting to discuss issues raised during the open consultation.

References

1. Thirteenth General Programme of Work 2019–2023. Geneva: World Health Organization; 2018 (http://www.who.int/about/what-we-do/gpw-thirteen-consultation/en/).
2. The selection and use of essential medicines. Report of the WHO Expert Committee, 2017 (including the 20th WHO Model List of Essential Medicines and the 6th Model List of Essential Medicines for Children). Geneva: World Health Organization; 2017 (WHO Technical Report Series, No. 1006; https://apps.who.int/iris/handle/10665/259481, accessed 21 February 2019).
3. Global Health Observatory data on national lists of medical devices. Geneva: World Health Organization; 2017 (https://www.who.int/gho/health_technologies/medical_devices/lists/en/).
4. Consultation on technical and operational recommendations for clinical laboratory testing harmonization and standardization, 22–24 January 2008, Maputo, Mozambique. Geneva: World Health Organization; 2008 (http://www.who.int/healthsystems/round9_9.pdf).
5. Guidance for development of national laboratory strategic plans. Brazzaville: WHO Regional Office for Africa; Atlanta (GA): Centers for Disease Control and Prevention; 2009 (http://www.who.int/hiv/amds/amds_guide_dev_nat_lab_strat.pdf).
6. Guidance for procurement of in vitro diagnostics and related laboratory items and equipment. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/255577).
7. Guide for national public health laboratory networking to strengthen integrated disease surveillance and response (IDSR). Brazzaville: WHO Regional Office for Africa; 2008 (http://www.afro.who.int/publications/guide-national-public-health-laboratory-networking-strengthen-integrated-disease).
8. Global Harmonization Task Force. Definition of the terms medical and in vitro diagnostic (IVD) medical device. Geneva: World Health Organization; 2012 (http://www.imdrf.org/docs/ghtf/find/891/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf#search, accessed 3 May 2018).

WHO sources used to select the general laboratory tests

Asia Pacific strategy for strengthening health laboratory services (2010–2015). New Delhi: WHO Regional Office for South-East Asia and Manila: WHO Regional Office for the Western Pacific; 2010 (http://www.wpro.who.int/health_technology/documents/asia_pacific_laboratory_strategy2010-2015.pdf?ua=1).

Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach, second edition. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/handle/10665/208825).

Guidelines on hepatitis B and C testing. Geneva: World Health Organization; 2017 (http://apps.who.int/iris/ /handle/10665/254621).

HEARTS Technical package for cardiovascular disease management in primary health care: access to essential medicines and technology. Geneva: World Health Organization; 2018 (WHO/NMH/NVI/18.3; http://apps.who.int/iris/handle/10665/260420).

Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health. Geneva: World Health Organization; 2015 (http://www.who.int/medical_devices/publications/interagency_med_dev_list/en/).

Laboratory quality standards and their implementation. Manila: WHO Regional Office for the Western Pacific; and New Delhi: WHO Regional Office for South-East Asia; 2011 (https://apps.who.int/iris/handle/10665/205405).

WHO expert meeting report on short, medium and longer term product development priorities in HIV-related diagnostics, 6–7 June 2012, Geneva, Switzerland. Geneva: World Health Organization; 2012 (https://apps.who.int/iris/handle/10665/75971).

WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. WHO Medical device technical series. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/255177).

WHO guide for the stepwise laboratory improvement process towards accreditation in the African Region (SLIPTA). Brazzaville: WHO Regional Office for Africa; 2015 (http://www.afro.who.int/publications/who-guide-stepwise-laboratory-improvement-process-towards-accreditation-slipta-african).

WHO list of priority medical devices for cancer management. WHO Medical device technical series. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/255262).

Manual of basic techniques for a health laboratory, 2nd edition. Geneva: World Health Organization; 2003 (https://apps.who.int/iris/handle/10665/42295).

Screening donated blood for transfusion-transmissible infections: recommendations. Geneva: World Health Organization; 2009 (http://apps.who.int/iris/handle/10665/44202).

Use of glycated haemoglobin (HbA1c) in the diagnosis of diabetes mellitus: abbreviated report of a WHO consultation. Geneva: World Health Organization; 2011 (WHO/NMH/CHP/CPM/11.1; https://apps.who.int/iris/handle/10665/70523).

The sources also included

WHO publications on medical devices (http://www.who.int/medical_devices/publications/en/).

Acknowledgements

WHO acknowledges the technical input of all SAGE IVD members and WHO programmes and comments from various nongovernmental organizations, industry, academics and other stakeholders and from the EDL Secretariat.

WHO thanks the Department for International Development, United Kingdom, for providing a funding grant to support the EDL.

Annex 1

Participants in the first meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics

Geneva, Switzerland, 16–20 April 2018

Members[8]

Professor G. Araj, Director of Clinical Microbiology, Department of Pathology and Laboratory Medicine, American University of Beirut Medical Center, Lebanon

Dr S. Best, former Director, National Serology Reference Laboratory, Fitzroy, Victoria, Australia

Dr R. Bhatia, former Director, Communicable Diseases, WHO Regional Office for South-East Asia, New Delhi, India

Dr J.Y. Carter, Technical Director, Clinical and Diagnostics, Amref Health Africa, Nairobi, Kenya

Professor F. Chappuis, Head, Division of Tropical and Humanitarian Medicine, and Associate Professor, University Hospitals of Geneva; Medical Advisor (human African trypanosomiasis), Médecins Sans Frontières, Switzerland

Professor J. Deeks, Biostatistics, Evidence Synthesis and Test Evaluation Research Group, Institute of Applied Health Research, University of Birmingham, Birmingham, England

Professor A.O. Emeribe, Laboratory of Haematology and Blood Transfusion Science, University of Calabar, Etagbor; Registrar and Chief Executive Officer, Medical Laboratory Science Council of Nigeria, Abuja, Nigeria

Professor H.Y. Faye-Kette, Microbiology, Bacteriology and Virology, Medical Sciences School, University Felix Houphouet-Boigny, Abidjan, Côte d'Ivoire

Dr S.A. Hojvat, consultant, Rockville (MD), USA

Professor H. Huang, Director, National Tuberculosis Clinical Laboratory, Centres for Disease Control, Beijing, China

Professor J. Jacobs, Tropical Laboratory Medicine, Institute of Tropical Medicine, University of Antwerp, Antwerp, Belgium

Dr N. Janejai, Deputy Director, National Institute of Health, Department of Medical Sciences, Nonthaburi, Thailand

[8] Unable to attend: Professor P.E. Castle, Department of Epidemiology and Population Health, Albert Einstein College of Medicine, New York City (NY), United States of America (USA); Dr W. Sikhondze, Technical Advisor and Research Coordinator, Swaziland National Tuberculosis Control Programme, Mbabane, Eswatini.

Professor A. Newland, Haematology, The Royal London Hospital, Barts Health NHS Trust, London, England

Professor M. Pai, Canada Research Chair in Epidemiology and Global Health; Director, McGill Global Health Programmes; Associate Director, McGill International TB Centre; McGill University, Montreal, Canada

Professor R. Peeling, Chair of Diagnostics Research, London School of Hygiene and Tropical Medicine; Director, International Diagnostics Centre, London, England

Professor O. Perovic, Principal Pathologist, Antimicrobial Resistance Laboratory and Culture Collection Centre for Healthcare-Associated Infections, Antimicrobial Resistance and Mycoses; Associate Professor, University of Witwatersrand, Johannesburg, South Africa

Dr K. Walia, Lead, Antimicrobial Surveillance Network, Senior Scientist, Division of Epidemiology and Communicable Diseases, Indian Council of Medical Research, New Delhi, India

Observers

Professor K. Cichutek, Paul-Ehrlich Institute, Langen, Germany

Dr C. Morris, National Institute for Biological Standards and Control, Ridge, Hertfordshire, England

Secretariat (World Health Organization, Geneva, Switzerland)

Ms A. Alic, Ethics Officer, Compliance and Risk Management and Ethics

Dr T. Besselaar, Technical Officer, High Threat Pathogens

Ms B. Cappello, Technical Officer, Innovation, Access and Use, Department of Essential Medicines and Health Products

Ms E. Cooke, Head, Regulation of Medicines and Other Health Technologies, Department of Essential Medicines and Health Products

Dr J. Cunningham, Technical Officer, Prevention Diagnostics and Treatment, Global Malaria Programme

Dr S. Garner, Coordinator, Innovation Access and Use, Department of Essential Medicines and Health Products

Dr C. Gilpin, Scientist, Laboratories, Diagnostics and Drug Resistance, Global TB Programme

Ms L. Hattingh, Berkeley (CA), United States of America (USA) (*WHO Consultant*)

Dr S. Hill, Director, Department of Essential Medicines and Health Products

Dr A. Ilbawi, Technical Officer, Management of Noncommunicable Diseases

Dr I. Knezevic, Team Leader, Technologies, Standards and Norms, Department of Essential Medicines and Health Products

Dr A.C. Kuesel, Scientist (Intervention Research), UNICEF/UNDP/World Bank/UN Special Programme for Research and Training in Tropical Diseases

Dr F.X. Lery, Coordinator, Technologies, Standards and Norms, Department of Essential Medicines and Health Products

Dr L. Moja, Technical Officer, Innovation, Access and Use, Department of Essential Medicines and Health Products

Dr F.G. Moussy, Scientist, Innovation, Access and Use, Department of Essential Medicines and Health Products

Mr D. Mubangizi, Coordinator, Prequalification Team, Department of Essential Medicines and Health Products

Murtagh, Evanston, IL, USA (*WHO Consultant*)

Dr W.A. Perea Caro, High Threat Pathogens, WHO Health Emergencies Programme

Ms M.M. Perez Gonzalez, Technical Officer, Prequalification Team, Department of Essential Medicines and Health Products

Dr C.L. Pessoa da Silva, Medical Officer, Surveillance Team, Antimicrobial Resistance

Mrs I. Prat, Technical Officer, Prequalification Team, Department of Essential Medicines and Health Products

Mr J. Quirin, Legal Officer, Office of the Legal Counsel

Ms M. Rabini, Technical Officer, Innovation, Access and Use, Department of Essential Medicines and Health Products

Ms A. Sands, Safety and Vigilance Team, Department of Essential Medicines and Health Products

Professor L. Schroeder, Chemical Pathology, Director of Point of Care Testing; Associate Director, Chemical Pathology, Clinical Pathology, Department of Pathology, University of Michigan, Ann Arbor (MI), USA (*WHO Consultant*)

Dr M. Simão, Assistant Director-General, Access to Medicines, Vaccines and Pharmaceuticals

Dr S. Swaminathan, Deputy Director-General for Programmes

Dr M. Taylor, Medical Officer, Human Reproduction

Dr W.S.K. Urassa, Scientist, Prequalification Team, Department of Essential Medicines and Health Products

Mrs A. Velazquez Berumen, Senior Adviser, Innovation, Access and Use, Department of Essential Medicines and Health Products

Dr L. Vojnov, Technical Officer (Diagnostics Adviser), Treatment and Care, HIV/AIDS

Annex 2

Declarations of interest of SAGE IVD members

Professor Madhukar Pai advised the Group that he had been a consultant with the Bill & Melinda Gates Foundation and provided technical assistance to their TB India Program. The consultancy ended on 31 March 2018. He is a member of the Scientific Advisory Committee of the Foundation for Innovative New Diagnostics (FIND) and serves on the Access Advisory Committee of the Global Alliance for TB Drug Development. Since 2015, he has also been part of WHO's Strategic and Technical Advisory Group for TB.

Dr Susan Best advised the Group that she was given support by DiaSorin to attend a European Society of Clinical Virology conference in Italy in September 2017, where she presented a poster that reported on the performance of the DiaSorin Liaison hepatitis B immunoassay in blood specimens collected from cadavers. DiaSorin did not financially support the work that led to the presentation.

Dr Jonathan Deeks advised the Group that he reviewed WHO guidelines related to diagnostics for TB, malaria, HIV and hepatitis with a view to harmonizing processes. Dr Deeks also developed background materials for the HIV department to support their guideline development.

Dr Sally Hojvat advised the Group that, in 2016–2017, she reviewed dossiers on two HPV diagnostic devices and subsequent responses on deficiencies from diagnostics companies for the WHO prequalification team. She also reviewed several documents on product technical specifications for the WHO prequalification team in 2016–2017. Additionally, she provides advice to a regulatory contractor for non-profit institutions and commercial diagnostic companies on matters related to the US Food and Drug Administration pre- and post-commercialization regulatory policy, which involves infectious disease diagnostics (except for HIV laboratory tests of moderate complexity). She provides advice to the same contractor on matters related to the protection of human subjects in clinical trials for diagnostic devices. Further, Dr Hojvat was the Director of the Division of Microbiology at the US Food and Drug Administration, which was responsible for reviewing and evaluating the safety and effectiveness of all IVD microbiology devices (reagents, software and instruments) submitted to the US Food and Drug Administration for pre-market device clearance, approval, waiver of the Clinical Laboratory Improvement Amendments and Emergency Use Authorization and was responsible for ensuring pre-market and post-market compliance associated with IVD microbiology devices. She also represented the US Food and Drug Administration on human subject protection

and was responsible for outreach on IVDs for infectious diseases, including the response to emerging pathogens such as influenza H1N1, Middle East respiratory syndrome, and Ebola virus, and potential biological threats such as anthrax and plague, working with US health and human services agencies (Biomedical Advanced Research and Development Authority, National Institutes of Health, Public Health Emergency Medical Countermeasures Enterprise), the Department of Defense research laboratories and WHO prequalification regulatory teams.

The EDL Secretariat reviewed the disclosures listed above and concluded that these experts had no conflict of interest in respect of the meeting and could fully participate.

This report presents the First WHO Model List of Essential In Vitro Diagnostics (EDL) and recommendations by the Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD), commissioned to act as an advisory body on matters of global policies and strategies related to in vitro diagnostics (IVDs). The report described the scope and recommended use of the List and details of the methods, the criteria for prioritizing IVDs and the procedures for establishing the List. It also includes the procedures for updating the List, its integration with other WHO initiatives and its adaption to national contexts. Finally, it contains recommendations from the SAGE IVD on EDLs.

ISBN 978 92 4 121026 3