World Health Organization

Executive summary

World Health Organization Model List of Essential In Vitro Diagnostics

First edition (2018)

Report of the first Strategic Advisory Group on In Vitro Diagnostics (SAGE-IVD)

WHO headquarters, Geneva, 16–20 April 2018

World Health Organization

Contents

World Health Organization

Executive summary

Access to good quality, affordable, and appropriate health products is indispensable to advance universal health coverage, address health emergencies, and promote healthier populations – the three strategic priorities of the World Health Organization (WHO) Thirteenth General Programme of Work 2019–2023.[1] Without access to In vitro diagnostics (IVDs), health providers cannot diagnose patients effectively and promptly or provide appropriate treatments.

In March 2017, the WHO Expert Committee on Selection and Use of Essential Medicines recommended the development of a Model List of Essential In Vitro Diagnostics (EDL), to complement the WHO Model List of Essential Medicines (EML). To support the EDL and to advise on other in vitro diagnostic initiatives, WHO created a Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE-IVD). The SAGE-IVD, which includes 19 multidisciplinary members with global representation, held its first meeting from 16–20 April 2018 at WHO headquarters, Geneva. The SAGE IVD made recommendations for the content, format and implementation of the first edition of the EDL.

It is foreseen that EDL will be an important tool in increasing access to appropriate, affordable and quality-assured IVDs, particularly where they are most needed to address health priorities.

Scope and selection of IVDs for inclusion in the first edition of the EDL

The EDL focusses on IVDs, a subset of medical devices intended for the in vitro examination of specimens derived from the human body, solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

The WHO developed a draft EDL, which was posted on the WHO website and sent to relevant external stakeholders for comment. The draft list, with the comments received, was provided to the SAGE-IVD members at their meeting for their review and recommendations.

The SAGE IVD confirmed a list of general IVD tests that should be available in primary health care settings, and in hospitals and reference laboratories, for routine patient care. The information to select the general diagnostic tests was compiled from existing WHO guidance, guidelines, technical manuals and the priority medical devices lists.

The disease-specific IVDs were selected from WHO evidence-based guidelines, information from the WHO Prequalification of In Vitro Diagnostics Programme (PQ), or from other WHO IVD assessment processes.

EDL content and format

The first edition of the EDL consists of:

- 58 general laboratory tests that can be used for routine patient care and for the detection and diagnosis of a wide array of diseases communicable and noncommunicable, in the disciplines of clinical chemistry, blood transfusion, serology, microbiology, mycology,

[1] WHO (2018). Thirteenth General Programme of Work 2019–2023 (http://www.who.int/about/what-we-do/gpw-thirteen-consultation/en/).

parasitology and haematology. These tests support routine diagnosis and monitoring of many conditions such as diabetes, cardiovascular, anaemia, liver function.

- 55 types of laboratory tests needed for the detection, diagnosis and monitoring of HIV, tuberculosis, malaria, hepatitis B and C, syphilis and human papilloma virus. For each category of test, the EDL specifies: test category and purpose; assay format; specimen type; and, health care facility level for most appropriate use (e.g. primary care with no or minimal laboratories versus facilities with laboratories). Links to WHO guidelines or publications and, when available, to prequalification or endorsed products. The EDL refers to tests according to their biological targets and does not use brand names.

EDL intended audience and use

The EDL is not prescriptive; rather it is expected that the EDL will provide guidance and serve as a reference to Member States and other parties involved in developing and/or updating lists of national essential IVDs and/or medical devices, and selecting and implementing such IVDs.

While the EDL provides a list of important tests required at various levels of the health system, ranging from primary health care to reference hospital and laboratories, it is important to note that the EDL alone cannot have an impact. It requires an integrated, connected, tiered laboratory system, with adequate human resources, training, laboratory infrastructure, and regulatory and quality assurance systems. Impact also requires Member States to adopt and adapt the EDL, to develop national or regional EDLs, and to implement the supply mechanisms necessary to ensure access to the required IVDs.

In order to effectively use the EDL and adapt it to national needs, Member States will need to consider a variety of factors, including local demographics and burden of disease; treatment facilities; access to reagents and basic infrastructure; training and experience of available personnel; local and unmet testing gaps; supply chain and transport links; facility quality assurance coverage and capacity; local availability of treatments; financial resources; information technology capabilities; local disease elimination priorities; and environmental factors. To that end, information that supports the selection and use of the IVDs on the EDL, and links to relevant WHO clinical guidelines, lists of prequalified IVDs and IVDs recommended by WHO disease control departments, and other relevant resources, will be consolidated on the WHO website together with the EDL. This compendium of materials is intended to support country uptake and facilitate implementation.

Next steps

The EDL will be updated annually. WHO will issue a call for applications to add IVD test categories to the next edition of the EDL in mid-2018. The first EDL will be expanded significantly over the next few years, incorporating other important areas such as antimicrobial resistance, additional noncommunicable diseases (NCDs), emerging pathogens, emergencies and outbreaks, and neglected tropical diseases.

WHO acknowledges the technical input from all SAGE-IVD members, and the comments from stakeholders, and thanks the Department for International Development, United Kingdom, for providing a grant to support this process.

World Health Organization

Recommendations of the Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE-IVD)

Background

The Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE-IVD):

- Welcomed the creation of SAGE-IVD by WHO to act as an advisory body with respect to matters of global policies and strategies related to IVDs.

- Supports WHO's focus on universal health coverage, to ensure that all people have access to a full spectrum of essential, quality health services, including diagnostics. Essential medicines require essential diagnostics, and SAGE-IVD applauds WHO for the decision to create a WHO Model List of Essential In Vitro Diagnostics (EDL), to complement the EML, which has been a very successful public health strategy in enhancing access to medicines.

Recommendations

- Recognizing the importance of tests for a wide variety of diseases, SAGE-IVD reviewed and agreed on a proposal for the first EDL, which should include a broad list of basic 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, TB, malaria, HBV/HCV, and HPV and syphilis infections.

- Consider the following tests be included in future editions of the EDL: antimicrobial resistance, neglected tropical diseases, NCDs, outbreaks/emergencies and sepsis.

- Include a detailed preface to the EDL to explain the objectives, limitations and guidance for its use. The preface should include: the scope of the EDL; a definition of the health service levels referred to; the rationale for the contents; and stress the need to adapt the list to local or regional settings and conditions (one size does not fit all).

- Emphasize that while the EDL provides a list of important tests required at various levels of the health system, the list itself cannot have an impact without an integrated, connected, tiered laboratory system, with adequate human resources, training, laboratory infrastructure, regulatory and quality assurance systems.

- Member States can adapt the EDL and develop national or regional EDLs, as well as implement the mechanisms necessary to ensure impact.

- Revise and update various WHO technical documents that constitute a resource for EDL to make them relevant and current. This task should be prioritized, and if need be, supported by WHO collaborating centres, other institutions and SAGE-IVD.

- Support EDL via a dedicated web page that harmonizes all IVDs information available on the WHO website.

- Review and acknowledge that the WHO prequalification process plays an important role in increasing access to IVDs of assured quality, safety and performance. SAGE-IVD appreciates that

EDL and the WHO Prequalification of In Vitro Diagnostics Programme (PQ) are complementary processes in improving access to IVDs for Member States.

List of participants

SAGE-IVD members

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

Susan Best, Former Director, National Serology Reference Laboratory, Australia.

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Apologies received from: Philip Edward Castle, Professor, Department of Epidemiology and Population Health, Albert Einstein College of Medicine, United States of America; and Welile Sikhondze, Technical Advisor and Research Coordinator, Swaziland National TB Control Program, Swaziland.

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Lucy Hattingh, Maurine Murtagh, Lee Schroeder, external consultants

Declaration of interests

Declaration of interests of SAGE-IVD members

Professor Madhukar Pai advised that he consulted 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 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 STAG TB Advisory Committee.

Dr Susan Best advised she was provided 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 when used with blood specimens collected from cadavers. DiaSorin did not financially support the work that led to the presentation.

Dr Jonathan Deeks advised that he completed a review of 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 that in 2016–2017 she received two HPV diagnostic device dossiers and subsequent deficiency responses from diagnostics companies for the WHO PQ team. She also looked at several product technical specification documents for the WHO PQ team in 2016–2017. Additionally, Dr Hojvat provides advice to a regulatory contractor (Dr Elliot) for non-profit institutions and commercial diagnostic companies on matters related to the US Food and Drug Administration (FDA) pre- and post-commercialization regulatory policy, which involves infectious disease diagnostics (except for HIV moderate complexity laboratory tests). She provides advice to the same contractor on matters related to human subject protection as they relate to clinical trials for diagnostic devices. Further, Dr Hojvat worked as the Director of the Division of Microbiology at the FDA and her division was responsible for the review and evaluation of safety and effectiveness of all IVD microbiology devices (reagents, software and instruments) submitted to the FDA for pre-market device clearance/approval/CLIA waiver and emergency use authorization and responsible for pre-market and post-market compliance actions associated with IVD microbiology devices. She also represented FDA on human subject protection issues and was responsible for outreach activities concerning infectious disease IVD issues, including response to emerging pathogens, e.g. influenza H1N1, MERS, Ebola etc. and potential bio-threats such as anthrax, plague etc., working with USA health and human services agencies (NIH, CDC, BARDA, PHEMCE), the Department of Defense research laboratories and WHO PQ regulatory teams

The EDL Secretariat reviewed the above noted disclosures and determined that there was no conflict of interest in respect of the meeting and the full participation of these experts.

World Health Organization

Annex 1: WHO Model List of Essential In Vitro Diagnostics, first edition

Preface

Introduction

The World Health Organization (WHO) published the first edition of the Model List of Essential In Vitro Diagnostics (EDL) in May 2018, in recognition that IVDs are an essential component to advance universal health coverage, address health emergencies, and promote healthier populations, which are the three strategic priorities of the WHO Thirteenth General Programme of Work (2019–2023) (GPW). The EDL is also intended to complement the WHO Model List of Essential Medicines (EML) and enhance its impact.

Objectives of the Model List of Essential In Vitro Diagnostics (EDL)

The EDL outlines a group of IVDs that are recommended by WHO for use at various levels of a tiered national health care system. The EDL is not intended to be prescriptive with respect to the IVDs listed or the levels at which such IVDs can/should be used; rather country programmes should make the ultimate decisions about which IVDs are selected and where they are implemented, based on national or regional burden of disease, unmet needs and priorities.

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

While the EDL provides a list of important tests required at various levels of the health care system, it is important to note that the EDL itself cannot have an impact without an integrated, connected, tiered laboratory system, with adequate human resources, training, laboratory infrastructure, and regulatory/quality assurance systems. Impact also requires Member States to adopt and adapt the EDL and develop national and regional EDLs, as well as to implement the selection and supply mechanisms necessary to ensure access to the IVDs.

Scope of the first edition of the EDL

Based on the EDL selection criteria described below, the EDL consists:

- A group of general laboratory tests that can be used for routine patient care as well as for the detection and diagnosis of a wide array of disease conditions – communicable and NCDs. These IVDs are grouped by test discipline (e.g. clinical chemistry, serology, haematology, microbiology and mycology) and specific test type (e.g. bilirubin, complete blood count, etc.).

- IVDs designed for the detection, diagnosis and monitoring of each of the following WHO key disease areas: HIV, TB, malaria, HBV/HCV, and HPV and syphilis. These IVDs are grouped by disease area and analyte tested.

The EDL does *not* list specific test brands, but rather consists of IVDs described according to their biological targets. Where specific products in categories of tests contained in the EDL have been prequalified by WHO or are recommended by a WHO disease programme, a link is provided to that information, which is updated regularly.

EDL content and format

For each specific test listed in the first edition of the EDL, the following are described:

- Test purpose: Purpose for which the test can be utilized.
- Assay format: The assay format or formats in which the test is generally available, e.g. enzyme immunoassay, nucleic acid testing.
- Specimen type: The types of specimens that can be used for the test.
- Facility level: The level of the tiered health care delivery system for which the test is suggested, as described below.
- Link to WHO guidance: If there is existing WHO guidance available on the test or category of testing, a link is provided to the appropriate location on the WHO website.
- WHO PQ or endorsed products: For each specific test for which there are brands of products either prequalified by WHO or otherwise endorsed by WHO, a link is provided.

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

I IVDs for Primary health care;

II IVDs for Health care facilities with clinical laboratories.

Recommended use of the EDL

In order to effectively use the EDL and adapt it to national needs, WHO recognizes that Member States will need to consider a variety of factors. These include, among others: local demographics and burden of disease; local disease elimination priorities; local availability of treatments; training and experience of available personnel; local unmet needs and testing gaps; supply chain and transport links; quality assurance capacity; financial resources; information technology capabilities; and environmental factors.

To that end, information that supports the selection and use of IVDs on the EDL, such as relevant WHO clinical guidelines, selected systematic reviews, key references, lists of prequalified IVDs and IVDs recommended by WHO disease control departments, as well as other relevant resources on quality assurance, basic techniques, procurement and maintenance guidance, will be collated and maintained on the WHO website on an IVD-specific webpage linked to the EDL.

The EDL should not be used in isolation, but in the context of the scope of testing services that meet the clinical needs and expectations in each country through their own particular laboratory networks. An illustrative example of a tiered health care delivery and laboratory network in

resource-limited countries is set out in Figure 1. The pyramid of testing reflects that there are generally a large number of primary care facilities and that they serve most patients directly for primary care needs. As one goes up the levels of the system, there are a smaller number of centralized facilities serving fewer patients directly. In the case of national reference laboratories and some provincial laboratories, they may not serve patients directly or they may offer a broad set of specialist consultative services, and act more as referral centres for quality assurance and training or for conducting complex tests (either using samples drawn at facilities lower in the system and transported or by receiving patients referred directly from other facilities).

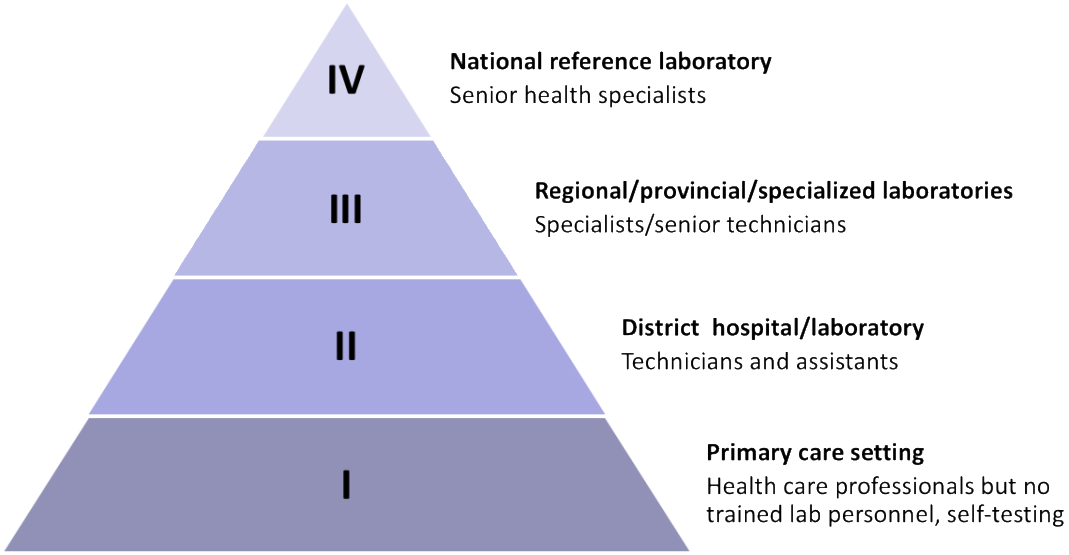

Figure 1. The types of testing that are appropriate at each tier will be country-specific and will include, among others, factors such as access to electricity, reagent grade water, phlebotomy and specialized human resources.[2]

For purposes of the first edition of the EDL and to simplify its presentation and use, IVDs are listed for two tiers: primary care settings where no or minimal laboratories are available (Level I in Figure 1) or for laboratory-based facilities (Levels II, III, and IV in Figure 1).

Process of development of the first edition of the EDL

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 colleagues in the various WHO disease programmes. It was then posted online for open consultation. WHO also created a Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE-IVD) to support the development of the EDL and to advise on other IVD policies and initiatives. SAGE-IVD held its first meeting from 16–20 April 2018 at WHO headquarters, Geneva, where it made recommendations for the content, format and implementation of the first edition of the EDL, as well as its processes moving forward.

[2] Adapted from: WHO (2017). Guidance for procurement of in vitro diagnostics and related laboratory items and equipment (http://www.who.int/diagnostics_laboratory/publications/procurement/en/).

Selection of IVDs for inclusion in the first edition of the EDL

The selection of the diagnostics tests for the EDL took into account the following priorities:

- IVDs for primary care settings, providing an essential diagnostics package that can form the basis for screening and case management of patients at entry-level health care facilities.
- Public health approach, providing information on access to affordable, quality-assured IVDs, targeting high burden diseases, both communicable diseases and NCDs, and diseases of public health importance.
- IVDs for priority diseases such as HIV, TB, malaria, hepatitis HBV/HCV, and HPV and syphilis infections.

Specifically, the general laboratory diagnostics in the first edition of the EDL were compiled based on existing WHO guidance, guidelines and technical manuals and priority medical devices lists, which are referenced at the end of the list.

The disease-specific IVDs were selected from WHO evidence-based guidelines, which are referred to in the EDL with links to the respective documents. An additional factor considered by WHO was the availability of evidence from the WHO Prequalification of In Vitro Diagnostics Programme (PQ), or from other WHO IVD assessment processes, as applicable, which further support the choice of certain diagnostic test categories. Links to relevant documents are provided in the EDL by type of test.

Process for updating the EDL going forward

The EDL will be expanded and updated annually with the intention to ultimately cover a broad, comprehensive spectrum of disease. WHO will issue a call for applications to add IVD test categories to the next edition of the EDL in mid-2018. The call will request applicants to provide information on clinical accuracy or impact of the proposed IVDs. The first EDL will be expanded significantly over the next few years, incorporating tests for other important areas such as antimicrobial resistance, additional NCDs, emerging pathogens, emergencies and outbreaks, and neglected tropical diseases. It is foreseen that the EDL will be an important tool to increase access to appropriate, affordable, and quality-assured IVDs, particularly where they are most needed to address health priorities.

Relationship between the EDL and List of Prequalified In Vitro Diagnostics

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

Implementation of the EDL by countries

It will be important that Member States adopt and adapt the EDL to develop their own national EDLs. These national EDLs will then need to be implemented to ensure impact. Implementation requires countries to invest in integrated, connected, tiered laboratory systems, with adequate human resources, training, laboratory infrastructure, and regulatory and quality assurance systems.

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 medicine.

Health care facility with laboratory support: District, regional, provincial or specialized hospitals/laboratories and national reference laboratories. Trained laboratory technicians, specialist expertise and laboratory infrastructure/equipment are available at the appropriate level. Note: 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: a device which, whether used alone or in combination, is intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. It includes reagents, calibrators, control material, test kits, etc.[3]

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.

Primary health care: 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.

[3] Global Harmonization Task Force (2012). Definition of the terms medical device and in vitro diagnostic (IVD) medical device (http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf#search, accessed 3 May 2018).

Acronyms

AMR	antimicrobial resistance
EDL	World Health Organization Model List of Essential In Vitro Diagnostics
EML	World Health Organization Model List of Essential Medicines
GPW	WHO General Programme of Work
IVDs	in vitro diagnostics
NCDs	noncommunicable diseases
PQ	WHO Prequalification
SAGE-IVD	Strategic Advisory Group of Experts on In Vitro Diagnostics
TB	Mycobacterium tuberculosis
WHO	World Health Organization

References

Additional materials to assist countries in the selection and implementation of IVDs can be found on the WHO website (www.who.int). These include, but are not limited to:

Guidance for procurement of in vitro diagnostics and related laboratory items and equipment. Second edition. Geneva: World Health Organization; 2017 (http://www.who.int/diagnostics_laboratory/publications/procurement/en/).

WHO Global model regulatory framework for medical devices including in vitro diagnostic medical devices. WHO Medical device technical series. Geneva: World Health Organization; 2017 (http://www.who.int/medical_devices/publications/global_model_regulatory_framework_meddev/en/).

Consultation on technical and operational recommendations for clinical laboratory testing harmonization and standardization. Geneva: World Health Organization; 2008 (http://www.who.int/healthsystems/round9_9.pdf).

Global Health Observatory data data. Geneva: World Health Organization; 2017 (http://www.who.int/gho/en/).

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).

Laboratory quality standards and their implementation. WHO Regional Office for the Western Pacific and WHO Regional Office for South-East Asia; 2011 (http://www.who.int/medical_devices/publications/lab_quality_standards/en/).

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).

Guidance for development of national laboratory strategic plans. Brazzaville: WHO Regional Office for Africa and Atlanta (Georgia): United States Centers for Disease Control and Prevention (CDC); 2009 (http://www.who.int/hiv/amds/amds_guide_dev_nat_lab_strat.pdf).

Guidance for procurement of in vitro diagnostics and related laboratory items and equipment. Geneva: World Health Organization; 2017 (http://www.who.int/diagnostics_laboratory/publications/procurement/en/).

WHO expert meeting report on short, medium and longer term product development priorities in HIV-related diagnostics. Geneva: World Health Organization; 2012 (http://www.who.int/hiv/pub/meetingreports/hiv_diagnostics/en/).

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

WHO list of priority medical devices for cancer management; 2017 (http://www.who.int/medical_devices/publications/priority_med_dev_cancer_management/en/).

WHO publications on medical devices. Geneva: World Health Organization; 2018 (http://www.who.int/medical_devices/publications/en/).

World Health Organization

List of Essential In Vitro Diagnostics (EDL)

The first edition of the EDL is presented by health care facility level in two tiers:

I Primary health care; with section a for general IVDs; and section b for specific diseases

II Health care facilities with clinical laboratories, with section a for general IVDs; and section b for specific diseases,

As follows:

I List of Essential In Vitro Diagnostics (EDL): 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 tests are available, but there are either no laboratories, or only small laboratories with trained health care personnel but no trained laboratory technicians.

In case laboratory facilities are available in a primary health care facility, please refer to the IVDs described in the next tier.

It should be noted that in some cases sampling can take place where there are no laboratories, and then processed in the next tier.

I.a General IVDs for primary health care

Note: See list of WHO supporting documents at the end.

	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, VHFs) Safety monitoring when using certain drugs (e.g. Zidovudine for HIV)	Haemoglobinometer	Capillary whole blood Venous whole blood Serum Plasma
			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
	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

World Health Organization

I.a General IVDs for primary health care Note: See list of WHO supporting documents at the end.				
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**
Clinical chemistry and immunoassays	Albumin	To detect/monitor malnutrition, liver or 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 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
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.)

World Health Organization

I.b Disease-specific IVDs for primary health care						
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or endorsed products**	**WHO supporting documents**
Hepatitis B	Hepatitis B surface antigen (HBsAg)	Screening for acute and chronic hepatitis B (HBV) infection: infants over 12 months of age, children, adolescents, adults	RDT	Oral fluid Capillary whole blood	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	N/A	
Hepatitis C	Antibodies to HCV (anti-HCV)	Screening for HCV infection: infants over 18 months of age, children, adolescents, adults	RDT	Oral fluid Capillary whole blood	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
HIV	Antibodies to HIV 1/2 (anti-HIV) test	HIV self-testing	RDT	Oral fluid Capillary whole blood	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 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/
		For the diagnosis of HIV infection: adults, adolescents, children and infants over 18 months of age	RDT	Oral fluid Capillary whole blood		

World Health Organization

I.b Disease-specific IVDs for primary health care						
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or endorsed products**	**WHO supporting documents**
HIV	Combined HIV antibody/p24 antigen (anti-HIV/p24 Ag) test	For the diagnosis of HIV infection: adults, adolescents, children and infants over 18 months of age	RDT	Oral fluid Capillary whole blood	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	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/9789241151268/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
	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	N/A	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/

World Health Organization

I.b Disease-specific IVDs for primary health care						
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or endorsed products** (all TB tests are evaluated and guidelines developed through the WHO Global TB Programme)	**WHO supporting documents**
Tuberculosis	*Mycobacterium tuberculosis* bacteria	For the 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
		For the diagnosis of active TB	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 the diagnosis of latent TB infection	Intradermal 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	

World Health Organization

I.b Disease-specific IVDs for primary health care						
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or endorsed products**	**WHO supporting documents**
Syphilis	Antibodies to *Treponema pallidum*	For the diagnosis or as an aid in the diagnosis of *T. pallidum*	RDT	Capillary whole blood	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 (anti-HIV)	For diagnosis or as an aid in the diagnosis of HIV-1/2 and/or *T. pallidum*	RDT	Capillary whole blood	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

World Health Organization

I.2 List of Essential In Vitro Diagnostics (EDL): For health care facilities with clinical laboratories

This list includes 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.
Note: All diagnostic tests available at the primary care level are assumed to be available at higher levels as appropriate.
The list includes: section a for general laboratory equipment; and section b tests for specific diseases.

II.a General IVDs for health care facilities with clinical laboratories
Note: See list of WHO supporting documents at the end.

	Diagnostic test	Test purpose	Assay format	Specimen type
Clinical chemistry and immunoassays	Alanine amino-transferase (ALT)	To assess liver function (often done with AST)	Optical and electro-analytical methods	Serum Plasma
	Albumin	To detect/monitor malnutrition, liver or kidney disease	Photometric, turbidimetric and nephelometric testing	Urine Serum Plasma
	Alkaline phosphatase	To detect/monitor malnutrition, Paget's disease or certain malignancies, including liver cancer	Colorimetric testing	Serum Plasma
	Aspartate amino-transaminase (AST)	To assess of liver function (often done with 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
	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), as well as 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

World Health Organization

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

Note: See list of WHO supporting documents at the end.

	Diagnostic test	Test purpose	Assay format	Specimen type
Clinical chemistry and immunoassays	Glucose	To diagnose and screen for diabetes and intermediate hypoglycaemia	Automated analyser	Plasma Serum
	Haemoglobin A1c (HbA1c)	Diagnosis and monitoring of diabetes mellitus	ELISA Automated analyser	Capillary venous 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 type 2 diabetes and CVD by measuring cholesterol, triglycerides and lipoproteins	Colourimetry Spectrophotometry	Plasma Serum
	Basic metabolic panel (BMP)	Includes glucose, sodium chloride, carbon dioxide, BUN, BUN/creatinine ratio and may include calcium	Photometric and colourimetric testing, ion-selective potentiometry (8-parameter automated clinical chemistry analyser)	Venous whole blood Serum Plasma
	Comprehensive metabolic panel	BMP plus magnesium, protein, albumin, globulin, alb/glob ratio, bilirubin (direct or total), alkaline phosphatase, ALT/AST, eGFR	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 Urine Peritoneal fluid (Amylase)
	Troponin T/I	For the diagnosis of myocardial infarction	Enzyme immunoassay (handheld or large automated instrument)	Venous whole blood Plasma
	Urinalysis	Detection of substances or cellular material in the urine associated with metabolic disorders, renal dysfunction or UTIs	Automated chemical analyser	Urine
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 Chagas, HTLV in the blood supply etc. (see also EDL sections on HIV, hepatitis C, hepatitis B, syphilis)	EIA (microplate) Manual method	Serum Plasma
			CLIA/ECL (automated instrument)	Serum Plasma
Serology	Human chorionic gonadotropin (hCG)	Pregnancy	Optical method	Serum

World Health Organization

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

Note: See list of WHO supporting documents at the end.

	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
	Culture	Initial step in the process of bacterial species detection and identification to support selection of appropriate antibiotic treatment regimens	Culture on growth media plates and incubator followed by recovery of isolates and speciation (traditional manual techniques or automated equipment)	Disease appropriate specimens (e.g. venous whole blood, urine, stool, etc.)
	Blood culture	For the diagnosis of bacterial and fungal blood stream infections (sepsis)	Blood culture bottle and incubator followed by recovery of isolates and speciation (traditional manual techniques or automated equipment)	Venous whole blood
	Antimicrobial susceptibility testing	Final step in the process of selection of appropriate antibiotic treatment regimens after species identification	Antimicrobial susceptibility testing of isolates – may be done manually using disc diffusion technique or using automated platforms	Microbial isolates
Haematology	Haematocrit (Ht)	Diagnosis and monitoring of anaemia Volume of red blood cells as a percentage of total blood volume	Microhaematocrit centrifuge	Capillary or venous whole blood
	Prothrombin time test and international normalized ratio (PT/INR)	To detect/diagnose a bleeding disorder or excessive clotting disorder (PT); monitor performance of anticoagulant medications (INR)	Handheld or automated coagulation analyser	Citrate plasma
	Platelet count	Diagnosis of thrombocytopenia Marker to manage severe infections associated with bleeding and sepsis (i.e. VHF, meningococcemia) and certain haematological disorders	Haemocytometer	Capillary whole blood
			Haematology analyser	Venous whole blood
			Flow cytometer	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 (WBC, RBC, platelets, Hb and Ht) includes lymphocytes, monocytes and granulocytes (for three-part differential)	Venous whole blood

World Health Organization

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

	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or endorsed products	WHO supporting documents
Hepatitis B	Hepatitis B surface antigen (HBsAg)	Screening for acute and chronic hepatitis B (HBV) infection: infants over 12 months of age, children, adolescents, adults	RDT	Venous whole blood Plasma Serum	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
	Virological (HBV DNA – quantitative)	Staging to assess the need for HBV treatment in chronic HBV infection and monitoring of response to treatment	NAT	Serum Plasma		
	Hepatitis B e antigen (HBeAg)	Staging to assess the need for HBV treatment in chronic HBV infection	EIA	Serum Plasma	N/A	
			CLIA	Serum Plasma	N/A	
	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	N/A	
			CLIA/ECL (automated instrument)	Serum Plasma	N/A	
	Antibodies to hepatitis B surface antigen (anti-HBs)	Determining effectiveness of HBV immunization at patient and at a population level Also used as a marker for recovery from HBV infection	EIA (microplate) Manual method	Serum Plasma	N/A	
			CLIA/ECL (automated instrument)	Serum Plasma	N/A	

World Health Organization

II.b Disease-specific IVDs for health care facilities with clinical laboratories						
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or endorsed products**	**WHO supporting documents**
Hepatitis C	Antibodies to HCV (anti-HCV)	Screening for HCV infection: infants over 18 months of age, children, adolescents, adults	RDT	Venous whole blood Plasma Serum	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 HCV past or present infection: infants over 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 the diagnosis of viraemic HCV infection	CLIA/ECL (automated instrument)	Serum Plasma		
	HCV RNA (qualitative or quantitative)	For the diagnosis of viraemic HCV infection and monitoring of response to treatment as a test of cure	NAT	Serum Plasma		

World Health Organization

II.b Disease-specific IVDs for health care facilities with clinical laboratories						
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or endorsed products**	**WHO supporting documents**
HIV	Antibodies to HIV-1/2 (anti-HIV) test	For the diagnosis of HIV infection: adults, adolescents, children and infants over 18 months of age	RDT	Venous whole blood Plasma Serum	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/ 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/
			CLIA/ECL (automated instrument)	Serum Plasma		
		For screening for HIV in the blood supply and in blood products	EIA (microplate) Manual method	Serum Plasma	N/A	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 over 18 months of age	RDT	Venous whole blood Plasma Serum	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
			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	N/A	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		

World Health Organization

II.b Disease-specific IVDs for health care facilities with clinical laboratories						
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or endorsed products**	**WHO supporting documents**
HIV	HIV qualitative virological or quantitative virological	For the diagnosis of HIV infection in infants under 18 months of age	NAT	Capillary whole blood Venous whole blood Dried blood spot Serum Plasma	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/
	HIV quantitative virological	Monitoring of response to antiviral treatment	NAT	Dried blood spot Serum Plasma	http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/public_report/en/	
	CD4 cell enumeration (quantitative)	For staging of advanced HIV disease	Flow cytometry	Capillary whole blood Venous whole blood	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	CSF Venous whole blood Serum Plasma	N/A	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	CSF Serum Plasma		

World Health Organization

II.b Disease-specific IVDs for health care facilities with clinical laboratories						
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or endorsed 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	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
	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	N/A	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/

World Health Organization

II.b Disease-specific IVDs for health care facilities with clinical laboratories						
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or endorsed products**	**WHO supporting documents**
Malaria	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	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

World Health Organization

II.b Disease-specific IVDs for health care facilities with clinical laboratories						
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or endorsed products** (all TB tests are evaluated and guidelines developed through the WHO Global TB Programme)	**WHO supporting documents**
Tuberculosis	*Mycobacterium tuberculosis* bacteria	For the 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 the diagnosis and treatment monitoring of active TB including drug-resistant TB	Bacterial culture	Sputum or other specimen types		
	M. tuberculosis DNA	For the diagnosis of active TB and simultaneous detection of rifampicin resistance	Cartridge-based NAT	Sputum or EPTB 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	
	M. tuberculosis DNA mutations associated with resistance	For the detection of resistance for first-line anti-TB medicines	Molecular 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 the detection of resistance for second-line anti-TB medicines	Molecular 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	

World Health Organization

II.b Disease-specific IVDs for health care facilities with clinical laboratories						
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or endorsed products** (all TB tests are evaluated and guidelines developed through the WHO Global TB Programme)	**WHO supporting documents**
Tuberculosis	*M. tuberculosis* culture-based DST	To detect resistance to first-line and/or second-line anti-TB medicines	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/	
	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	
	Immune response	For the diagnosis of latent TB infection	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	

World Health Organization

II.b Disease-specific IVDs for health care facilities with clinical laboratories						
	Diagnostic test	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or endorsed products**	**WHO supporting documents**
HPV	Human papillomavirus (HPV) DNA	For cervical cancer screening	Nucleic acid test	Cervical cells collected in test specific transport fluid	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	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		
		For screening blood and blood products	EIA (Microplate) Manual method	Serum Plasma	N/A	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

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World Health Organization

Acronyms

ALT	alanine aminotransferase
AST	aspartate aminotransferase
BMP	basic metabolic panel
BUN	blood urea nitrogen
CBC	complete blood count
CLIA	chemiluminescence immunoassay
CRP	C-reactive protein
CSF	cerebrospinal fluid
CVD	cardiovascular disease
DST	drug susceptibility testing
ECL	electrochemiluminescence
eGFR	estimated glomerular filtration rate
EIA	enzyme immunoassay
ELISA	enzyme linked immunosorbent assay
EPTB	extrapulmonary tuberculosis
Hb	haemoglobin
HbA1c	haemoglobin A1c
hCG	human chorionic gonadotropin
Ht	haematocrit
HTLV	human T-lymphotropic virus
IGRA	interferon gamma release assay
INR	international normalized ratio
LAMP	loop mediated isothermal amplification
LPA	line probe assay
NAT	nucleic acid test
PT	prothrombin time
RBC	red blood cell count
RDT	rapid diagnostic test
UTI	urinary tract infection
TST	tuberculin skin test
WBC	white blood cell count
VHF	viral haemorrhagic fever

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