

**World Health Organization Model List of Essential In Vitro Diagnostics**

**First edition (2018)**

# 16 May 2018

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# Acronyms

|  |  |
| --- | --- |
| ALT | alanine aminotransferase |
| AMR | antimicrobial resistance |
| 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 |
| EDL | World Health Organization Model List of Essential In Vitro  Diagnostics |
| eGFR | estimated glomerular filtration rate |
| EIA | enzyme immunoassay |
| ELISA | enzyme linked immunosorbent assay |
| EML | World Health Organization Model List of Essential  Medicines |
| EPTB | extrapulmonary tuberculosis |
| GPW | WHO General Programme of Work |
| 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 |
| IVDs | in vitro diagnostics |
| LAMP | loop mediated isothermal amplification |
| LPA | line probe assay |
| NAT | nucleic acid test |
| NCDs | noncommunicable diseases |
| PQ | WHO Prequalification |
| PT | prothrombin time |
| RBC | red blood cell count |
| RDT | rapid diagnostic test |
| SAGE-IVD | Strategic Advisory Group of Experts on In Vitro Diagnostics |
| TB | Mycobacterium tuberculosis |
| TST | tuberculin skin test |
| UTI | urinary tract infection |
| VHF | viral haemorrhagic fever |
| WBC | white blood cell count |
| WHO | World Health Organization |

# 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).

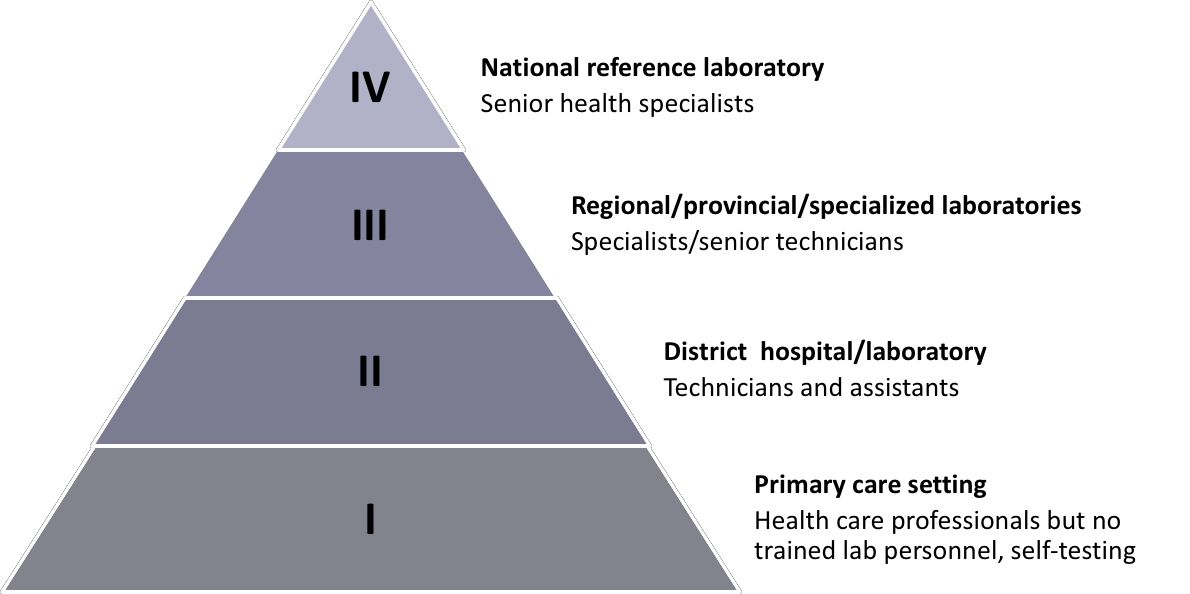


Figure 1. The types of testing that are appropriate at each tier will be country-specific and will include, among others, factors such as access to electricity, reagent grade water, phlebotomy and specialized human resources.1

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.

### 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:

1 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/>).

* + 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.2

**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.

2 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-](http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf#search) [terms-120516.pdf#search,](http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf#search) accessed 3 May 2018).

# Additional materials to assist countries in the selection and implementation of IVDs

These include, but are not limited to: WHO website ([www.who.int](http://www.who.int/)).

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/e](http://www.who.int/medical_devices/publications/global_model_regulatory_framework_meddev/en/) [n/](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-](http://www.afro.who.int/publications/who-guide-stepwise-laboratory-improvement-process-towards-accreditation-slipta-african) [towards-accreditation-slipta-african](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-](http://www.afro.who.int/publications/guide-national-public-health-laboratory-networking-strengthen-integrated-disease) [strengthen-integrated-disease](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/](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/](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/>).

# List of Essential In Vitro Diagnostics (EDL)

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

1. Primary health care; with section a for general IVDs; and section b for specific diseases
2. Health care facilities with clinical laboratories, with section a for general IVDs; and section b for specific diseases, As follows:

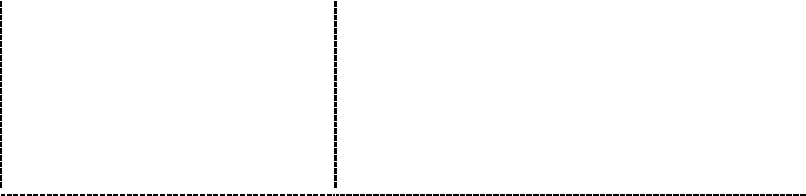
## List of Essential In Vitro Diagnostics (EDL): For primary health care

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.



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| --- | --- | --- | --- | --- |
| **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 |



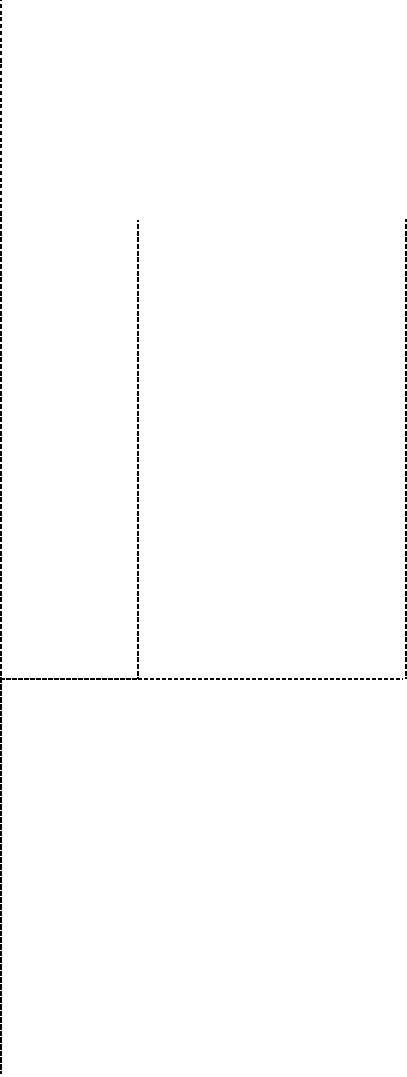


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| **I.a General IVDs for primary health care**  Note: See list of WHO supporting documents at the end. | | | | |
|  | **Diagnostic test** | **Test purpose** | **Assay format** | **Specimen type** |
| Clinical chemistry and  immunoassays | Albumin | 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.) |

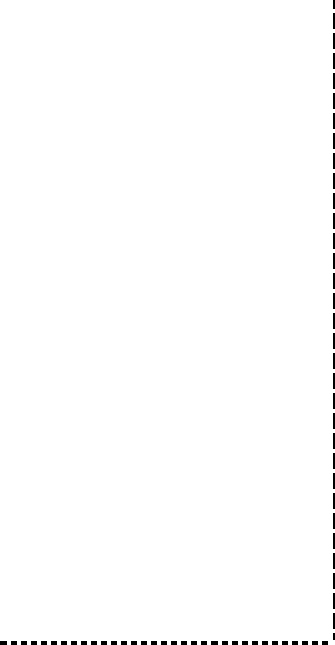




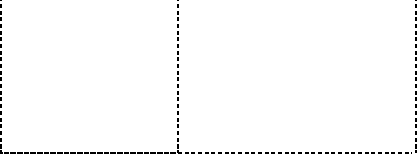
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| **I.b Disease-specific IVDs for primary health care** | | | | | | |
|  | **Diagnostic test** | **Test purpose** | **Assay format** | **Specimen type** | **WHO prequalified or endorsed products** | **WHO supporting documents** |
| Hepatitis B | Hepatitis 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/di](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/public_report/en/) [agnostics\_laboratory/e](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/public_report/en/) [valuations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/public_report/en/) [list/hbsag/public\_repor](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/public_report/en/) [t/en/](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/10665/25](http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1) [4621/9789241549981-eng.pdf?sequence=1](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/di](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report/en/) [agnostics\_laboratory/e](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report/en/) [valuations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report/en/)  [list/hcv/public\_report/e](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report/en/) [n/](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/10665/25](http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1) [4621/9789241549981-eng.pdf?sequence=1](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/di](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/) [agnostics\_laboratory/e](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/) [valuations/pq-list/self-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/) [testing\_public-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/) [report/en/](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/10665/25> 1655/9789241549868-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 |  |



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| **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 | For the diagnosis of | RDT | Oral fluid | [http://www.who.int/di](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/) | Consolidated guidelines on HIV testing services (2015) |
|  | antibody/p24 | HIV infection: adults, |  | Capillary whole blood | [agnostics\_laboratory/e](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/) | [http://www.who.int/hiv/pub/guidelines/hiv-testing-](http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/) |
|  | antigen (anti- | adolescents, children |  |  | [valuations/pq-list/hiv-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/) | [services/en/](http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/) |
|  | HIV/p24 Ag) test | and infants over 18 |  |  | [rdts/public\_report/en/](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/) |  |
|  |  | months of age |  |  |  |  |
| 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/di](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/) [agnostics\_laboratory/e](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/) [valuations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/) [list/malaria/public\_rep](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/) [ort/en/](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/10665/162441/1/9](http://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf) [789241549127\_eng.pdf](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/97892](http://www.who.int/malaria/publications/atoz/978924151268/en/) [4151268/en/](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/10665/445](http://apps.who.int/iris/bitstream/handle/10665/44530/9789241501125_eng.pdf?sequence=1)  [30/9789241501125\_eng.pdf?sequence=1](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/10665/162441/1/9](http://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf) [789241549127\_eng.pdf](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/10665/442](http://apps.who.int/iris/bitstream/handle/10665/44208/9789241547826_eng.pdf?sequence=1) [08/9789241547826\_eng.pdf?sequence=1](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/](http://www.wpro.who.int/mvp/lab_quality/mm_sop/en/)  [en/](http://www.wpro.who.int/mvp/lab_quality/mm_sop/en/) |



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| **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/bitstre](http://apps.who.int/iris/bitstream/10665/162712/1/9789241508612_eng.pdf) [am/10665/162712/1/9789241](http://apps.who.int/iris/bitstream/10665/162712/1/9789241508612_eng.pdf)  [508612\_eng.pdf](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/10665/25918](http://apps.who.int/iris/bitstream/handle/10665/259180/9789241512572-eng.pdf?sequence=1) [0/9789241512572-eng.pdf?sequence=1](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/10665/162712/1/978](http://apps.who.int/iris/bitstream/10665/162712/1/9789241508612_eng.pdf) [9241508612\_eng.pdf](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/bitstre](http://apps.who.int/iris/bitstream/10665/249154/1/9789241511186-eng.pdf?ua=1) [am/10665/249154/1/9789241](http://apps.who.int/iris/bitstream/10665/249154/1/9789241511186-eng.pdf?ua=1)  [511186-eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/249154/1/9789241511186-eng.pdf?ua=1) |
|  | Immune | For the diagnosis of | Intradermal | N/A | Latent TB infection: Updated |  |
| response | latent TB infection | skin test (TST) |  | and consolidated guidelines for |
|  |  |  |  | programmatic management |
|  |  |  |  | (2018) |
|  |  |  |  | [http://apps.who.int/iris/bitstre](http://apps.who.int/iris/bitstream/handle/10665/260233/9789241550239-eng.pdf%3Bjsessionid%3D6D1BB246312B378ACFEBF9BFFAFEB0ED?sequence=1) |
|  |  |  |  | [am/handle/10665/260233/978](http://apps.who.int/iris/bitstream/handle/10665/260233/9789241550239-eng.pdf%3Bjsessionid%3D6D1BB246312B378ACFEBF9BFFAFEB0ED?sequence=1) |
|  |  |  |  | [9241550239-](http://apps.who.int/iris/bitstream/handle/10665/260233/9789241550239-eng.pdf%3Bjsessionid%3D6D1BB246312B378ACFEBF9BFFAFEB0ED?sequence=1) |
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| **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/diagnostic](http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/) [s\_laboratory/evaluations/PQ\_li](http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/) [st/en/](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/10665/85](http://apps.who.int/iris/bitstream/handle/10665/85343/9789241505840_eng.pdf?sequence=1)  [343/9789241505840\_eng.pdf?sequence=1](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/diagnostic](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/) [s\_laboratory/evaluations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/) [list/hiv-rdts/public\_report/en/](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/10665/25](http://apps.who.int/iris/bitstream/handle/10665/252849/WHO-RHR-17.01-eng.pdf?sequence=1)  [2849/WHO-RHR-17.01-eng.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/252849/WHO-RHR-17.01-eng.pdf?sequence=1) |



## 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.

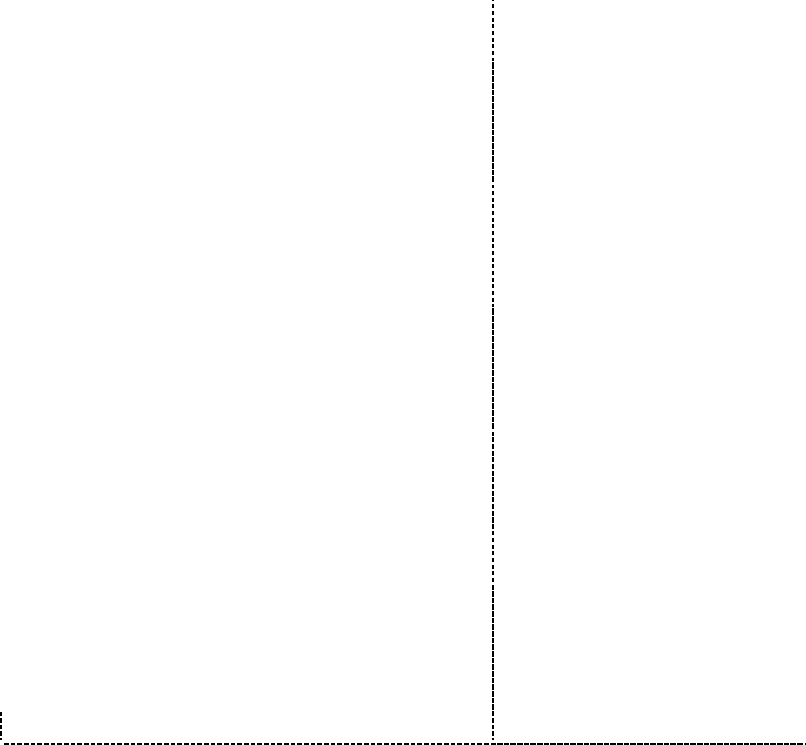


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| **II.a General IVDs for health care facilities with clinical laboratories**  Note: See list of WHO supporting documents at the end. | | | | |
|  | **Diagnostic test** | **Test purpose** | **Assay format** | **Specimen type** |
| Clinical chemistry 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 |

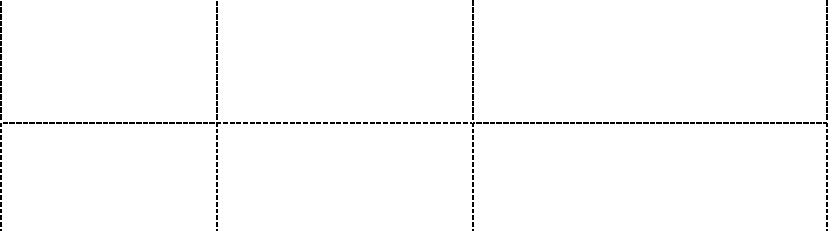
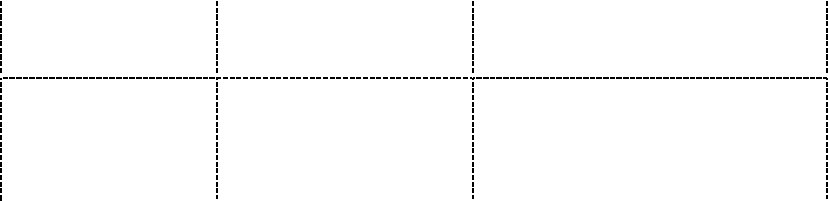
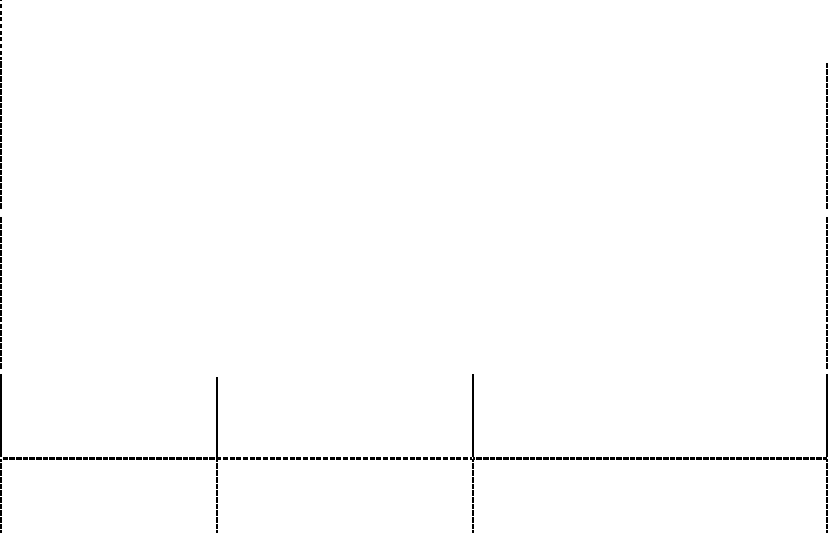




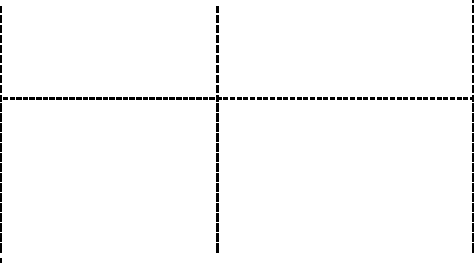
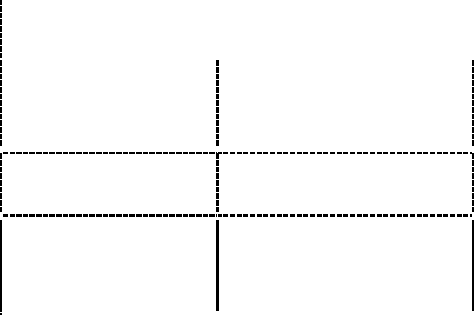
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| **II.a General IVDs for health care facilities with clinical laboratories**  Note: See list of WHO supporting documents at the end. | | | | |
|  | **Diagnostic test** | **Test purpose** | **Assay format** | **Specimen type** |
| Clinical  chemistry 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 |



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| **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 | Haemocytometer | Capillary whole blood |
|  | Marker to manage severe infections associated with bleeding and | Haematology analyser | Venous whole blood |
|  | sepsis (i.e. VHF, meningococcemia) and certain haematological  disorders | 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 |



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| **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/diagnostic](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/public_report/en/) [s\_laboratory/evaluations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/public_report/en/) [list/hbsag/public\_report/en/](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/](http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1) [10665/254621/9789241549981-](http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1)  [eng.pdf?sequence=1](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 |  |



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

**Diagnostic test**

**Test purpose**

**Assay format**

**Specimen type**

Antibodies to HCV

(anti-HCV)

Screening for HCV

infection: infants over 18 months of age, children, adolescents, adults

RDT

**WHO prequalified or endorsed**

**products**

[http://www.who.int/diagnostic](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report/en/) [s\_laboratory/evaluations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report/en/) [list/hcv/public\_report/en/](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report/en/)

**WHO supporting documents**

Hepatitis C

EIA (microplate)

Manual method CLIA/ECL

(automated

Venous whole blood

Plasma Serum Serum Plasma Serum Plasma

Guidelines on hepatitis B and C

testing (February 2017) [http://apps.who.int/iris/bitstream/h](http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1) [andle/10665/254621/978924154998](http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1)

[1-eng.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1)

instrument)

Antibodies to HCV Screening for HCV past or (anti-HCV) and HCV present infection: infants core antigen (HCV over 18 months of age, cAg) children, adolescents,

adults

For the diagnosis of

viraemic HCV infection

EIA (microplate)

Manual method CLIA/ECL

(automated

instrument)

CLIA/ECL

(automated instrument)

NAT

Serum

Plasma Serum Plasma

HCV core antigen

(HCV cAg)

Serum

Plasma

HCV RNA (qualitative

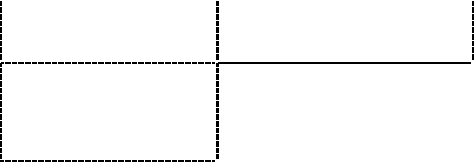
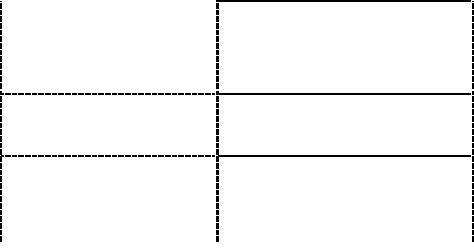
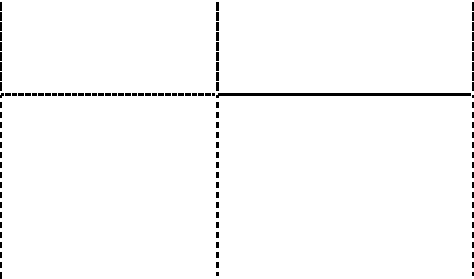
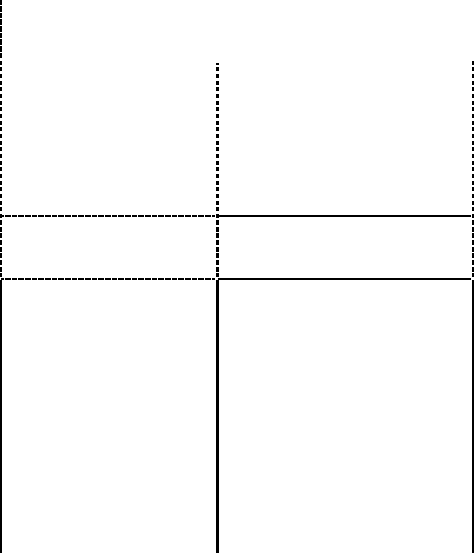
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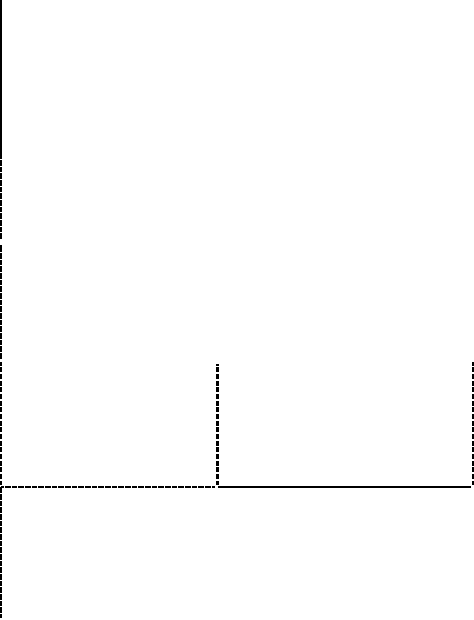
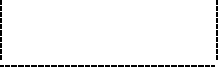
viraemic HCV infection and monitoring of response to treatment as a test of cure

Serum

Plasma



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| **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 RDT infection: adults,  adolescents, children and infants over 18 months of age  EIA (microplate) Manual method CLIA/ECL  (automated instrument) | | Venous whole blood Plasma  Serum  Serum Plasma Serum Plasma | [http://www.who.int/diagnostic](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/) [s\_laboratory/evaluations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/) [list/self-testing\_public-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/) [report/en/](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/](http://apps.who.int/iris/bitstream/handle/10665/251655/9789241549868-eng.pdf?sequence=1) [10665/251655/9789241549868-](http://apps.who.int/iris/bitstream/handle/10665/251655/9789241549868-eng.pdf?sequence=1)  [eng.pdf?sequence=1](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/hi](http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/) [v-testing-services/en/](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-](http://www.who.int/hiv/pub/prep/prep-implementation-tool/en/)  [implementation-tool/en/](http://www.who.int/hiv/pub/prep/prep-implementation-tool/en/) |
|  |  | For screening for HIV in EIA (microplate) the blood supply and in Manual method blood products CLIA/ECL  (automated instrument) | | Serum Plasma Serum Plasma | N/A | Screening donated blood for transfusion transmissible infections: Recommendations (2009)  [http://apps.who.int/iris/bitstream/handle/](http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&amp;isAllowed=y) [10665/44202/9789241547888\_eng.pdf?se](http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&amp;isAllowed=y)  [quence=1&isAllowed=y](http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&amp;isAllowed=y) |
|  | Combined HIV antibody/p24 antigen (anti-HIV/p24 Ag) test | For the diagnosis of HIV RDT infection: adults,  adolescents, children and  infants over 18 months of EIA (microplate) age Manual method  CLIA/ECL  (automated instrument) | | Venous whole blood Plasma  Serum Serum Plasma Serum Plasma | [http://www.who.int/diagnostic](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/) [s\_laboratory/evaluations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/) [list/hiv-rdts/public\_report/en/](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/](http://apps.who.int/iris/bitstream/handle/10665/179870/9789241508926_eng.pdf?sequence=1) [10665/179870/9789241508926\_eng.pdf?s](http://apps.who.int/iris/bitstream/handle/10665/179870/9789241508926_eng.pdf?sequence=1)  [equence=1](http://apps.who.int/iris/bitstream/handle/10665/179870/9789241508926_eng.pdf?sequence=1) |
| For screening for HIV in the blood supply and in blood products | EIA (microplate) Manual method CLIA/ECL  (automated instrument) | Serum Plasma Serum Plasma | N/A | Screening donated blood for transfusion transmissible infections: Recommendations (2009)[http://apps.who.int/iris/bitstream/h](http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&amp;isAllowed=y) [andle/10665/44202/9789241547888\_eng.](http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&amp;isAllowed=y)  [pdf?sequence=1&isAllowed=y](http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&amp;isAllowed=y) |



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| **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/diagnostic](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/public_report/en/) [s\_laboratory/evaluations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/public_report/en/) [list/hiv-vrl/public\_report/en/](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-](http://www.who.int/hiv/pub/arv/arv-2016/en/)  [2016/en/](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/diagnostic](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/public_report/en/)  [s\_laboratory/evaluations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/public_report/en/)  [list/hiv-vrl/public\_report/en/](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/diagnostic](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/public_report/en/) [s\_laboratory/evaluations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/public_report/en/)  [list/hiv-vrl/public\_report/en/](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/](http://apps.who.int/iris/bitstream/handle/10665/260399/9789241550277-eng.pdf?sequence=1) [10665/260399/9789241550277-](http://apps.who.int/iris/bitstream/handle/10665/260399/9789241550277-eng.pdf?sequence=1)  [eng.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/260399/9789241550277-eng.pdf?sequence=1) |
|  | EIA | CSF  Serum Plasma |  |





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| **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/diagnostic](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/)  [s\_laboratory/evaluations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/) [list/malaria/public\_report/en/](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/](http://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf) [162441/1/9789241549127\_eng.pdf](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/](http://www.who.int/malaria/publications/atoz/978924151268/en/) [atoz/978924151268/en/](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/](http://apps.who.int/iris/bitstream/handle/10665/44530/9789241501125_eng.pdf?sequence=1) [10665/44530/9789241501125\_eng.pdf?se](http://apps.who.int/iris/bitstream/handle/10665/44530/9789241501125_eng.pdf?sequence=1) [quence=1](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/](http://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf) [162441/1/9789241549127\_eng.pdf](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/](http://apps.who.int/iris/bitstream/handle/10665/44208/9789241547826_eng.pdf?sequence=1) [10665/44208/9789241547826\_eng.pdf?se](http://apps.who.int/iris/bitstream/handle/10665/44208/9789241547826_eng.pdf?sequence=1) [quence=1](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](http://www.wpro.who.int/mvp/lab_quality/mm_sop/en/)  [/mm\_sop/en/](http://www.wpro.who.int/mvp/lab_quality/mm_sop/en/) |





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| **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/diagnostic](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/) [s\_laboratory/evaluations/pq-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/) [list/malaria/public\_report/en/](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 |





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| **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](http://apps.who.int/iris/bitstream/10665/162712/1/9789241508612_eng.pdf)  [/9789241508612\_eng.pdf](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](http://apps.who.int/iris/bitstream/handle/10665/259180/9789241512572-eng.pdf?sequence=1)  [/10665/259180/9789241512572-](http://apps.who.int/iris/bitstream/handle/10665/259180/9789241512572-eng.pdf?sequence=1)  [eng.pdf?sequence=1](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](http://apps.who.int/iris/bitstream/10665/162712/1/9789241508612_eng.pdf)  [/162712/1/9789241508612\_eng.pdf](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/10665/2](http://apps.who.int/iris/bitstream/handle/10665/254792/WHO-HTM-TB-2017.04-eng.pdf%3Bjsessionid%3DE02D0994930EDBD9A4BC5BB3D3A28568?sequence=1) [54792/WHO-HTM-TB-2017.04-](http://apps.who.int/iris/bitstream/handle/10665/254792/WHO-HTM-TB-2017.04-eng.pdf%3Bjsessionid%3DE02D0994930EDBD9A4BC5BB3D3A28568?sequence=1)  [eng.pdf;jsessionid=E02D0994930EDBD9A4BC5BB3D](http://apps.who.int/iris/bitstream/handle/10665/254792/WHO-HTM-TB-2017.04-eng.pdf%3Bjsessionid%3DE02D0994930EDBD9A4BC5BB3D3A28568?sequence=1) [3A28568?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/254792/WHO-HTM-TB-2017.04-eng.pdf%3Bjsessionid%3DE02D0994930EDBD9A4BC5BB3D3A28568?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](http://apps.who.int/iris/bitstream/10665/112472/1/9789241506335_eng.pdf)  [/9789241506335\_eng.pdf](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](http://apps.who.int/iris/bitstream/10665/250586/1/9789241511261-eng.pdf?ua=1)  [/9789241511261-eng.pdf?ua=1](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/10665/2](http://apps.who.int/iris/bitstream/handle/10665/246131/9789241510561-eng.pdf?sequence=1) [46131/9789241510561-eng.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/246131/9789241510561-eng.pdf?sequence=1) |  |





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| **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\_te](http://www.who.int/tb/publications/2018/WHO_technical_report_concentrations_TB_drug_susceptibility/en/) [chnical\_report\_concentrations\_TB\_drug\_susceptibil](http://www.who.int/tb/publications/2018/WHO_technical_report_concentrations_TB_drug_susceptibility/en/)  [ity/en/](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/10665/1](http://apps.who.int/iris/bitstream/handle/10665/193633/9789241509633_eng.pdf%3Bjsessionid%3D9A9EB886DC17658BF7FDF86758D7A9F9?sequence=1) [93633/9789241509633\_eng.pdf;jsessionid=9A9EB8](http://apps.who.int/iris/bitstream/handle/10665/193633/9789241509633_eng.pdf%3Bjsessionid%3D9A9EB886DC17658BF7FDF86758D7A9F9?sequence=1)  [86DC17658BF7FDF86758D7A9F9?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/193633/9789241509633_eng.pdf%3Bjsessionid%3D9A9EB886DC17658BF7FDF86758D7A9F9?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/10665/2](http://apps.who.int/iris/bitstream/handle/10665/260233/9789241550239-eng.pdf%3Bjsessionid%3D6D1BB246312B378ACFEBF9BFFAFEB0ED?sequence=1) [60233/9789241550239-](http://apps.who.int/iris/bitstream/handle/10665/260233/9789241550239-eng.pdf%3Bjsessionid%3D6D1BB246312B378ACFEBF9BFFAFEB0ED?sequence=1)  [eng.pdf;jsessionid=6D1BB246312B378ACFEBF9BFFA](http://apps.who.int/iris/bitstream/handle/10665/260233/9789241550239-eng.pdf%3Bjsessionid%3D6D1BB246312B378ACFEBF9BFFAFEB0ED?sequence=1) [FEB0ED?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/260233/9789241550239-eng.pdf%3Bjsessionid%3D6D1BB246312B378ACFEBF9BFFAFEB0ED?sequence=1) |  |





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| **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/](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/public_report_hpv/en/) [evaluations/pq-list/public\_report\_hpv/en/](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/handl](http://apps.who.int/iris/bitstream/handle/10665/70505/WHO_IVB_10.12_eng.pdf?sequence=1) [e/10665/70505/WHO\_IVB\_10.12\_eng.pd](http://apps.who.int/iris/bitstream/handle/10665/70505/WHO_IVB_10.12_eng.pdf?sequence=1)  [f?sequence=1](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/](http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/) [evaluations/PQ\_list/en/](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/handl](http://apps.who.int/iris/bitstream/handle/10665/85343/9789241505840_eng.pdf?sequence=1) [e/10665/85343/9789241505840\_eng.pd](http://apps.who.int/iris/bitstream/handle/10665/85343/9789241505840_eng.pdf?sequence=1)  [f?sequence=1](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/handl](http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&amp;isAllowed=y) [e/10665/44202/9789241547888\_eng.pd](http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&amp;isAllowed=y)  [f?sequence=1&isAllowed=y](http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&amp;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/](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/)  [evaluations/pq-list/hiv-](http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/) [rdts/public\_report/en/](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/handl](http://apps.who.int/iris/bitstream/handle/10665/252849/WHO-RHR-17.01-eng.pdf?sequence=1) [e/10665/252849/WHO-RHR-17.01-](http://apps.who.int/iris/bitstream/handle/10665/252849/WHO-RHR-17.01-eng.pdf?sequence=1)  [eng.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/252849/WHO-RHR-17.01-eng.pdf?sequence=1) |

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