1. Second Model List of Essential In Vitro Diagnostics (EDL)

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

I. Community and health settings without laboratories, with two sections:
   a. General IVDs for community and health settings without laboratories
   b. Disease-specific IVDs for community and health settings without laboratories

II. Health care facilities with clinical laboratories, with three sections:
   a. General IVDs for clinical laboratories
   b. Disease-specific IVDs for clinical laboratories
   c. Disease-specific IVDs for blood screening laboratories

Note: The specimen types listed for each diagnostic test category comprise all possible specimens for that category; however, not all test brands within each category will be validated for all the specimen types listed.

Immunoassays are available in various formats – manual microplate assays and automated platforms – with various types of chemical detection (e.g. turbidimetry, chemiluminescence and electrochemiluminescence assays).

I. List of Essential In Vitro Diagnostics (EDL): For community settings and health facilities without laboratories

These lists contain tests for community settings and health facilities that include health posts and centres, doctors' offices, outreach clinics, ambulatory care and home-based and self-testing. If laboratory facilities are available in community settings, please refer to the IVDs described in Section II. If laboratory facilities are not available, specimens may be collected, transported to and processed at a higher tier of the health system. The tests in this section of the EDL are also assumed to be available, in combination with the extended list in Section II, at healthcare facilities with laboratories.

I.a General IVDs for use in community settings and health facilities without laboratories				
Discipline	**Diagnostic test**	**Test purpose**	**Assay format**	**Specimen type**
Blood typing	A, B and O and rhesus factor (Rh)	To determine A, B and O groups and Rh type	Slide agglutination test	Capillary whole blood Venous whole blood[1]
Clinical chemistry	Albumin	To detect or monitor kidney disease	Dipstick	Urine
	Bilirubin	To detect or monitor liver disease and bile duct disorders	Dipstick	Urine
	Glucose	• To diagnose and screen for diabetes and intermediate hyperglycaemia • To diagnose hypoglycaemia	Dipstick	Capillary whole blood Urine
			Glucometer	Capillary whole blood
	Ketones	To diagnose diabetic ketoacidosis	Dipstick	Urine
	Haemoglobin A1c (HbA1c)	To diagnose and monitor diabetes mellitus	Handheld and small analyser	Capillary whole blood
	Whole blood lactate	To assess metabolic acidosis, diabetic keto-acidosis, sepsis and dehydration	Handheld analyser	Venous whole blood[1]
Haematology	Haemoglobin (Hb)	• To diagnose and monitor anaemia • To monitor the safety of certain drugs (e.g. zidovudine for HIV infection) • To screen potential blood donors	Haemoglobinometer	Capillary whole blood Venous whole blood[1]
		• Clinical marker for certain severe infections (e.g. malaria, viral haemorrhagic fevers) • To aid in the diagnosis of intravascular haemolysis, renal conditions, rhabdomyolysis (myoglobinuria)	Dipstick	Urine
Microbiology	Urinalysis test strips	To detect urinary tract infections	Multi-parameter strips (dipstick)	Urine
Pregnancy testing	Human chorionic gonadotropin (hCG)	To aid in the early detection of pregnancy	Rapid diagnostic test (RDT) (dipstick and cassette), latex agglutination	Urine (early morning)

[1] If a phlebotomist is available.

I.b Disease-specific IVDs for use in community settings and health facilities without laboratories

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Cholera	*Vibrio cholerae* Antigen	For initial detection or exclusion of a cholera outbreak (Not for use in case management)	RDT	Stool Rectal swab	N/A	Interim technical note: The use of cholera rapid diagnostic tests, (2016) https://www.who.int/cholera/task_force/Interim-guidance-cholera-RDT.pdf
Hepatitis B virus (HBV) infection	Hepatitis B surface antigen (HBsAg)	To screen for acute and chronic HBV infection: infants > 12 months of age, children, adolescents and adults	RDT	Capillary whole blood Venous whole blood[1]	Public reports of WHO-prequalified IVDs https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/public_report/en/	Guidelines on hepatitis B and C testing (February 2017) https://apps.who.int/iris/handle/10665/254621
	Hepatitis B e antigen (HBeAg)	Staging to assess need for HBV treatment in chronic HBV infection	RDT	Capillary whole blood Venous whole blood[1]	N/A	
Hepatitis C virus (HCV) infection	Anti-HCV antibody	To screen for HCV infection: infants > 18 months of age, children, adolescents and adults	RDT	Oral fluid Capillary whole blood Venous whole blood[1]	Public reports of WHO prequalified IVDs http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report	Guidelines on hepatitis B and C testing (February 2017) https://apps.who.int/iris/handle/10665/254621

[1] If a phlebotomist is available.

Commented [SS1]: ID 221 (a) MSF We are not aware of an HBeAg RDT in the market with good performance and quality assured.

I.b Disease-specific IVDs for use in community settings and health facilities without laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
HIV infection	HIV 1/2 antibody (anti-HIV Ab)	HIV self-testing	RDT	Oral fluid Capillary whole blood Venous whole blood[1]	Public reports of WHO prequalified IVDs https://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/	Guidelines on HIV self-testing and partner notification (2016) https://apps.who.int/iris/handle/10665/251655 Consolidated guidelines on HIV testing services (July 2015) https://apps.who.int/iris/handle/10665/179870 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 Consolidated guidelines on HIV testing services (2015) https://apps.who.int/iris/handle/10665/179870
		To diagnose HIV infection: adults, adolescents, children and infants > 18 months of age	RDT	Oral fluid Capillary whole blood Venous whole blood[1]	Public reports of WHO prequalified IVDs http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report	
	Combined HIV antibody/p24 antigen (anti-HIV/p24 Ag)	For the diagnosis of HIV infection: adults, adolescents, children and infants > 18 months of age	RDT	Capillary whole blood Venous whole blood[1]		
	Qualitative HIV virological nucleic acid test	For diagnosis of HIV infection in infants < 18 months of age	Point-of-care nucleic acid test	Capillary whole blood Venous whole blood[1] Dried blood spots	Public reports of WHO prequalified IVDs http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/public_report	

[1] If a phlebotomist is available.

Commented [SS2]: ID 221 (b) MSF
Nucleic acid testing at Tier 1 level (without laboratory) is still a bit theoretical. In principle, there are some tests such as Cepheid Xpert Edge but it remains to be a very expensive option in terms of instrument and the complexity of supply management needs to be taken into consideration for tier1. We know from experience that even placing them in settings with a dedicated laboratory space and staff the difficulty of keeping them functioning most of the time.
Finally, the rising MTCT rates are not because of lack of POC EID at Tier 1 but due to suboptimal PMTCT programs

I.b Disease-specific IVDs for use in community settings and health facilities without laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
HIV infection *continued*	CD4 cell enumeration	• For staging advanced HIV disease • For monitoring response to antiretroviral therapy. (In settings where viral load is not available)	Point-of-care flow cytometry platform	Capillary whole blood Venous whole blood[1]	Public reports of WHO prequalified IVDs https://www.who.int/diagnostics_laboratory/evaluations/pq-list/cd4/public_report	Consolidated guidelines on HIV testing services (2015) https://apps.who.int/iris/handle/10665/179870 Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy (2017) https://apps.who.int/iris/handle/10665/255884
	Cryptococcal antigen	For screening and diagnosis of cryptococcal meningitis in people with advanced HIV disease	RDT	Capillary whole blood Venous whole blood[1]	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/handle/10665/260399 Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy (2017) https://apps.who.int/iris/handle/10665/255884

[1] If a phlebotomist is available.

I.b Disease-specific IVDs for use in community settings and health facilities without laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Influenza	Influenza A and B antigen detection	To aid in the diagnosis of seasonal influenza infection (Not recommended for surveillance testing)	RDT	Nasal swab	N/A	Use of influenza rapid diagnostic tests (2010) https://apps.who.int/iris/handle/10665/44304/
			Instrument-based point-of-care immunoassay	Nasopharyngeal swab Nasopharyngeal aspirate or wash		WHO recommendations on the use of rapid testing for influenza diagnosis: https://www.who.int/influenza/resources/documents/RapidTestInfluenza_WebVersion.pdf
	Influenza A and B nucleic acid test	For diagnosis of seasonal influenza infection	Point-of-care nucleic acid test	Nasal swab Nasopharyngeal swab Nasopharyngeal aspirate or wash	N/A	Manual for the laboratory diagnosis and virological surveillance of influenza (2011) https://apps.who.int/iris/handle/10665/44518
						Global Epidemiological Surveillance Standards for Influenza: https://www.who.int/influenza/resources/documents/WHO_Epidemiological_Influenza_Surveillance_Standards_2014.pdf
						Guidance on clinical management of influenza infections: https://www.who.int/influenza/resources/documents/clinical_management_2012

I.b Disease-specific IVDs for use in community settings and health facilities without laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Malaria	*Plasmodium* spp. antigens; species- specific (e.g. HRP2) and/ or pan-species specific (e.g. pan-pLDH)	For diagnosis of one or more human malaria species (*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale*)	RDT	Capillary whole blood Venous whole blood[1]	Public reports of WHO prequalified IVDs http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report	WHO guidelines for the treatment of malaria, third edition (2015) https://apps.who.int/iris/handle/10665/162441 Malaria rapid diagnostic test performance. Results of WHO product testing of malaria RDTs: Round 8 (2016-2018) https://www.who.int/malaria/publications/atoz/9789241514965 WHO good practices for selecting and procuring rapid diagnostic tests for malaria (2011) https://apps.who.int/iris/handle/10665/44530 Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests https://www.who.int/malaria/publications/atoz/rdt_selection_criteria

[1] If a phlebotomist is available.

[1] If a phlebotomist is available.

I.b Disease-specific IVDs for use in community settings and health facilities without laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products[1]	WHO supporting documents
Syphilis	Antibodies to *Treponema pallidum*	For diagnosis or as an aid in the diagnosis of *T. pallidum*	RDT	Capillary whole blood Venous whole blood[2]	N/A	WHO laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus (2013) http://apps.who.int/iris/bitstream/handle/10665/85343/9789241505840_eng.pdf
	Combined antibodies to *T. pallidum* and to HIV-1/2	For diagnosis or as an aid in the diagnosis of HIV-1/2 and/or *T. pallidum*	RDT	Capillary whole blood Venous whole blood[2]	Public reports of WHO prequalified IVDs https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv_syphilis/en/	WHO Information note on the use of dual HIV/syphilis rapid diagnostic tests (RDT) (2017) http://apps.who.int/iris/handle/10665/252849
Tuberculosis (TB)	Tuberculin skin (Mantoux) test (TST)	For diagnosis of latent TB infection	Intradermal test	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
Visceral leishmaniasis	rK39 antigen test for visceral leishmaniasis	To aid in the diagnosis of clinically suspected visceral leishmaniasis	RDT	Serum[2] Capillary whole blood Venous whole blood[2]	N/A	WHO Technical Report Series 949 https://apps.who.int/iris/handle/10665/44412

[1] All TB tests are evaluated and guidelines developed by the WHO global TB programme.
[2] If a phlebotomist is available.

II. Health care facilities with clinical laboratories

These lists contain additional tests for district, regional, provincial or specialized hospitals or laboratories and national reference laboratories. It is assumed that trained laboratory technologists, specialist expertise and laboratory infrastructure and equipment are available at the appropriate level. All diagnostic tests available in community settings and health facilities as described in Section I are assumed to be available at higher levels, as appropriate. The list comprises sections for:

a. General IVDs for use in clinical laboratories
b. Disease-specific IVDs for use in clinical laboratories
c. Disease-specific IVDs for blood screening laboratories

II.a General IVDs for use in clinical laboratories

Discipline	Diagnostic test	Test purpose	Assay format	Specimen type	WHO supporting documents
Anatomical pathology[1]	Histopathology	Assessment of tissue for infection, neoplasia, inflammatory and degenerative disorders	Macroscopic assessment of tissue and selection of areas for microscopic examination. Microscopy of tissue sections mounted on slides and stained most commonly with haematoxylin and eosin in the first instance, then treated with a variety of special stains, selected case-by-case to identify pathogens and other abnormal features	Surgical resection Biopsy Core biopsy Cell block	WHO priority medical devices for cancer management https://apps.who.int/iris/handle/10665/255262 Basic histopathology and anatomical pathology services for developing countries with variable services https://apps.who.int/iris/handle/10665/119675
	Cytology (cytopathology)	Assessment of cells for infection, neoplasia, inflammatory and degenerative disorders	Microscopy of stained cells on slides	Cervical specimen for Papanicolaou (Pap) smear Body fluids: e.g. cerebrospinal fluid, urine, pleural and peritoneal fluids Fine-needle aspirate (FNA) of lymph node, spleen, other tissues, bone marrow aspirate, sputum, bronchial brushings, bronchoalveolar lavage (BAL), skin samples	

[1] Note: The tests described in this section require specialized anatomical pathology laboratories and trained anatomical pathologists.

[1] Note: The tests described in this section require specialized anatomical pathology laboratories and trained anatomical pathologists.

II.a General IVDs for use in clinical laboratories *continued*

Discipline	Diagnostic test	Test purpose	Assay format	Specimen type	WHO supporting documents
Anatomical pathology[1] *continued*	Immunohisto-chemistry (IHC)	Assessment of cells for specific markers to identify infection, neoplasia, inflammatory and degenerative disorders	Microscopy of histopathology tissue sections mounted on slides and stained with antibodies to specific markers. Refer to EDL sections on disease-specific tests for individual assays	Surgical resection Biopsy Core biopsy Cell block	
	Post-mortem examination	Determination of cause of death and correlation with pre-mortem clinical features and investigations	Macroscopic assessment and microscopy of tissue sections. Procedures selected case by case	Cadaver	International guidelines for the determination of death – Phase I https://www.who.int/patientsafety/montreal-forum-report.pdf

[1] Note: The tests described in this section require specialized anatomical pathology laboratories and trained anatomical pathologists.

II.a General IVDs for use in clinical laboratories *continued*

Discipline	Diagnostic test	Test purpose	Assay format	Specimen type
Bacteriology, mycology and parasitology	Urinalysis test strips	Detection of urinary tract infections (UTIs)	Multi-parameter strips including nitrite test	Urine
	Microscopy	Microbial morphology, presence or absence of white blood cells, red blood cells versus squamous epithelial cells for presumptive identification; presence of casts and crystals in urine	Microscopic examination of slides as wet preparations or treated with organism-specific chemical stains (e.g. Gram stain, Giemsa stain, modified Ziehl-Nielsen stain, stains for fungi)	Disease-appropriate specimens (e.g. venous whole blood, urine, stool, cerebrospinal fluid) or cultures
	Culture	Initial step in detection and identification of bacterial and fungal species for selection of appropriate antibiotic regimens	Culture on growth media plates or broth in an incubator followed by recovery of isolates and species identification (traditional manual techniques or automated equipment)	Disease-appropriate specimens (e.g. urine, stool, cerebrospinal fluid, etc.)
	Blood culture	For the detection of bacterial and fungal bloodstream infections (sepsis)	Blood culture bottle in an incubator followed by recovery of isolates (traditional manual techniques or automated equipment)	Venous whole blood
	Genus and species identification of bacteria and fungi	For the identification of the genus or species of bacteria or fungi from cultured isolates	A range of biochemical tests that may be performed manually or on automated equipment.	Isolates from bacterial or fungal cultures
	Antimicrobial susceptibility testing (AST)	Final step in selection of appropriate antibiotics after species identification and interpretation by EUCAST[1] and CLSI guidelines[2] Note: WHO regards the development of antimicrobial resistance (AMR) a high-priority global health issue. See WHO Global Antimicrobial Resistance Surveillance (GLASS) programme: http://www.who.int/glass/en/	Antimicrobial susceptibility testing of isolates May be done manually by disc diffusion, gradient tests, broth microdilution or automated platforms	Microbial isolates

[1] EUCAST, European Committee on Antimicrobial Susceptibility Testing: Breakpoint tables for interpretation of MICs and zone diameters Version 9.0.
[2] CLSI, Clinical and Laboratory Standards Institute: CLSI M 100 Performance Standards for Antimicrobial Susceptibility Testing, 29th Edition.

II.a General IVDs for use in clinical laboratories *continued*

Discipline	Diagnostic test	Test purpose	Assay format	Specimen type
Clinical chemistry	Alanine amino-transferase (ALT)	To assess liver function	Optical methods, automated chemistry analyser if available	Serum Plasma
	Albumin	To detect or monitor malnutrition, kidney, liver disease or malabsorption	Optical methods, automated chemistry analyser if available	Serum Plasma
		To detect or monitor kidney disease	Optical methods, automated chemistry analyser if available	Urine
	Alkaline phosphatase (ALP)	To aid in diagnosis of hepatobiliary diseases and bone disorders	Optical methods, automated chemistry analyser if available	Serum Plasma
	Aspartate amino-transferase (AST)	To assess liver function	Optical methods, automated chemistry analyser if available	Serum Plasma
	Basic metabolic panel (BMP)	To measure the levels of glucose, sodium, potassium chloride, carbon dioxide, blood urea nitrogen (BUN), BUN:creatinine ratio, glomerular filtration rate (eGFR) and may include calcium *Note: Result time sensitive for emergency and critical care*	Photometric and colorimetric testing, ion-selective potentiometry (8-parameter automated clinical chemistry analyser)	Venous whole blood Serum Plasma
	Bilirubin	To detect or monitor liver disease, bile duct disorders and red cell destruction	Optical methods, automated chemistry analyser if available	Serum Plasma
	Direct and indirect bilirubin	To detect or monitor liver disease, bile duct disorders and haemolytic anaemia and to differentiate between these causes of jaundice	Optical methods, automated chemistry analyser if available	Serum Plasma

II.a General IVDs for use in clinical laboratories *continued*

Discipline	Diagnostic test	Test purpose	Assay format	Specimen type
Clinical chemistry *continued*	Blood pH and gases	To assess lung function, metabolic or kidney disorders and monitor oxygen therapy To measure blood pH, O_2 and CO_2, serum bicarbonate, anion gap *Note: Result time sensitive for emergency and critical care*	Blood gas analysers, including portable analysers for emergency and critical care	Arterial whole blood ~~Venous whole blood~~
	Blood urea nitrogen (BUN)	To assess kidney function *Note: Result time sensitive for emergency and critical care*	Optical methods, automated chemistry analyser if available	Serum Plasma Venous whole blood
	Comprehensive metabolic panel (CMP)	To measure levels of basic metabolic panel parameters plus magnesium, total protein, albumin, globulin, albumin:globulin ratio, bilirubin (direct or total), alkaline phosphatase (ALP), alanine and aspartate aminotransferases (ALT and AST) • To aid in the diagnosis of bacterial, viral and fungal meningitis	As for basic metabolic panel (14 or more parameter automated clinical chemistry analyser) Glucose, Total Protein	Serum Plasma Cerebrospinal fluid
	C-reactive protein (CRP)	To detect inflammation as an indicator of various conditions, e.g. sepsis, upper respiratory infections *Note: Result time sensitive for emergency and critical care*	RDT Latex agglutination assay Immunoassay	Venous whole blood Serum Plasma
	Creatinine	• To estimate glomerular filtration rate (eGFR) and urine albumin:creatinine ratio (ACR) and urine protein:creatinine ratio • To monitor kidney function for management of severe infections (i.e. sepsis, Lassa fever) and antimicrobial regimen adjustment *Note: Result time sensitive for emergency and critical care*	Optical methods, automated chemistry analyser if available	Serum Urine
	Electrolytes (sodium, potassium, chloride, bicarbonate)			

Commented [SS3]: ID 132 (a)

Commented [SS4]: ID 221 (c) MSF
Aside from detection of inflammation, CRP can also be used for monitoring response to treatment or recovery from inflammation

Commented [SS5]: ID 221 (d) MSF
Would also put - to monitor for kidney function (in general) similar to BUN. It is not only to monitor kidney function for management of severe infections.

To monitor fluid, electrolyte and acid-base balance *Note: Result time sensitive for emergency and critical care*	Automated chemistry	analyser Serum Plasma

II.a General IVDs for use in clinical laboratories *continued*

Discipline	Diagnostic test	Test purpose	Assay format	Specimen type
Clinical chemistry *continued*	Gamma-glutamyl transferase (GGT)	• To assess hepatobiliary function • To distinguish between bone and hepatobiliary causes of raised ALP	Optical methods, automated chemistry analyser if available	Plasma Serum
	Glucose	To diagnose and screen for diabetes and intermediate hyperglycaemia, to diagnose hypoglycaemia *Note: Result time sensitive for emergency and critical care*	Optical methods, automated chemistry analyser if available	Plasma Serum
	Glucose-6-phosphate dehydrogenase activity (G6PD)	For screening newborns for G6PD deficiency	Semi-quantitative fluorescent spot test	Venous whole blood
	Haemoglobin A1c (HbA1c)	To diagnose and monitor diabetes mellitus	Immunoassay	Venous whole blood
	Lipase or amylase	To assess acute pancreatitis and other pancreatic disorders *Note: Lipase result time sensitive for emergency and critical care*	Optical methods, automated chemistry analyser if available	Serum Plasma Peritoneal fluid (amylase)
	Lipid profile	To assess risk of cardiovascular disease (CVD) by measuring cholesterol, triglycerides, low-density lipoproteins (LDL) and high-density lipoproteins (HDL)	Optical methods, automated chemistry analyser if available	Plasma Serum
	Phosphate	• To monitor chronic kidney disease • To prevent and manage tumour lysis syndrome	Optical methods, automated chemistry analyser if available	Serum Plasma
	Procalcitonin	To guide antibiotic therapy or discontinuation in sepsis and lower respiratory tract infection (For use only in tertiary care facilities and above)	RDT	Serum Plasma
			Point-of-care immunoassay instrument	Venous whole blood Capillary whole blood Plasma
			Immunoassay	Serum

Commented [SS6]: ID 132 (b)
Add to aid I diagnosis of bacterial fungal and viral meningitis, and add CSF to specimens for this purpose

Commented [SS7]: ID 221 (e) MSF
reclassify under hematology instead of clinical chemistry

II.a General IVDs for use in clinical laboratories *continued*

Discipline	Diagnostic test	Test purpose	Assay format	Specimen type
Clinical chemistry *continued*	Thyroid-stimulating hormone (TSH)	To screen for hypothyroidism and hyperthyroidism	Immunoassay	Serum Plasma Capillary whole blood (neonates)
	Troponin T/I	To diagnose myocardial infarction *Note: Result time sensitive for emergency and critical care*	Immunoassay (handheld or large automated instrument)	Venous whole blood Serum Plasma
	Uric acid	• To diagnose and monitor gout • To prevent and manage tumour lysis syndrome	Optical methods, automated chemistry analyser if available	Serum Plasma
	Urine chemistry	To detect and quantify substances in the urine associated with metabolic disorders, renal dysfunction or urinary tract infections *Note: Result time sensitive for emergency and critical care*	Automated chemical analyser	Urine

II.a General IVDs for use in clinical laboratories *continued*

Discipline	Diagnostic test	Test purpose	Assay format	Specimen type
Haematology	Blood cross-matching	To determine blood compatibility for blood transfusions *Note: Result time sensitive for emergency and critical care*	Slide and/or tube agglutination test	Venous whole blood Capillary blood
	Complete blood count (CBC) Automated	• To evaluate overall health and to detect a wide range of disorders, including anaemia, infections, leukaemias, red blood cell, white blood cell and platelet abnormalities and primary immune diseases~~disorders~~ • To diagnose and monitor chemotherapy-associated myelotoxicity • To aid in the diagnosis of bacterial, viral and fungal meningitis *Note: Result time sensitive for emergency and critical care*	Automated haematology analyser, total and differential counts of white blood cell (WBC), red blood cell (RBC), platelets, haemoglobin (Hb) and haematocrit (Hct) Total and differential counts of White Blood Cells (WBC), Red Blood Cells (RBC)	Capillary whole blood Venous whole blood Cerebrospinal fluid
	D-Dimer	To diagnose disseminated intravascular coagulation	Immunoassay	Citrate plasma
	Direct antiglobulin test, (DAT) also known as direct Coombs test	• To aid in the diagnosis of the cause of immune haemolytic anaemias • To investigate a blood transfusion reaction • To diagnose haemolytic disease of the newborn	Red blood cell agglutination	Venous whole blood
	Fibrinogen	To diagnose disseminated intravascular coagulation	Hand-held or automated coagulation analyser (fibrinogen activity) Enzyme immunoassay (EIA) (fibrinogen antigen)	Citrate plasma
	Haematocrit (Hct)	To diagnose and monitor anaemia *Note: Result time sensitive for emergency and critical care*	Micro-haematocrit method (if automated haematology analyser not available) Haematology analyser (preferred)	Capillary whole blood Venous whole blood

Commented [SS8]: ID122: To make consistent wording with later section

Commented [SS9]: ID 132 (c)

II.a General IVDs for use in clinical laboratories *continued*

Discipline	Diagnostic test	Test purpose	Assay format	Specimen type
Haematology *continued*	Haemoglobin (Hb)	• To diagnose and monitor anaemia and polycythaemia • To monitor the safety of certain drugs (e.g. zidovudine for HIV infection) • To screen potential blood donors • Clinical marker for certain severe infections (e.g. malaria, viral haemorrhagic fevers) • Aid in the diagnosis of intravascular haemolysis, renal conditions, rhabdomyolysis (myoglobinuria)	Haemoglobinometer, if automated haematology analyser not available Haematology analyser (preferred)	Capillary whole blood Venous whole blood
	Indirect antiglobulin test (IAT), also known as indirect Coombs test or red blood cell antibody screen	• To screen for antibodies to red blood cells before a blood transfusion or in pregnancy • To aid in the diagnosis of haemolytic anaemia and blood transfusion reaction	Red blood cell agglutination	Serum
	Iron studies: Iron Ferritin Total iron-binding capacity (TIBC) or transferrin Calculated transferrin saturation	To diagnose iron deficiency and overload	Optical methods (iron and TIBC) Immunoassay[1] (ferritin and transferrin)	Serum Plasma
	Partial thromboplastin time (PTT), also known as activated partial thromboplastin time (APTT)	• To diagnose a bleeding disorder or a thrombotic disorder • To monitor anticoagulant therapy	Hand-held or automated coagulation analyser	Citrate plasma
	Peripheral blood film examination	For detection of red blood cell, white blood cell and platelet abnormalities, malignancies and parasites and for white blood cell differential count	Romanowsky stained blood films	Capillary whole blood Venous whole blood

II.a General IVDs for use in clinical laboratories *continued*				
Discipline	**Diagnostic test**	**Test purpose**	**Assay format**	**Specimen type**
Haematology *continued*	Platelet count	• Diagnosis of thrombocytopenia or thrombocytosis • Marker to manage severe infections associated with bleeding and sepsis (e.g. viral haemorrhagic fever, meningococcaemia) and certain haematological disorders *Note: Result time sensitive for emergency and critical care*	Haemocytometer, if automated haematology analyser is not available	Capillary whole blood Venous whole blood
			Haematology analyser (preferred)	
	Prothrombin time and international normalized ratio (PT/INR)	To detect or diagnose a bleeding disorder or thrombotic disorder (prothrombin time (PT)); monitor performance of anticoagulant medications (International normalized ratio (INR)) *Note: Result time sensitive for emergency and critical care*	Hand-held or automated coagulation analyser	Citrate plasma
	White blood cell count	To aid in the diagnosis of infections and leukaemias	Haemocytometer, if automated haematology analyser not available	Capillary whole blood Venous whole blood
			Haematology analyser (preferred)	
	Sickle cell testing	To aid in the diagnosis of sickle cell anaemia, sickle cell trait and other sickling disorders	Sodium metabisulfite slide test	Venous whole blood
			Haemoglobin solubility	
		For the diagnosis of sickle cell anaemia, sickle cell trait and other sickling disorders	Haemoglobin electrophoresis	Venous whole blood
Serology	Human chorionic gonadotropin (hCG)	• To detect and/or confirm pregnancy • To detect germ cell neoplasms	Optical method	Serum
			Immunoassay	

Commented [SS10]: ID 221 (f) MSF
suggest to add Rapid diagnostic test

II.b Disease-specific IVDs for use in clinical laboratories

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Cancer	Alpha-fetoprotein (AFP) immunoassay	For screening for hepatocellular carcinoma (HCC) in high-risk individuals with liver cirrhosis or with a family history, in conjunction with ultrasound For staging and disease monitoring of germ cell tumours	Immunoassay	Serum Plasma	N/A	Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection (2018). https://apps.who.int/iris/handle/10665/273174 Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection. https://apps.who.int/iris/handle/10665/154590 WHO classification of tumours of the urinary system and male genital organs. WHO classification of tumours, 4th edition, volume 8. http://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/Who-Classification-Of-Tumours-Of-The-Urinary-System-And-Male-Genital-Organs-2016 WHO classification of tumours of female reproductive organs. WHO classification of tumours, 4th edition, volume 6. http://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/WHO-Classification-Of-Tumours-Of-Female-Reproductive-Organs-2014
	Basic panel for immunohisto-chemical (IHC) testing for diagnosis of lymphoma	To aid in the diagnosis, sub-classification, prognosis and treatment of lymphoma (including HIV-associated conditions)	IHC testing	Formalin-fixed paraffin-embedded tissue (FFPE)[1]	N/A	WHO classification of tumours of haematopoietic and lymphoid tissues. WHO classification of tumours, revised 4th edition, volume 2. https://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/Who-Classification-Of-Tumours-Of-Haematopoietic-And-Lymphoid-Tissues-2017

[1] Only for use in specialized anatomical pathology laboratories - see Anatomical Pathology section under II. a General IVDs for use in clinical laboratories.

Commented [SS11]: ID 330 WHO NCD
Test purpose: for diagnosis and staging of hepatoblastoma
**the use of AFP in combination with abdominal US to screen patients with genetic syndromes associated with higher risk of hepatoblastoma (e.g. Beckwith-Wiedemann uniparental disomy is outside the scope).
Supporting evidence. AFP is an essential biomarker for the risk stratification of children with hepatoblastoma. The Children's Hepatic tumors International Collaboration (CHIC) developed a risk stratification system for use in international clinical trials on the basis of prognostic features present at diagnosis (Meyers RL, lancet oncol 2017; Czauderna P, Eur J Cancer 2016) – formulating in the backbone risk groupings (5 groups). The information on AFP is essential for the risk stratification of patients, as key component to identify the backbone of the affected patients. A plasma level of AFP less than or equal to 100 ng/mL at diagnosis is a strong independent prognostic factors and when present, it defines a 'backbone 5 risk group', associated with poor prognosis. For patients with higher- risk

Commented [SS12]: ID 332 WHO NCD:
Proposed antigens for implementation of the lymphoma and other lymphoproliferative disorders panel. CD138, kappa and lambda chains, PAX5.
CD138/ syndecan-1, is a proteoglycan strongly expressed on multiple myeloma cells. CD138 is present on the surface membrane of 95% of plasma cells in paraffin wax sections and negative on other haemopoietic cells, endothelial cells other lymphomas. The use of antibodies to CD138 enables assessment of malignant plasmacytosis in the bone marrow, taking into account occasional heterogeneity in tumour antigen expression. CD138 is the gold standard marker to identify plasma cells (Wei A, J Clin Pathol 2003). As highly specific of plasma cells, the presence of a neoplastic clone CD138 positive in bone marrow biopsy sample is generally suggestive of multiple myeloma (Wijdenes J, Br J Haematol. 1996; Rawstron AC, Haematologica 2008).
Detection of clonality **with kappa and lambda immunohistochemical analysis** in bone marrow biopsy specimens. Sensitivity and specificity for the diagnosis of multiple myeloma (monoclonal) versus reactive

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Cancer *continued*	Basic panel ~~of~~ ~~immunohisto-chemical (IHC)~~ diagnosis of solid tumours	To aid in diagnosis, prognosis and treatment of solid childhood cancer	IHC testing FISH	Formalin-fixed paraffin-embedded tissue (FFPE)[1]	N/A	WHO classification of tumours, 4thedition. http://publications.iarc.fr/Book-And-Report-Series/Who-Iarc- WHO list of priority medical devices for cancer management https://apps.who.int/iris/bitstream/handle/10665/255262/9789241565462-eng.pdf
	BCR-ABL1 and ABL1 transcripts	For diagnosis and therapeutic monitoring of chronic myelocytic leukaemia (CML) and CML variants (neutrophilic CML) and prognosis of acute lymphoblastic leukaemia (ALL)	Nucleic acid test	Whole blood	N/A	WHO classification of tumours of haematopoietic and lymphoid tissues. WHO classification of tumours, revised 4th edition, volume 2. https://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/Who-Classification-Of-Tumours-Of-Haematopoietic-And-Lymphoid-Tissues-2017 20th Essential Medicines List (2017) https://apps.who.int/iris/handle/10665/273826
	~~Essential flow cytometry~~ panel of antibodies for leukaemia	To aid in the diagnosis of acute leukaemias	Flow cytometry FISH	Bone marrow Peripheral blood Body fluid Tissue Lymph node	N/A	WHO classification of tumours of haematopoietic and lymphoid tissues. WHO classification of tumours, revised 4th edition, volume 2. https://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/Who-Classification-Of-Tumours-Of-Haematopoietic-And-Lymphoid-Tissues-2017 WHO list of priority medical devices for cancer management. https://apps.who.int/iris/handle/10665/255262

[1] Only for use in specialized anatomical pathology laboratories - see Anatomical Pathology section under II. a General IVDs for use in clinical laboratories.

Commented [WKL13]: ID 141 (a) Abbott
Add FISH technology as an acceptable assay format for cancer diagnostics. Remove assay format from the diagnostic test column to allow for other technologies

Commented [SS14]: ID 331 WHO NCD:
Proposed extension of the IHC panel for the diagnosis of solid tumors.
Germ cell tumors. Add to the pane **HCG**, **PLAP** for choriocarcinoma, **CD30** for embryonal carcinoma, **AFP** and **PLAP** for yolk sac tumor, **Oct ¾, NANOG, CD117/c-kit** and **SALL4** for seminoma.
The transcription factors OCT3/4 and NANOG are very sensitive and specific markers that stain both embryonal carcinoma and seminoma but are negative in yolk sac tumor (Santagata S, Am J Surg Pathol. 2007; Cheng L, J pathol 2007; Jones TD, Am J Surg Pathol. 2004).
The stem cell marker, SALL4 has been shown to stain all subtypes of germ cell tumors with high sensitivity in the pivotal experience on SALL4, 22 seminomas, 7 dysgerminomas, 22 embryonal carcinomas, and 14 of 15 yolk sac tumors displayed strong and diffuse SALL positivity in >90% of tumor cells (80% of tumor cells were strongly positive in the remaining yolk sac tumor). Five of 7 choriocarcinomas and 9 of 18 teratomas were also variably positive for SALL4. In contrast, only 10 (esophageal, gastric, and colonic adenocarcinomas) of 170 metastatic somatic tumors demonstrated focally weak SALL4 reactivity (<25% tumor cells). (Cao D, Cancer 2009). The experience was

Commented [SS15]: ID 333 WHO NCD:
Addition to the flow cytometry panel. HLA DR, CD5, CD23, CD43.
CD5, CD23 and CD43 are markers useful in the diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL).
The WHO, IWCLL, and NCCN diagnostic criteria for CLL is based on the morphology and immunophenotype of the neoplastic B-cells with co-expression of CD19, CD5, CD23, with weak CD20 and monoclonal surface immunoglobulin (slg) expression (Swerdlow SH, WHO press 2008; Hallek M, Blood 2008; NCCN guidelines for the management of CLL, 2019). In 2018, the European Research Initiative on CLL (ERIC) & European Society for Clinical Cell Analysis (ESCCA

II.b Disease-specific IVDs for use in clinical laboratories *continued*						
Disease	**Diagnostic test**	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or recommended products**	**WHO supporting documents**
Cancer *continued*	Faecal immunochemical test (FIT)	Screening for colorectal cancer	Latex agglutination immuno-turbidimetry	Stool	N/A	WHO priority medical devices for cancer management https://apps.who.int/iris/handle/10665/255262 Colorectal cancer screening. IARC Handbooks of Cancer Prevention, volume 17 http://publications.iarc.fr/Book-And-Report-Series/Iarc-Handbooks-Of-Cancer-Prevention/Colorectal-Cancer-Screening-2019
	Human chorionic gonadotrophin (hCG) plus beta-hCG	To aid in the diagnosis of and surveillance for germ cell tumours and gestational trophoblastic disease	Immunoassay	Plasma	N/A	WHO classification of tumours of the urinary system and male genital organs. WHO classification of tumours, 4th Edition, Volume 8 http://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/Who-Classification-Of-Tumours-Of-The-Urinary-System-And-Male-Genital-Organs-2016 WHO classification of tumours of female reproductive organs. WHO classification of tumours, 4th edition, volume 6 http://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/WHO-Classification-Of-Tumours-Of-Female-Reproductive-Organs-2014

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Cancer *continued*	Lactate dehydrogenase (LDH) activity	To aid in the prognosis and monitoring of haematological malignancies (lymphoma) and germ cell tumours	Optical methods, automated chemistry analyser if available	Serum Plasma	N/A	WHO classification of tumours of haematopoietic and lymphoid tissues. WHO classification of tumours, revised 4th edition, volume 2 https://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/Who-Classification-Of-Tumours-Of-Haematopoietic-And-Lymphoid-Tissues-2017 WHO classification of tumours of the urinary system and male genital organs. WHO classification of tumours, 4th edition, volume 8 http://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/Who-Classification-Of-Tumours-Of-The-Urinary-System-And-Male-Genital-Organs-2016 WHO classification of tumours of female reproductive organs. WHO classification of tumours, 4th edition, volume 6 http://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/WHO-Classification-Of-Tumours-Of-Female-Reproductive-Organs-2014

Commented [SS16]: ID 313 UniNSW-A:
Purpose of this document: Review the LDH activity entry in the EDL with particular relevance to the following conditions:

1. Heart disease (mentioned as a role of LDH in reviews 1 and 2 of the LDH submission to EDL2)
2. Liver disease (mentioned as a role of LDH in review 2 of the LDH submission to EDL2)
3. Thrombotic thrombocytopenic purpura (TTP) (mentioned as a role of LDH in review 2 of the LDH submission to EDL2)
4. Pneumocystis infection (mentioned in the Pneumocystis PCR submission to EDL3 that LDH may be used in management of pneumocystis.)
5. Additionally, this document reviews the LDH entry in EDL2 with regard to the role of LDH testing in malignancy.

In the EDL2, the Test Purpose for LDH Activity states "To aid in the prognosis and monitoring of haematological malignancies (lymphoma) and germ cell tumours."

INTRODUCTORY COMMENTS

Assay of LDH activity in serum or plasma is a long-established chemical pathology test for a number of conditions. LDH is very widely distributed in the body, and damage to tissues such as heart, liver, kidney, skeletal muscle or red blood cells may case cells to release LDH, giving rise to an elevated reading in serum or plasma. Therefore LDH may be a sensitive assay for tissue damage, but the LDH could be derived from a variety of sources. The relative proportion of different LDH isoenzymes has been used to give a clue to the tissue origin of LDH in the circulation, but this step adds to the complexity of testing. Biomarkers with more specific tissue distribution have become available and have supplanted LDH in a number of settings. Apart from malignancy, there are very few systematic reviews or meta-analyses on the diagnostic role of LDH.

SPECIFIC CONDITIONS

1 HEART DISEASE The history of biomarkers in acute coronary syndrome (including myocardial infarction and unstable angina) was reviewed recently by Danese and Montagnana [1]. LDH was an early biomarker for myocardial infarction, but was supplanted by creatine kinase and other assays, which in turn were supplanted by troponins T and I. In their summary in Table 1, these authors gave Troponins T and I the top score of 4 for both sensitivity and specificity, whereas LDH scored 2 for sensitivity and 1 for specificity.

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Cancer *continued*	Oestrogen (ER) and progesterone (PgR) receptors	To aid in diagnosis, prognosis and treatment of breast cancer	Immunohisto-chemical testing	Formalin-fixed paraffin embedded tissue (FFPE)[1]	N/A	WHO classification of tumours of the breast. WHO classification of tumours, 4th edition, volume 4. http://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/WHO-Classification-Of-Tumours-Of-The-Breast-2012 WHO list of priority medical devices for cancer management https://apps.who.int/iris/handle/10665/255262/ WHO 20th Essential medicines List (2017) https://apps.who.int/iris/handle/10665/273826/ Guidelines for management of breast cancer. WHO Regional Office for the Eastern Mediterranean (2006) http://applications.emro.who.int/dsaf/dsa697.pdf
	Papanicolaou (Pap) smear test	For screening and as an aid in early diagnosis of cervical cancer	Microscopic examination of cervical cells on slides	Cervical smear from liquid cytology specimen	N/A	Guidelines for screening and treatment of precancerous lesion for cervical cancer prevention. WHO guidelines. (2013) https://apps.who.int/iris/handle/10665/94830
	Prostate specific antigen (PSA)	To aid in diagnosis, prognosis and monitoring of prostate cancer	Immunoassay	Peripheral blood	N/A	WHO classification of tumours of the urinary system and male genital organs. WHO classification of tumours, 4th edition, volume 8 http://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/Who-Classification-Of-Tumours-Of-The-Urinary-System-And-Male-Genital-Organs-2016

[1] Only for use in specialized anatomical pathology laboratories - see Anatomical Pathology section under II. a General IVDs for use in clinical laboratories.

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Cancer *continued*	Tyrosine-protein kinase receptor (erbB-2) or human epidermal growth factor receptor 2 (HER-2) overexpression	To aid in diagnosis, prognosis and treatment of breast cancer	Immunohisto-chemical testing as confirmatory test FISH	Formalin-fixed paraffin-embedded tissue (FFPE)[1] (Referred specimens must be fixed correctly before transport)	N/A	WHO classification of tumours of the breast. WHO classification of tumours, 4th edition, volume 4 http://publications.iarc.fr/Book-And-Report-Series/Who-Iarc-Classification-Of-Tumours/WHO-Classification-Of-Tumours-Of-The-Breast-2012 WHO list of priority medical devices for cancer management https://apps.who.int/iris/handle/10665/255262 WHO 20th Essential Medicines List (2017) https://apps.who.int/iris/handle/10665/273826

[1] Only for use in specialized anatomical pathology laboratories - see Anatomical Pathology section under II. a General IVDs for use in clinical laboratories.

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Hepatitis B	Hepatitis B virus (HBV) surface antigen (HBsAg)	Screening for acute and chronic hepatitis B virus (HBV) infection: infants > 12 months of age, children, adolescents and adults	RDT	Venous whole blood Plasma Serum	Public reports of WHO prequalified IVDs http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/public_report	Guidelines on hepatitis B and C testing (February 2017) http://apps.who.int/iris/handle/10665/254621
			Immunoassay	Plasma Serum		
	Quantitative HBV virological nucleic acid test	Staging to assess the need for treatment in chronic HBV infection and monitoring of response to treatment	Nucleic acid test	Serum Plasma Dried Blood Spot (DBS)	N/A	
	Hepatitis B e antigen (HBeAg)	Staging to assess the need for treatment in chronic HBV infection	Immunoassay	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	Immunoassay	Serum Plasma		
	Antibodies to hepatitis B surface antigen (anti-HBs)	To determine effectiveness of HBV vaccination at individual and population levels. Also used as a marker of recovery from HBV infection	Immunoassay	Serum Plasma	N/A	

Commented [WKL17]: ID 141(b) Abbott
Add Dried Blood Spot as an acceptable specimen type.

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Hepatitis C	Antibodies to hepatitis C virus (HCV) (anti-HCV)	Screening for HCV infection: infants > 18 months of age, children, adolescents and adults	RDT	Capillary whole blood Venous whole blood Plasma Serum	Public reports of WHO prequalified IVDs http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report	Guidelines on hepatitis B and C testing (February 2017) http://apps.who.int/iris/handle/10665/254621
			Immunoassay	Serum Plasma		
	Combined antibodies to HCV (anti-HCV) and HCV core antigen (HCVcAg)	Screening for past or present HCV infection: infants > 18 months of age, children, adolescents and adults	Immunoassay	Serum Plasma		
	HCV core antigen (HCVcAg)	For diagnosis of viraemic HCV	Immunoassay	Serum Plasma		
	Qualitative or quantitative HCV virological nucleic acid	For diagnosis of viraemic HCV and monitoring of response to treatment, and as a test of cure	Nucleic acid test	Capillary whole blood Venous whole blood Serum Plasma Dried Blood Spot (DBS)		

Commented [WKL18]: ID 141 (b) Abbott
Add DBS as an acceptable specimen type

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
HIV infection	Antibodies to HIV-1/2 (anti-HIV Ab)	For the diagnosis of HIV infection: adults, adolescents, children and infants > 18 months of age	RDT	Venous whole blood Plasma Serum	Public reports of WHO prequalified IVDs https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report	Guidelines on HIV self-testing and partner notification (2016) http://apps.who.int/iris/handle/10665/251655
			Immunoassay	Serum Plasma		Consolidated guidelines on HIV testing services (July 2015) https://apps.who.int/iris/handle/10665/179870 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
	Combined HIV antibody/p24 antigen (anti-HIV/p24 Ag)	For the diagnosis of HIV infection: adults, adolescents, children and infants > 18 months of age	RDT	Venous whole blood Plasma Serum		Consolidated guidelines on HIV testing services (2015) https://apps.who.int/iris/handle/10665/179870
			Immunoassay	Serum Plasma		
	Qualitative HIV virological nucleic acid test	For diagnosis of HIV infection in infants < 18 months of age	~~(only if validated by the manufacturer)~~	Nucleic acid test	Capillary whole blood Venous whole blood Dried blood spots Plasma	Public reports of WHO prequalified IVDs http://www.who.int/diagnostics_laboratory/ evaluations/pq-list/hiv- vrl/public_report
	Quantitative HIV virological nucleic acid test	• For monitoring response to antiviral treatment • For diagnosis of HIV infection in infants < 18 months of age		~~Nucleic acid test~~	Dried blood spots (whole blood or plasma) Serum Plasma1	

Commented [WKL19]: ID 141 (c) Abbott
Remove statement as laboratory should have the option to validate as well

Commented [WKL20]: ID 141 (d) Abbott
Add footnote "If phlebotomist is available" to insure proper draw of plasma

Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (2016) https://apps.who.int/iris/handle/10665/208825

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
HIV infection *continued*	CD4 cell enumeration	• For staging advanced HIV disease • For monitoring response to antiretroviral therapy. (In settings where viral load is not available)	Flow cytometry	Capillary whole blood Venous whole blood	Public reports of WHO prequalified IVDs https://www.who.int/diagnostics_laboratory/evaluations/pq-list/cd4/public_report	Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (2016) https://apps.who.int/iris/handle/10665/208825 Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy https://apps.who.int/iris/handle/10665/208825
	Cryptococcal antigen	For screening and diagnosis of cryptococcal meningitis in people living with advanced HIV disease	RDT	Cerebrospinal fluid Capillary whole blood 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/handle/10665/260399 Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy (2017) https://apps.who.int/iris/handle/10665/255884
			Immunoassay	Cerebrospinal fluid Serum Plasma		
	Histoplasma antigen	To aid in the diagnosis of disseminated histoplasmosis	Immunoassay	Urine	N/A	Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy (2017) https://apps.who.int/iris/handle/10665/255884
Human papilloma-virus (HPV) infection	HPV nucleic acid test	For cervical cancer screening	Nucleic acid test	Cervical smear from liquid cytology specimen or Cervical cells collected in test-specific transport fluid vessel	Public reports of WHO prequalified IVDs https://www.who.int/diagnostics_laboratory/	WHO human papillomavirus laboratory manual, first edition (2009) http://apps.who.int/iris/handle/10665/70505

Commented [WKL21]: ID 141 (e) Abbott
Comment is for HPV section below: Add liquid cytology as an acceptable specimen type and change "fluid" to "vessel" for cervical cell collection to account for acceptable collection devices not containing fluid.

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Malaria	*Plasmodium* spp. antigens; species-specific (e.g. HRP2) and/or pan-species-specific (e.g. pan-pLDH)	For diagnosis of one or more human malaria species (*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale*)	RDT	Capillary whole blood Venous whole blood	Public reports of WHO prequalified IVDs http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report	WHO guidelines for the treatment of malaria, third edition (2015) http://apps.who.int/iris/10665/162441 Malaria rapid diagnostic test performance: Results of WHO product testing of malaria RDTs: Round 8 (2016–2018) https://www.who.int/malaria/publications/atoz/9789241514965 Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests https://www.who.int/malaria/publications/atoz/rdt_selection_criteria WHO good practices for selecting and procuring rapid diagnostic tests for malaria (2011) http://apps.who.int/iris/handle/10665/44530

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Malaria *continued*	*Plasmodium* spp.	For diagnosis of one or more human malaria species (*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale*) and 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/10665/162441 Basic malaria microscopy Part I: Learner's guide (2010) http://apps.who.int/iris/handle/10665/44208 Malaria microscopy standard operating procedures (2015) http://www.wpro.who.int/mvp/lab_quality/mm_sop/en/
	Glucose-6-phosphate dehydrogenase (G6PD) activity	To determine G6PD activity (normal, intermediate, deficient) for a decision to administer 8-aminoquinoline group drugs for radical cure of *P. vivax* malaria	Semi-quantitative fluorescent spot test	Venous whole blood	N/A	WHO guidelines for the treatment of malaria, third edition (2015) http://apps.who.int/iris/10665/162441

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Neglected tropical diseases	Qualitative dengue virus nucleic acid test	For surveillance (serotype differentiation) and confirmation of outbreaks	Nucleic acid test	Serum Plasma Filter paper stored blood	N/A	Dengue: guidelines for diagnosis, treatment, prevention and control (2009) https://www.who.int/tdr/publications/documents/dengue-diagnosis.pdf
	Dengue virus antibody (immunoglobulin M) (IgM)	To aid in the diagnosis of dengue fever (always in combination with NS1) and for population surveys	RDT	Serum Venous whole blood	N/A	
			Immunoassay	Venous whole blood Filter paper stored blood Dried blood spots (DBS) Saliva		
	Dengue virus antigen (NS1)	To aid in the diagnosis of dengue fever (always in combination with IgM) and for population surveys	RDT	Serum Venous whole blood	N/A	
			Immunoassay	Serum Plasma		
	Kato-Katz	For surveillance and diagnosis of soil- transmitted helminthiasis and schistosomiasis caused by *Schistosoma mansoni*, *S. intercalatum*, *S. japonicum*, *S. mekongi*	Microscope slide examination	Fresh stool	N/A	Video of Kato-Katz method https://www.who.int/neglected_diseases/preventive_chemotherapy/Basic_Lab_methods_in_human_parasitology/en/index2.html

Commented [SS22]: ID 221(g) MSF
May we ask why leishmaniasis was not included?

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Primary Immuno-deficiencies	HIV 1/2 antibody (anti-HIV Ab)	For differential diagnosis of primary immunodeficiencies	RDT	Oral fluid Capillary whole blood Venous whole blood	N/A	N/A
	Immunoglobulin plasma levels (IgG, IgA, IgM)	To identify patients with low Ig levels and monitor replacement	Radial immuno-diffusion (RID)	Serum	N/A	
			Immunoassay	Serum Plasma		
	Lymphocyte subtype enumeration: T cells: CD3, CD4, CD8, B cells Cd 19 and/ or CD20 and NK cells CD16/56 cells (Refer to HIV infection for enumeration of CD4 cells only)	To aid in the diagnosis of primary and secondary immunodeficiencies	Flow cytometry	Venous whole blood	N/A	

Commented [SS23]: ID 122 IPOPI:
Justification:
Inclusion of a reference to the "Complete Blood Count (CBC)" detailed in page 24 of the list, also for Primary Immunodeficiencies (PIDs), as this would allow for non-PID experts to have in one page, all the disease-specific tests that are required for the diagnosis of a PID.

Commented [SS24]: ID 129 IPOPI:
Justification for the modification:
T-cells are CD3+ lymphocytes and are sometimes the only cell surface marker used to count for T-cells. CD4 and CD8 cell surface markers are T-cell subtypes, helper and cytotoxic, respectively.
The most severe PIDs affect the T-cell compartment and may harbor normal relative values of CD4 and/or CD8.B-cells are counted using either CD19 or CD20 cell surface markers.Some laboratories use one or the other and thus, both should be mentioned in the diagnostic toolkit for B-cell defects, leading to agammaglobulinemia or hypogammaglobulinemia.

Supportive documents:
1. Finak, G. et al. Standardizing Flow Cytometry Immunophenotyping Analysis from the Human ImmunoPhenotyping Consortium. Sci. Rep. 6, 20686; doi: 10.1038/srep20686 (2016).
2. Ma CS and Tangye SG (2019) Flow Cytometric-Based Analysis of Defects in Lymphocyte Differentiation and Function Due to Inborn Errors of Immunity. Front. Immunol. 10:2108. doi: 10.3389/fimmu.2019.02108
3. van Dongen JJM, van der Burg M, Kalina T, Perez-Andres M, Mejstrikova E, Vlkova M, Lopez-Granados E, Wentink M, Kienzler A-K, Philippe J, Sousa AE, van Zelm MC, Blanco E and Orfao A (2019) EuroFlow-Based Flowcytometric Diagnostic Screening and Classification of Primary Immunodeficiencies of the Lymphoid System. Front. Immunol. 10:1271. doi: 10.3389/fimmu.2019.01271
4. Madkaikar MR, Shabrish S, Kulkarni M, Aluri J, Dalvi A, Kelkar M and Gupta M (2019) Application of Flow Cytometry in Primary Immunodeficiencies: Experience From India. Front. Immunol. 10:1248. doi: 10.3389/fimmu.2019.01248

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Sexually transmitted infections	Qualitative test for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) infections	For the diagnosis of chlamydial and/or gonorrhoeal urogenital disease, extragenital infection and ocular infection	Nucleic acid test	Urine, urethral swabs endocervical swabs, vaginal swabs, rectal swabs, oropharyngeal swabs, Liquid cytology ocular swab	N/A	WHO sexually transmitted infection laboratory manual https://apps.who.int/iris/handle/10665/85343 Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations https://apps.who.int/iris/handle/10665/246200
	Antibodies to *Treponema pallidum*	For diagnosis or as an aid in the diagnosis of syphilis	RDT	Venous whole blood Plasma Serum	N/A	WHO laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus (2013) http://apps.who.int/iris/handle/10665/85343
			Immunoassay	Serum Plasma		
	Antibodies to *T. pallidum* and to HIV-1/2 (anti-HIV Ab)	For diagnosis or as an aid in diagnosis of HIV-1/2 infection and/or syphilis	RDT	Venous whole blood Plasma Serum	Public reports of WHO prequalified IVDs https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv_syphilis/en/	WHO Information note on the use of dual HIV/syphilis rapid diagnostic tests (RDT) (2017) http://apps.who.int/iris/handle/10665/252849/ Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations https://apps.who.int/iris/handle/10665/246200
	Non-treponemal rapid plasma reagin (RPR) test	For screening for syphilis and monitoring treatment effectiveness	Particle/charcoal agglutination assay	Serum Plasma	N/A	WHO sexually transmitted infection laboratory manual https://apps.who.int/iris/handle/10665/85343
	Non-treponemal venereal disease research laboratory (VDRL) test	For screening, diagnosis and confirmation of neurosyphilis	Flocculation test	Serum Plasma Cerebrospinal fluid	N/A	

Commented [SS25]: ID 141 (f) Abbott
Add ocular swab to account for sampling for infant blindness

II.b Disease-specific IVDs for use in clinical laboratories *continued*						
Disease	**Diagnostic test**	**Test purpose**	**Assay format**	**Specimen type**	**WHO prequalified or recommended products**	**WHO supporting documents**
Sexually transmitted infections *continued*	*T. pallidum* haemagglutination (TPHA) test	For confirmation of syphilis infection and diagnosis of early and late syphilis infection	Red cell agglutination assay	Serum (preferred) Plasma	N/A	Laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus https://www.who.int/reproductivehealth/publications/rtis/9789241505840
	T. pallidum particle agglutination (TPPA) test		Particle agglutination assay		N/A	

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products[1]	WHO supporting documents
Tuberculosis (TB)	*Mycobacterium tuberculosis* bacteria	For diagnosis, treatment and monitoring of active TB	Microscopy	Sputum or other specimen types	Implementing tuberculosis diagnostics: policy framework (2015) https://apps.who.int/iris/handle/10665/162712	Compendium of WHO guidelines and associated standards: Ensuring optimum delivery of the cascade of care for patients with tuberculosis, second edition (2018) https://apps.who.int/iris/handle/10665/272644 Implementing tuberculosis diagnostics: policy framework (2015) https://apps.who.int/iris/handle/10665/162712
		For diagnosis and treatment monitoring of active TB including drug-resistant TB	Bacterial culture	Sputum or other specimen types		
	M. tuberculosis DNA	For diagnosis of active TB and ~~simultaneous~~ detection of rifampicin resistance	Nucleic acid test	Sputum Broncho-alveolar lavage (BAL) or extra-pulmonary TB 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/handle/10665/254792 Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Policy update (2013) https://apps.who.int/iris/handle/10665/112472	
	M. tuberculosis DNA	For diagnosis of active TB	Nucleic acid test ~~Loop-mediated isothermal amplification (LAMP)~~	Sputum	The use of loop-mediated isothermal amplification (TB-LAMP) for the diagnosis of pulmonary tuberculosis: policy guidance (2016) http://apps.who.int/iris/10665/249154	

[1] All TB tests are evaluated and guidelines developed by the WHO global TB programme.

Commented [WKL27]: ID 141 (g) Abbott
Detection does not need to be simultaneous

Commented [SS26]: ID 93 (a) STOP TB
Regarding: Nucleic acid test of *M. tuberculosis* DNA

Request: Test category should be changed to be "for use in community settings and health facilities without laboratories" and the assay format should be "Point-of-care nucleic acid test"

The only WHO-recommended nucleic acid test for TB in the EDL uses the GeneXpert platform, which is also a platform for use of a WHO-prequalified nucleic acid test for diagnosis of HIV infection in infants <18 months of age (EID). While the nucleic acid test for TB is categorized in the EDL as being for use in clinical laboratories, the test for HIV EID is described as a point-of-care test and categorized for use in health facilities without laboratories. This represents a significant discordance, given the use of the TB and HIV EID tests on the same platform and given the TB test and its sample preparation also have minimal training and biosafety requirements. Furthermore the GeneXpert platform family includes a new system *GeneXpert Edge*, which is a portable, battery-operated system that allows for even further decentralization; this system received an approved change request by the WHO Prequalification Department in January 2019. To rectify the current discordance in the EDL, the nucleic acid test for TB should be listed as a point-of-care assay and should be categorized as being for use in health facilities without laboratories, as it currently is for HIV EID.

Commented [WKL28]: ID141 (h) Abbott
Remove LAMP and replace with nucleic acid test to accommodate broader acceptable technology description

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products[1]	WHO supporting documents
Tuberculosis *continued*	*M. tuberculosis* DNA mutations associated with resistance	For detection of resistance to first-line or second line anti-TB medicines	Nucleic acid test ~~Molecular line probe assay (LPA)~~	Sputum	The use of molecular line probe assays for the detection of resistance to isoniazid and rifampicin: policy update (2016) https://apps.who.int/iris/handle/10665/250586	Compendium of WHO guidelines and associated standards: Ensuring optimum delivery of the cascade of care for patients with tuberculosis, second edition (2018) https://apps.who.int/iris/handle/10665/272644
	~~*M. tuberculosis* DNA mutations associated with resistance~~	~~For detection of resistance for second-line anti-TB medicines~~	~~Molecular line probe assay (LPA)~~	~~Sputum~~	The use of molecular line probe assays for the detection of resistance to second-line anti-tuberculosis drugs: policy update (2016) http://apps.who.int/iris/handle/10665/246131	Implementing tuberculosis diagnostics: policy framework (2015) https://apps.who.int/iris/handle/10665/162712
	Drug susceptibility testing with *M. tuberculosis* culture	To detect resistance to first-line and/or second-line anti-TB medicines	Drug susceptibility testing	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	

[1] All TB tests are evaluated and guidelines developed by the WHO global TB programme.

Commented [WKL30]: ID 141 (h) Abbott
Remove LPA and replace with nucleic acid test to accommodate broader acceptable technology description

Commented [WKL29]: ID 141 (h) Abbott
Combine with the item below

Commented [WKL31]: ID 141 (h) Abbott
Combine with item above

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products[1]	WHO supporting documents
Tuberculosis *continued*	Lipoarabino-mannan (LAM) antigen	To aid in the diagnosis of TB in seriously ill HIV-positive inpatients	RDT	Urine	The use of lateral flow urine lipoarabinomannan assay (LF-LAM) for the diagnosis and screening of active tuberculosis in people living with HIV: policy update (2015) http://apps.who.int/iris/handle/10665/193633	Compendium of WHO guidelines and associated standards: Ensuring optimum delivery of the cascade of care for patients with tuberculosis, second edition (2018) https://apps.who.int/iris/handle/10665/272644 Implementing tuberculosis diagnostics: policy framework (2015) https://apps.who.int/iris/handle/10665/162712
	Immune response by Interferon-gamma release assay (IGRA)	For diagnosis of latent TB infection	Immunoassay or ELISPOT assay	Venous whole blood		Latent TB Infection: updated and consolidated guidelines for programmatic management (2018) http://apps.who.int/iris/handle/10665/260233

[1] All TB tests are evaluated and guidelines developed by the WHO global TB programme.

Commented [SS32]: ID 93 (b)STOP TB:
Regarding: RDT for Lipoarabinomannan (LAM) antigen

Request: Test category should be changed to be "for use in community settings and health facilities without laboratories", and the test purpose should be changed from "To aid in the diagnosis of TB in seriously ill HIV-positive inpatients" to "To aid in the diagnosis of TB in seriously ill HIV-positive in-patients, and in the diagnosis of TB in HIV-positive adult out-patients with signs and symptoms of TB"
WHO Global TB Programme policy guidance—*The use of lateral flow urine lipoarabinomannan assay (LF-LAM) for the diagnosis and screening of active tuberculosis in people living with HIV* and the WHO HIV Department *Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy* describe the TB LAM test as a point-of-care test, and it is currently recommended for use for inpatients living with HIV with CD4<100 cells/mm^3 or who are seriously ill. The current guidance indicates that this recommendation also applies to HIV positive adult *out-patients* who are seriously ill regardless of CD4 count or with unknown CD4 count, based on generalization of data from in-patients. Furthermore, an update of this guidance is expected in October 2019, and as already announced by WHO at the IAS conference (Mexico, July 2019), the recommendations for use in out-patient settings will be further expanded to indicate HIV-positive adults with signs and symptoms of TB. Therefore, given the recommendations apply to outpatients and CD4 testing is not a requirement for use of the test, there is no need for a clinical laboratory to run this RDT, and the EDL should therefore indicate its category as for use in facilities without laboratories. Furthermore, the test purpose in the EDL should not be restricted to in-patients, and instead should indicate "To aid in the diagnosis of TB in seriously ill HIV-positive inpatients and in the diagnosis of TB in HIV-positive adult out-patients with signs and symptoms of TB"

II.b Disease-specific IVDs for use in clinical laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Zika virus infection	Detection of IgM antibodies to Zika virus	To aid in the diagnosis of suspected Zika virus infection[1]	Immunoassay	Serum (Not to be used with cerebrospinal fluid)	N/A	Laboratory testing for Zika virus infection interim guidance https://www.who.int/csr/resources/publications/zika/laboratory-testing
	Virological detection of Zika virus	To diagnose acute Zika virus infection[2,3]	Nucleic acid test	Venous whole blood Serum Plasma Urine CSF	WHO listing through Emergency Use Assessment and Listing (EUAL) procedure: https://www.who.int/diagnostics_laboratory/eual-zika-virus/zika/en/	

[1] Because of potential cross-reactivity with dengue and other flaviviruses and persistence of Zika IgM antibody that may reflect infection prior to pregnancy, currently available Zika virus IgM test results should not be used alone for clinical decision-making in pregnancy.

[2] Zika virus RNA is typically detectable in serum by NAT assays only within the first week of infection. A negative result does not rule out infection.

[3] To reduce risk of false-positive results in pregnant women, a positive NAT test should be confirmed by re-extraction and repeat NAT testing of the same specimen.

II.c Disease-specific IVDs for blood screening laboratories

Organism	Screening test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Hepatitis B virus (HBV)	Hepatitis B surface antigen (HBsAg)	For screening blood donations for HBV	RDT[1,2]	Capillary whole blood Venous whole blood Plasma Serum	Public reports of WHO prequalified IVDs https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/public_report	Screening donated blood for transfusion transmissible infections: recommendations (2009) http://apps.who.int/iris/handle/10665/44202
			Particle agglutination assay[1,2]	Plasma Serum		
			Immunoassay[1]	Plasma Serum		
Hepatitis C virus (HCV)	Antibodies to HCV (anti-HCV)	For screening blood donations for HCV	RDT[1,2]	Capillary whole blood Venous whole blood Plasma Serum	Public reports of WHO prequalified IVDs https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report	
			Immunoassay[1]	Serum Plasma		
	Combined antibodies to HCV (anti-HCV) and HCV core antigen (HCV cAg)	For screening blood donations for HCV	Immunoassay[1]	Serum Plasma		

NOTE: Please refer to the Haematology section for information on General IVDs for blood transfusion.

[1] The only assays recommended for blood screening are those that have been validated for this purpose by the manufacturer.
[2] May be performed in laboratories with small throughput, in remote areas or emergency situations.

NOTE: Please refer to the Haematology section for information on General IVDs for blood transfusion.

II.c Disease-specific IVDs for blood screening laboratories *continued*

Organism	Screening test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
HIV	Antibodies to HIV-1/2 (anti-HIV Ab) test	For screening blood donations for HIV	RDT[1]	Capillary whole blood Venous whole blood Serum Plasma	Public reports of WHO prequalified IVDs https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report	Screening donated blood for transfusion transmissible infections: recommendations (2009) http://apps.who.int/iris/handle/10665/44202
			Particle agglutination assay[1]	Serum Plasma		
			Immunoassay[1,2]	Serum Plasma		
	Combined HIV antibody/p24 antigen (anti-HIV/p24 Ag) test	For screening blood donations for HIV	Immunoassay[1,2]	Serum Plasma		
Treponema pallidum	Antibodies to T. pallidum	For screening blood donations for syphilis	Immunoassay[1,2,3]	Serum Plasma	N/A	
Other transfusion-transmitted organisms	To screen for e.g. *Trypanosoma cruzi*, human T-lymphotropic virus (HTLV I/II), Zika virus, *Babesia* and West Nile virus in blood donations, depending on local risk of contamination.		Immunoassay[1,2]	Serum Plasma	N/A	

[1] The only assays recommended for blood screening purposes are those that have been validated for this purpose by the manufacturer.
[2] May be performed in laboratories with small throughput, in remote areas or emergency situations.
[3] In populations with a high incidence of syphilis, screening should be performed with a non-treponemal assay: venereal disease research laboratory (VDRL) or rapid plasma reagin (RPR)

NOTE: Please refer to the Haematology section for information on General IVDs for blood transfusion.

Commented [SS33]: ID 221 (h) MSF
Malaria should be added to this list of additional consideration based on epidemiological context