First WHO Model List of Essential In Vitro Diagnostics
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Abbreviations and acronyms

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

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

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

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

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

While the EDL provides a list of tests required at various levels of the health care system, the EDL cannot be useful without an integrated, connected, tiered laboratory system, with adequate human resources, training, laboratory
infrastructure and regulatory and quality-assurance systems (5). Its impact also requires adoption and adaptation of the EDL by Member States, establishment of national and regional EDLs and the selection and supply mechanisms necessary to ensure access to the IVDs.

This report presents the first EDL and describes the process by which it was established and proposed next steps.
2. First WHO Model List of Essential In Vitro Diagnostics

2.1 Explanatory notes

2.1.1 Scope of the first EDL

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

The EDL consists of:

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

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

2.1.2 Content and format

The first EDL consists of:

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

for a total of 62 test categories and 107 test formats.

For each test listed in the EDL, the following are described:

- test purpose;
- assay format;
- specimen type;
2.1.3 Recommended use of the EDL

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

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

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

2.1.4 Glossary

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

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

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

Medical device. Any article, apparatus, instrument, machine, appliance, implant, reagent for in vitro use, software, material or other similar related articles,
intended to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

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

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

2.2 Model List of Essential In Vitro Diagnostics

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

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

I. For primary health care

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

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2 WHO documents used to compile general laboratory tests for the first EDL are listed under “Sources used for general laboratory tests.”
tests are available, but there are either no laboratories or only small laboratories with trained health care personnel but no trained laboratory technicians. If laboratory facilities are available in a primary health care facility, please refer to the IVDs described in the next tier. In some cases, samples may be taken where there are no laboratories and processed at the next tier.
## I.a General IVDs for primary health care

<table>
<thead>
<tr>
<th>Use</th>
<th>Diagnostic test</th>
<th>Test purpose</th>
<th>Assay format</th>
<th>Specimen type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haematology</td>
<td>Haemoglobin (Hb)</td>
<td>Diagnosis and monitoring of anaemia</td>
<td>Haemoglobinometer</td>
<td>Capillary whole blood</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Key clinical marker for severe infections (i.e. malaria, dengue, viral haemorrhagic fevers)</td>
<td></td>
<td>Venous whole blood</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Safety monitoring when using certain drugs (e.g. Zidovudine for HIV infection)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dipstick</td>
<td>Urine</td>
</tr>
<tr>
<td>White blood cell count</td>
<td></td>
<td>Surrogate marker for certain infections, inflammation or certain cancers (e.g. leukaemia)</td>
<td>Haematology analyser</td>
<td>Capillary whole blood</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Venous whole blood</td>
</tr>
<tr>
<td>Complete blood count (CBC)</td>
<td></td>
<td>To detect anaemia, infections and leukaemia</td>
<td>Haemocytometer (to measure WBC) and Wright, May-Grünwald or Giemsa stain (for differential detection of parasites, malignant cells)</td>
<td>Capillary whole blood</td>
</tr>
<tr>
<td>(CBC) manual (only as back-up to automated method)</td>
<td></td>
<td></td>
<td></td>
<td>Venous whole blood</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Peripheral blood film examination</td>
<td>Capillary whole blood</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Venous whole blood</td>
</tr>
<tr>
<td>Use</td>
<td>Diagnostic test</td>
<td>Test purpose</td>
<td>Assay format</td>
<td>Specimen type</td>
</tr>
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<td>----------------------------------------</td>
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</tr>
<tr>
<td>Clinical chemistry and immunoassays</td>
<td>Albumin</td>
<td>To detect/monitor kidney disease</td>
<td>Dipstick</td>
<td>Urine</td>
</tr>
<tr>
<td></td>
<td>Bilirubin</td>
<td>To detect/monitor liver disease, liver/pancreas and bile duct disorders, and red cell destruction</td>
<td>Dipstick</td>
<td>Urine</td>
</tr>
<tr>
<td></td>
<td>Glucose</td>
<td>To diagnose and screen for diabetes and intermediate hyperglycaemia, to diagnose hypoglycaemia</td>
<td>Dipstick</td>
<td>Capillary whole blood Urine</td>
</tr>
<tr>
<td></td>
<td>Haemoglobin A1c (HbA1c)</td>
<td>Diagnosis and monitoring of diabetes mellitus</td>
<td>Handheld and small analyser</td>
<td>Capillary whole blood</td>
</tr>
<tr>
<td></td>
<td>Whole blood lactate</td>
<td>To assess metabolic acidosis, diabetic keto-acidosis, sepsis and dehydration</td>
<td>Electro-analytical method Handheld analyser</td>
<td>Arterial whole blood Venous whole blood</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>Blood typing</td>
<td>To determine blood compatibility for blood transfusions; Rh typing for pregnant women</td>
<td>Antisera for agglutination</td>
<td>Capillary whole blood Venous whole blood</td>
</tr>
<tr>
<td>Serology</td>
<td>Human chorionic gonadotropin (hCG)</td>
<td>Pregnancy</td>
<td>Dipstick</td>
<td>Urine</td>
</tr>
<tr>
<td>Use</td>
<td>Diagnostic test</td>
<td>Test purpose</td>
<td>Assay format</td>
<td>Specimen type</td>
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</tr>
<tr>
<td>Microbiology, mycology and parasitology</td>
<td>Urine dipstick and urine microscopy</td>
<td>Detection of UTIs (dipstick) and identification of red and white blood cells, casts, squamous epithelial cells, bacteria, yeast, <em>Schistosoma haematobium</em> and other cellular components (microscopy)</td>
<td>Multi-parameter strips (dipstick) and light microscopy</td>
<td>Urine</td>
</tr>
<tr>
<td>Microscopy</td>
<td>Microbial morphology, presence/absence of white blood cells versus squamous epithelial cells for presumptive identification</td>
<td>Microscopic examination of slides as wet preparations or which have been treated with a variety of organism-specific chemical stains (e.g. Gram stain)</td>
<td>Disease appropriate specimens (e.g. venous whole blood, urine, stool, etc.)</td>
<td></td>
</tr>
<tr>
<td>Disease</td>
<td>Diagnostic test</td>
<td>Test purpose</td>
<td>Assay format</td>
<td>Specimen type</td>
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<tr>
<td></td>
<td></td>
<td>Staging to assess the need for HBV treatment in chronic HBV infection</td>
<td>RDT</td>
<td>Capillary whole blood</td>
</tr>
<tr>
<td>Hepatitis B e antigen (HBeAg)</td>
<td></td>
<td>Screening for HCV infection: infants &gt; 18 months of age, children, adolescents, adults</td>
<td>RDT</td>
<td>Oral fluid Capillary whole blood</td>
</tr>
<tr>
<td>Disease</td>
<td>Diagnostic test</td>
<td>Test purpose</td>
<td>Assay format</td>
<td>Specimen type</td>
</tr>
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</tr>
</tbody>
</table>

For the diagnosis of HIV infection: adults, adolescents, children and infants over 18 months of age

<table>
<thead>
<tr>
<th>WHO prequalified or recommended products</th>
<th>WHO supporting documents</th>
</tr>
</thead>
</table>

Guidelines on HIV self-testing and partner notification (2016) http://apps.who.int/iris/bitstream/handle/10665/251655/9789241549868-eng.pdf?sequence=1

Consolidated guidelines on HIV testing services (July 2015) http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/

<table>
<thead>
<tr>
<th>Disease</th>
<th>Diagnostic test</th>
<th>Test purpose</th>
<th>Assay format</th>
<th>Specimen type</th>
<th>WHO prequalified or recommended products</th>
<th>WHO supporting documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease</td>
<td>Diagnostic test</td>
<td>Test purpose</td>
<td>Assay format</td>
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<td>WHO prequalified or recommended products</td>
<td>WHO supporting documents</td>
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</tr>
<tr>
<td></td>
<td></td>
<td><em>Plasmodium</em> spp.</td>
<td>For diagnosis of one or more human malaria species (<em>P. falciparum</em>, <em>P. vivax</em>, <em>P. malariae</em>, <em>P. ovale</em> and <em>P. knowlesi</em>) and monitoring response to treatment</td>
<td>Light microscopy (if good quality microscopy available)</td>
<td>Capillary whole blood</td>
<td></td>
</tr>
</tbody>
</table>
**Table I.b continued**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Diagnostic test</th>
<th>Test purpose</th>
<th>Assay format</th>
<th>Specimen type</th>
<th>WHO prequalified or recommended products*</th>
<th>WHO supporting documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Malaria microscopy standard operating procedures (2015) <a href="http://www.wpro.who.int/mvp/lab_quality/mm_sop/en/">http://www.wpro.who.int/mvp/lab_quality/mm_sop/en/</a></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Tuberculosis</strong></td>
<td></td>
</tr>
</tbody>
</table>

* All TB tests are evaluated and guidelines developed through the WHO Global TB Programme.
Table I.b continued

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

This list is for district, regional, provincial or specialized hospitals or laboratories and national reference laboratories. Trained laboratory technicians, specialist expertise and laboratory infrastructure and equipment are available at the appropriate level. All diagnostic tests available at the primary care level are assumed to be available at higher levels, as appropriate. The list comprises: section a for general laboratory equipment and section b for tests for specific diseases.
<table>
<thead>
<tr>
<th>Diagnostic test</th>
<th>Test purpose</th>
<th>Use</th>
<th>Specimen type</th>
<th>Assay format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alanine aminotransferase (ALT)</td>
<td>To assess liver function (often done with aspartate aminotransferase AST))</td>
<td>Clinical chemistry and immunoassays</td>
<td>Serum, plasma</td>
<td>Optical and electro-analytical methods</td>
</tr>
<tr>
<td>Alkaline phosphatase</td>
<td>To detect or monitor malnutrition, liver or kidney disease</td>
<td></td>
<td>Urine, Serum, Plasma</td>
<td>Photometric, turbidimetric and nephelometric testing</td>
</tr>
<tr>
<td>Albumin</td>
<td>To detect liver function</td>
<td></td>
<td>Serum, Plasma</td>
<td>Colorimetric testing</td>
</tr>
<tr>
<td>Aspartate aminotransferase (AST)</td>
<td>To assess liver function (often done with alanine aminotransferase ALT))</td>
<td></td>
<td>Serum, Plasma</td>
<td>Colorimetric testing</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>To detect/monitor liver disease, liver/pancreas and bile duct disorders, and red cell destruction</td>
<td></td>
<td>Serum, Plasma</td>
<td>Electro-analytical methods, including portable analysers</td>
</tr>
<tr>
<td>Blood pH and gases</td>
<td>To assess kidney function and disease</td>
<td></td>
<td>Arterial whole blood, Venous whole blood</td>
<td>Measurement of blood pH, oxygen and carbon dioxide</td>
</tr>
<tr>
<td>Blood urea nitrogen (BUN)</td>
<td>To assess kidney function and disease</td>
<td></td>
<td>Serum, Plasma</td>
<td>Optical and electro-analytical methods</td>
</tr>
<tr>
<td>Use</td>
<td>Diagnostic test</td>
<td>Test purpose</td>
<td>Assay format</td>
<td>Specimen type</td>
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<td>-----------------</td>
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<td>--------------</td>
<td>---------------</td>
</tr>
</tbody>
</table>
| Clinical chemistry and immunoassays continued | Creatinine | To estimate glomerular filtration rate (eGFR) and urine albumin/creatinine ratio  
Key clinical marker for management of severe infections (i.e. sepsis, Lassa fever), and antimicrobial regimen adjustment | Optical and electro-analytical methods | Serum  
Urine |
| Electrolytes | | To monitor organ damage and electrolyte alterations | Optical and electro-analytical methods | Serum  
Plasma |
| Glucose | | To diagnose and screen for diabetes and intermediate hyperglycaemia, to diagnose hypoglycaemia | Automated analyser | Plasma  
Serum |
| Haemoglobin A1c (HbA1c) | | Diagnosis and monitoring of diabetes mellitus | ELISA  
Automated analyser | Capillary whole blood  
Venous whole blood |
| C-reactive protein (CRP) | | To detect inflammation as an indicator of various conditions (e.g. cardiovascular disease [CVD] – high sensitivity CRP required - sepsis) | RDT  
EIA | Venous whole blood  
Serum  
Plasma |
| Lipid profile | | To assess risk of developing CVD and type 2 diabetes by measuring cholesterol, triglycerides and lipoproteins | Colourimetry  
Spectrophotometry | Plasma  
Serum |
<table>
<thead>
<tr>
<th>Use</th>
<th>Diagnostic test</th>
<th>Test purpose</th>
<th>Assay format</th>
<th>Specimen type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical chemistry and immunoassays</td>
<td>Basic metabolic panel (BMP)</td>
<td>Includes glucose, sodium chloride, carbon dioxide, blood urea nitrogen (BUN), BUN/creatinine ratio, glomerular filtration rate (eGFR) and may include calcium</td>
<td>Photometric and colorimetric testing, ion-selective potentiometry (8-parameter automated clinical chemistry analyser)</td>
<td>Venous whole blood Serum Plasma</td>
</tr>
<tr>
<td></td>
<td>Comprehensive metabolic panel</td>
<td>BMP plus magnesium, protein, albumin, globulin, albumin/globulin ratio, bilirubin (direct or total), alkaline phosphatase, alanine and aspartate aminotransferases (ALT and AST)</td>
<td>As with BMP (14 or more parameter automated clinical chemistry analyser)</td>
<td>Venous whole blood Serum Plasma</td>
</tr>
<tr>
<td></td>
<td>Amylase and lipase</td>
<td>To assess acute pancreatitis</td>
<td>Colourimetric and photometric analysers</td>
<td>Serum Peritoneal fluid (Amylase)</td>
</tr>
<tr>
<td></td>
<td>Troponin T/I</td>
<td>For diagnosis of myocardial infarction</td>
<td>EIA (handheld or large automated instrument)</td>
<td>Venous whole blood Plasma</td>
</tr>
<tr>
<td></td>
<td>Urinalysis</td>
<td>Detection of substances in the urine associated with metabolic disorders, renal dysfunction or urinary tract infections</td>
<td>Automated chemical analyser</td>
<td>Urine</td>
</tr>
</tbody>
</table>

Table II.a continued
<table>
<thead>
<tr>
<th>Use</th>
<th>Diagnostic test</th>
<th>Test purpose</th>
<th>Assay format</th>
<th>Specimen type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood transfusion</td>
<td>Blood cross-matching</td>
<td>To determine blood compatibility for blood transfusions; Rh typing for pregnant women</td>
<td>Antisera for agglutination</td>
<td>Venous whole blood</td>
</tr>
<tr>
<td>Transfusion transmitted infections</td>
<td>Antisera for agglutination</td>
<td>To screen for e.g. Chagas, human T-lymphotropic virus (HTLV) in the blood supply etc. (see also EDL sections on HIV &amp; syphilis)</td>
<td>EIA (microplate) Manual method</td>
<td>Serum Plasma</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CLIA/ECL (automated instrument)</td>
<td>Serum Plasma</td>
</tr>
<tr>
<td>Serology</td>
<td>Human chorionic gonadotropin (hCG)</td>
<td>Pregnancy</td>
<td>Optical method</td>
<td>Serum</td>
</tr>
<tr>
<td>Microbiology, mycology and parasitology</td>
<td>Urine dipstick and urine microscopy</td>
<td>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)</td>
<td>Multi-parameter strips (dipstick) and light microscopy</td>
<td>Urine</td>
</tr>
<tr>
<td>Microscopy</td>
<td>Microbial morphology, presence or absence of white blood cells versus squamous epithelial cells for presumptive identification</td>
<td>Microscopic examination of slides as wet preparations or which have been treated with organism-specific chemical stains (e.g. Gram stain)</td>
<td>Disease appropriate specimens (e.g. venous whole blood, urine, stool, cerebrospinal fluid, etc.)</td>
<td></td>
</tr>
<tr>
<td>Use</td>
<td>Diagnostic test</td>
<td>Test purpose</td>
<td>Assay format</td>
<td>Specimen type</td>
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</tr>
<tr>
<td>Microbiology, mycology and parasitology</td>
<td>Culture</td>
<td>Initial step in detection and identification of bacterial species for selection of appropriate antibiotic regimens</td>
<td>Culture on growth media plates in an incubator followed by recovery of isolates and species identification (traditional manual techniques or automated equipment)</td>
<td>Disease appropriate specimens (e.g., venous whole blood, urine, stool, cerebrospinal fluid etc.)</td>
</tr>
<tr>
<td>Blood culture</td>
<td></td>
<td>For the diagnosis of bacterial and fungal bloodstream infections (sepsis)</td>
<td>Blood culture bottle in an incubator followed by recovery of isolates and species identification (traditional manual techniques or automated equipment)</td>
<td>Venous whole blood</td>
</tr>
<tr>
<td>Antimicrobial susceptibility testing</td>
<td></td>
<td>Final step in selection of appropriate antibiotic regimens after species identification</td>
<td>Antimicrobial susceptibility testing of isolates – may be done manually by disc diffusion technique or automated platforms</td>
<td>Microbial isolates</td>
</tr>
<tr>
<td>Haematology</td>
<td>Haematocrit (Ht)</td>
<td>Diagnosis and monitoring of anaemia Volume of red blood cells as a percentage of total blood volume</td>
<td>Micro-haematocrit centrifuge</td>
<td>Capillary or venous whole blood</td>
</tr>
</tbody>
</table>
### Table II.a continued

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

<table>
<thead>
<tr>
<th>Disease</th>
<th>Diagnostic test</th>
<th>Test purpose</th>
<th>Assay format</th>
<th>Specimen type</th>
<th>WHO prequalified or recommended products</th>
<th>WHO supporting documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virological (HBV DNA – quantitative)</td>
<td></td>
<td>Staging to assess the need for treatment in chronic HBV infection and monitoring of response to treatment</td>
<td>Nucleic acid test</td>
<td>Serum Plasma</td>
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</tbody>
</table>
### Table II.b continued

<table>
<thead>
<tr>
<th>Disease</th>
<th>Diagnostic test</th>
<th>Test purpose</th>
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<th>WHO supporting documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B continued</td>
<td>Hepatitis B e antigen (HBeAg)</td>
<td>Staging to assess the need for HBV treatment in chronic HBV infection</td>
<td>EIA</td>
<td>Serum</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Plasma</td>
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<td></td>
<td></td>
<td></td>
<td>CLIA</td>
<td>Serum</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IgM-specific antibodies to hepatitis B</td>
<td>For the diagnosis of acute HBV infection – used for</td>
<td>EIA (microplate) Manual method</td>
<td>Serum</td>
<td>Serum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>core antigen (IgM anti-HBc)</td>
<td>outbreak investigation</td>
<td></td>
<td></td>
<td>Plasma</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>CLIA/ECL</td>
<td>Serum</td>
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<td></td>
<td></td>
<td></td>
<td>Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antibodies to hepatitis B surface</td>
<td>To determine effectiveness of HBV vaccination at</td>
<td>EIA (microplate) Manual method</td>
<td>Serum</td>
<td>Serum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>antigen (anti-HBs)</td>
<td>patient and at a population level Also used as a</td>
<td></td>
<td></td>
<td>Plasma</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>marker for recovery from HBV infection</td>
<td></td>
<td>CLIA/ECL</td>
<td>Serum</td>
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<td>Plasma</td>
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### Table II.b continued

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<tbody>
<tr>
<td></td>
<td>Antibodies to HCV (anti-HCV)</td>
<td></td>
<td>EIA (microplate) Manual method</td>
<td>Serum Plasma</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>CLIA/ECL (automated instrument)</td>
<td>Serum Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Antibodies to HCV (anti-HCV) and HCV core antigen (HCV cAg)</td>
<td>Screening for past or present HCV infection: infants &gt; 18 months of age, children, adolescents, adults</td>
<td>EIA (microplate) Manual method</td>
<td>Serum Plasma</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>CLIA/ECL (automated instrument)</td>
<td>Serum Plasma</td>
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<tr>
<td></td>
<td>HCV core antigen (HCV cAg)</td>
<td>For diagnosis of viraemic HCV</td>
<td>CLIA/ECL (automated instrument)</td>
<td>Serum Plasma</td>
<td></td>
<td></td>
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<tr>
<td>Disease</td>
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</tr>
<tr>
<td>Hepatitis C continued</td>
<td>HCV RNA (qualitative or quantitative)</td>
<td>For diagnosis of viraemic HCV and monitoring of response to treatment as a test of cure</td>
<td>Nucleic acid test</td>
<td>Serum, Plasma</td>
<td>WHO prequalified or recommended products</td>
<td>WHO supporting documents</td>
</tr>
</tbody>
</table>

Guidelines on HIV self-testing and partner notification (2016) http://apps.who.int/iris/bitstream/handle/10665/251655/9789241549868-eng.pdf?sequence=1

Consolidated guidelines on HIV testing services (July 2015) http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/
<table>
<thead>
<tr>
<th>Disease</th>
<th>Diagnostic test</th>
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</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>CLIA/ECL (automated instrument)</td>
<td>Serum</td>
<td>WHO supporting documents</td>
<td></td>
</tr>
</tbody>
</table>
Table II.b continued

<table>
<thead>
<tr>
<th>Disease</th>
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Table II.b continued

<table>
<thead>
<tr>
<th>Disease</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>EIA</td>
<td>Cerebrospinal fluid</td>
<td>Serum Plasma</td>
<td></td>
</tr>
<tr>
<td>Disease</td>
<td>Diagnostic test</td>
<td>Test purpose</td>
<td>Assay format</td>
<td>Specimen type</td>
<td>WHO prequalified or recommended products</td>
<td>WHO supporting documents</td>
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<tr>
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</tr>
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</table>
Malaria microscopy standard operating procedures (2015) http://www.wpro.who.int/mvp/lab_quality/mm_sop/en/ |
<table>
<thead>
<tr>
<th>Disease</th>
<th>Diagnostic test</th>
<th>Test purpose</th>
<th>Assay format</th>
<th>Specimen type</th>
<th>WHO prequalified or recommended products</th>
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</tr>
</thead>
</table>

For screening newborns for G6PD deficiency
<table>
<thead>
<tr>
<th>Disease</th>
<th>Diagnostic test</th>
<th>Test purpose</th>
<th>Assay format</th>
<th>Specimen type</th>
<th>WHO prequalified or recommended products*</th>
<th>WHO supporting documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuberculosis</td>
<td></td>
<td>For diagnosis and treatment monitoring of active TB including drug-resistant TB</td>
<td>Bacterial culture</td>
<td>Sputum or other specimen types</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* All TB tests are evaluated and guidelines developed through the WHO Global TB Programme.
Table II.b continued

<table>
<thead>
<tr>
<th>Disease</th>
<th>Diagnostic test</th>
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<tr>
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</tr>
</thead>
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<tr>
<th>Disease</th>
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<tr>
<th>Disease</th>
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<th>Test purpose</th>
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<tr>
<th>Disease</th>
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<th>Specimen type</th>
<th>WHO prequalified or recommended products</th>
<th>WHO supporting documents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Syphilis</strong></td>
<td>Antibodies to <em>Treponema pallidum</em></td>
<td>For diagnosis or as an aid in the diagnosis of <em>T. pallidum</em></td>
<td>RDT</td>
<td>Venous whole blood Plasma Serum</td>
<td>Public reports of WHO prequalified IVDs (<a href="http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/">http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/</a>)</td>
<td>WHO laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus (2013) <a href="http://apps.who.int/iris/bitstream/handle/10665/85343/9789241505840_eng.pdf?sequence=1">http://apps.who.int/iris/bitstream/handle/10665/85343/9789241505840_eng.pdf?sequence=1</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Serum Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EIA (Microplate Manual method)</td>
<td>Serum Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CLIA/ECL (automated instrument)</td>
<td>Serum Plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease</td>
<td>Diagnostic test</td>
<td>Test purpose</td>
<td>Assay format</td>
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</tr>
<tr>
<td>Syphilis continued</td>
<td>For screening blood and blood products</td>
<td>EIA (Microplate) Manual method</td>
<td>Serum, Plasma</td>
<td></td>
<td></td>
<td>Screening donated blood for transfusion transmissible infections (2009) <a href="http://apps.who.int/iris/bitstream/handle/10665/44202/9789241547888_eng.pdf?sequence=1&amp;isAllowed=y">Link</a></td>
</tr>
<tr>
<td>Combined antibodies to <em>T. pallidum</em> and to HIV-1/2 (anti-HIV)</td>
<td>For the diagnosis or as an aid in the diagnosis of HIV-1/2 and/or <em>T. pallidum</em></td>
<td>RDT</td>
<td>Venous whole blood, Plasma, Serum</td>
<td></td>
<td><a href="http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/">Link</a></td>
<td>WHO Information note on the use of dual HIV/ syphilis rapid diagnostic tests (RDT) (2017) <a href="http://apps.who.int/iris/bitstream/handle/10665/252849/WHO-RHR-17.01-eng.pdf?sequence=1">Link</a></td>
</tr>
</tbody>
</table>
3. Methods used to establish the List

3.1 Strategic Advisory Group of Experts on In Vitro Diagnostics

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

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

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

4 Except where policy and technical recommendations on IVD are provided through WHO established advisory mechanisms, such as for HIV, tuberculosis and malaria. For these, SAGE IVD would accept such recommendations without further review and incorporate such advice in its consideration of organization-wide policies.
f. provide high level advice on development and maintenance of appropriate standards for IVDs, including methodologies for evidence review;

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

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

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

3.2 Selection of IVDs for inclusion in the first EDL

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

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

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

- principles that should guide preparation of the EDL;

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5 WHO documents reviewed to compile and propose the general laboratory tests for the first EDL are listed under “Sources used for general laboratory test.”
Methods used to establish the List

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

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

3.3 **Principles that should guide preparation of the EDL**

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

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

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

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

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6 WHO documents reviewed to compile and propose the general lab tests for the first draft EDL are listed in the reference section under WHO sources for general laboratories.
- helping IVD designers and manufacturers to develop new or improved IVDs, including through target product profiles; and
- supporting the rational use of medicines in the WHO Model List of Essential Medicines.

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

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

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

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

3.4 **Draft first EDL proposed by the Secretariat**

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

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

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

- A chart of the laboratory tests chosen for inclusion, consisting of IVD tests for physiological evaluation of patients and detection and diagnosis of diseases and IVD tests for the detection, diagnosis and monitoring of WHO priority diseases: HIV infection, TB, malaria, hepatitis B, hepatitis C, syphilis and HPV infection. The list will include links to WHO technical information.

- Procedures for revising the EDL, including methods for assessing candidate IVDs for inclusion, priorities for inclusion of IVDs in subsequent EDLs and procedures for addressing applications for inclusion or deletion.

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

3.4.1 Method for assessing IVDs for inclusion or deletion

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

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

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

The SAGE IVD also agreed that:

- assessment of the clinical accuracy of a test in the setting in which it would be used will generally be required;
- the required accuracy of a tests will be difficult to decide, given that clinical accuracy depends on reference standards, patient populations and testing protocols;
- randomized controlled clinical trials are not necessarily applicable for assessing the performance of IVDs; and
- evidence of impact on disease detection and management may be easier to obtain and more useful than evidence of impact on patient outcomes.

3.4.2 Identification of high-priority IVDs for the EDL

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

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

Antimicrobial resistance

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

Fungal diseases

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

Influenza

The gold standard in testing is polymerase chain reaction, for which there are a number of commercial kits. The Centers for Disease Control and Prevention in the USA (USCDC) has an in-house test that is updated regularly; primers and probes are made available only to national reference laboratories and public health laboratories.
Reproductive health
The priority IVDs for reproductive health are point-of-care tests for syphilis, HPV infection and *N. gonorrhoeae*. WHO recommends that all pregnant women be screened for syphilis as part of the universal health coverage package. HPV testing and treatment of pre-cancerous cervical lesions are also part of the package for women, and WHO will launch a campaign on HPV testing in 2018. Point-of-care testing for *N. gonorrhoeae* is considered important to ensure appropriate selection of antibiotic.

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

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

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

SAGE IVD agreed that the above list of priority conditions, with the addition of sepsis, could usefully guide prioritization of IVDs for inclusion in
the next editions of EDL. With regard to antimicrobial resistance, SAGE IVD agreed that the GLASS list of priority pathogens for surveillance should guide assessment of candidate IVDs for the EDL.
4. Integration of the EDL with other WHO initiatives

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

WHO Expert Committee on Biological Standardization

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

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

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

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

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

The SAGE IVD agreed that:

- existing recommendations for IVD use in the proposed WHO priority disease areas would form the basis for inclusion of IVDs in the first edition of the EDL;
testing for cryptococcal antigen in blood and cerebrospinal fluid would be included in the HIV section; and

- tests included in the EDL should be commercially available.

**General laboratory tests**

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

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

**WHO Prequalification of In Vitro Diagnostics**

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

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

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

- burden of disease associated with the target condition;

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7 WHO documents reviewed to compile and propose the general lab tests for the first draft EDL are listed in the reference section under WHO sources for general laboratories.
- health interventions associated with the IVD;
- existence of WHO recommendations for the IVD;
- EDL listing of the IVD;
- current demand for similar tests; and
- expectation of donor funding for supplying the IVD.

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

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

The SAGE IVD agreed that all applications should include:

- information on the applicant:
  - name of and information about the person or organization making the application; and
  - name(s) of and information about the people or institutions consulted on or supporting the application;

- the disease or condition addressed:
  - evidence of the public health importance of the disease or condition;
  - how the candidate IVD contributes to diagnosis or treatment; and
  - how the disease or condition affects the mortality, morbidity, quality of life or economic status of patients;

- description of the IVD:
  - intended use, test utility and method;
  - specimen type and sample volume;
  - performance;
  - how results are provided to the intended user;
  - storage and transport requirements; and
  - biosafety requirements;

- summary of evidence:
  - studies of diagnostic accuracy;
  - evaluations;
  - clinical evidence;
  - non-clinical data: appraisals of quality and ease of use;

- social issues:
  - ethics;
- human rights; and
- equity;

- impact on health care system:
  - comparative cost and cost–effectiveness;
  - resource and budget impact on health care systems, including human resources and supplies of consumables; and
  - sustainability;

- proposed text for the EDL.

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

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

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

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

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

- Recognizing the importance of tests for a wide variety of diseases, the EDL should include a broad list of general laboratory tests, as well as tests for the following initial set of diseases, pursuant to WHO policy and for which there is high-quality guidance: HIV infection, TB, malaria, hepatitis B, hepatitis C, HPV infection and syphilis.

- The EDL Secretariat should consider including tests for the following priority diseases or conditions in future editions of the EDL: antimicrobial resistance, neglected tropical diseases, noncommunicable diseases, outbreaks and emergencies and sepsis.

- The EDL Secretariat should include a detailed preface to the EDL to explain its objectives, limitations and guidance for use. The preface should include: the scope of the EDL, definitions of health service levels, the rationale for the contents and the importance of adapting the list to local or regional settings and conditions.

- The EDL Secretariat should emphasize that, while the EDL provides a list of important tests for use at various levels of the health system, the list will not be useful without an integrated, connected, tiered laboratory system, with adequate human resources, training, laboratory infrastructure and regulatory and quality assurance systems.

- Member States can adapt the EDL and prepare national or regional EDLs; they should also ensure the necessary mechanisms for impact.

- Revise and update the WHO technical documents that constitute resources for the EDL to ensure that they are relevant and current. This task should be a priority, if necessary supported by WHO collaborating centres, other institutions and SAGE IVD.

- Support EDL with a dedicated page on the WHO website containing information on IVDs and laboratories.

- The EDL Secretariat should review the WHO prequalification process, and acknowledge that it plays an important role in increasing access to IVDs of assured quality, safety and performance. SAGE IVD appreciates that EDL and prequalification are complementary in improving access of Member States to IVDs.

On 20 April 2018, an open session was held with SAGE IVD members and representatives of nongovernmental organizations, trade associations and
WHO Member States to discuss the outcomes of the first SAGE IVD meeting. It was agreed that, for future EDLs, an open session will be held before the SAGE IVD meeting to discuss issues raised during the open consultation.
References


WHO sources used to select the general laboratory tests


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


The sources also included

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

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

WHO thanks the Department for International Development, United Kingdom, for providing a funding grant to support the EDL.
Annex 1

Participants in the first meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics
Geneva, Switzerland, 16–20 April 2018

Members

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

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

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

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

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

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

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

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

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

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

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

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

8 Unable to attend: Professor P.E. Castle, Department of Epidemiology and Population Health, Albert Einstein College of Medicine, New York City (NY), United States of America (USA); Dr W. Sikhondze, Technical Advisor and Research Coordinator, Swaziland National Tuberculosis Control Programme, Mbabane, Eswatini.
Professor A. Newland, Haematology, The Royal London Hospital, Barts Health NHS Trust, London, England

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

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

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

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

Observers

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

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

Secretariat (World Health Organization, Geneva, Switzerland)

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

Dr T. Besselaar, Technical Officer, High Threat Pathogens

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

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

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

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

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

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

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

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

Dr I. Knezevic, Team Leader, Technologies, Standards and Norms, Department of Essential Medicines and Health Products
First WHO Model List of Essential In Vitro Diagnostics

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

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

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

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

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

Murtagh, Evanston, IL, USA (WHO Consultant)

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

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

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

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

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

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

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

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

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

Dr S. Swaminathan, Deputy Director-General for Programmes

Dr M. Taylor, Medical Officer, Human Reproduction

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

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

Dr L. Vojnov, Technical Officer (Diagnostics Adviser), Treatment and Care, HIV/AIDS
Annex 2

Declarations of interest of SAGE IVD members

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

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

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

Dr Sally Hojvat advised the Group that, in 2016–2017, she reviewed dossiers on two HPV diagnostic devices and subsequent responses on deficiencies from diagnostics companies for the WHO prequalification team. She also reviewed several documents on product technical specifications for the WHO prequalification team in 2016–2017. Additionally, she provides advice to a regulatory contractor for non-profit institutions and commercial diagnostic companies on matters related to the US Food and Drug Administration pre- and post-commercialization regulatory policy, which involves infectious disease diagnostics (except for HIV laboratory tests of moderate complexity). She provides advice to the same contractor on matters related to the protection of human subjects in clinical trials for diagnostic devices. Further, Dr Hojvat was the Director of the Division of Microbiology at the US Food and Drug Administration, which was responsible for reviewing and evaluating the safety and effectiveness of all IVD microbiology devices (reagents, software and instruments) submitted to the US Food and Drug Administration for pre-market device clearance, approval, waiver of the Clinical Laboratory Improvement Amendments and Emergency Use Authorization and was responsible for ensuring pre-market and post-market compliance associated with IVD microbiology devices. She also represented the US Food and Drug Administration on human subject protection
and was responsible for outreach on IVDs for infectious diseases, including the response to emerging pathogens such as influenza H1N1, Middle East respiratory syndrome, and Ebola virus, and potential biological threats such as anthrax and plague, working with US health and human services agencies (Biomedical Advanced Research and Development Authority, National Institutes of Health, Public Health Emergency Medical Countermeasures Enterprise), the Department of Defense research laboratories and WHO prequalification regulatory teams.

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