

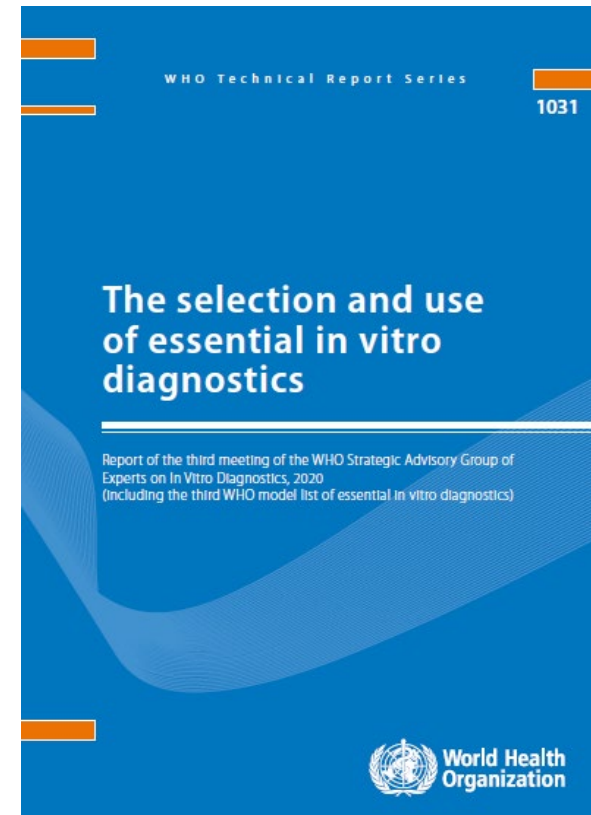
WHO model list of essential in vitro diagnostics (EDL)

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What is the EDL?

The WHO model list of essential in vitro diagnostics (EDL) is an evidence-based register of categories of IVD tests and recommendations (e.g., assay format, test purpose, specimen type) for those tests.

- First edition (May 2018): 62 unique IVDs
- Second edition (November 2019): 113 unique IVDs
- Third edition (January 2021): 142 unique IVDs



Objectives of the EDL

The EDL is intended to support IVD policy development to improve people access to IVD testing and clinical laboratory services

- To provide evidence-based guidance for countries to create or update their national EDL
- To prioritize IVDs that should be available at different levels of the healthcare system
- To inform United Nations agencies and NGOs that support the selection, procurement, supply or donation of IVDs
- To provide guidance to the private health technology and manufacturing sectors about the IVDs priorities required to address global health issues

Scope of EDL 3

The EDL includes general and disease-specific tests for non-communicable disease (NCD) and infectious diseases

General tests	Disease-specific
Anatomical pathology	Aspergillosis
Blood typing	Cancer
Clinical chemistry	Chagas disease
Clinical microbiology	Cholera
Clinical pathology	COVID-19
Haematology	Diabetes mellitus
Pregnancy testing	Endocrine disorders
	Hepatitis B
	Hepatitis C
	HIV
	Human papillomavirus
	Influenza
	Malaria
	Neglected tropical diseases
	Pneumocystis pneumonia
	Primary immunodeficiencies
	Streptococcal pharyngitis
	Sickling disorders
	Sexually transmitted infections
	Syphilis
	Tuberculosis
	Vaccine preventable diseases
	Visceral leishmaniasis
	Zika virus

Presentation of the EDL 3

The WHO EDL is presented by health-care facility level in **two tiers** and a “Do Not Do” recommendations section

Community settings and health facilities without laboratories



I.a General tests (arranged by discipline)

I.b Disease-specific tests (arranged by disease)

Health care facilities with clinical laboratories



II.a General tests (arranged by discipline)

II.b Disease-specific tests (arranged by disease)

II.c Bloods screening tests

Do Not Do recommendations



Refer to test categories that have been listed for discontinuation

Example of EDL 3 entry

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
Diabetes mellitus <i>continued</i>	Haemoglobin A1c (HbA1c)	To diagnose and monitor diabetes mellitus	Handheld and small analysers	Capillary whole blood	N/A	HEARTS-D: diagnosis and management of type 2 diabetes (2020) https://www.who.int/publications/i/item/who-ucn-ncd-20.1 https://www.who.int/health-topics/diabetes#tab=tab_1
Hepatitis B virus (HBV) infection	Hepatitis B surface antigen (HBsAg)	To screen for HBV infection, or to aid in the diagnosis of chronic and acute HBV infection: infants > 12 months of age, children, adolescents and adults	RDT	Capillary whole blood Venous whole blood ¹⁰	Public reports of WHO prequalified IVDs https://extranet.who.int/pqweb/vitro-diagnostics/prequalification-reports/whopr?field_whoprcategory=63	Guidelines on hepatitis B and C testing (February 2017) https://apps.who.int/iris/handle/10665/254621 https://www.who.int/news-room/fact-sheets/detail/hepatitis-b

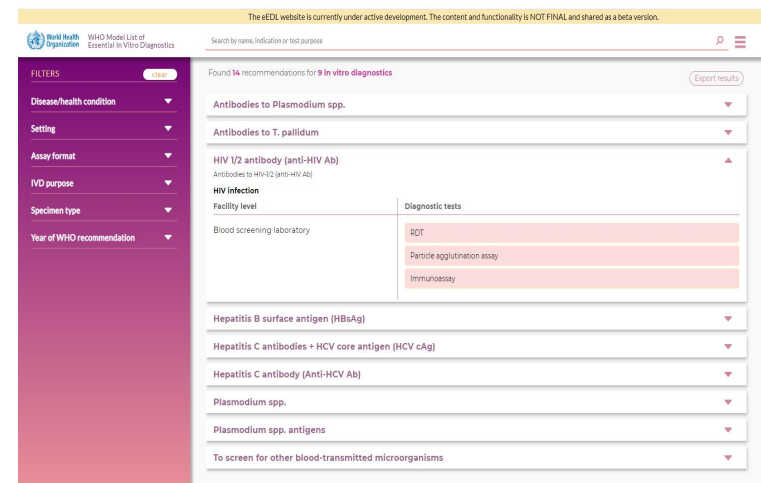
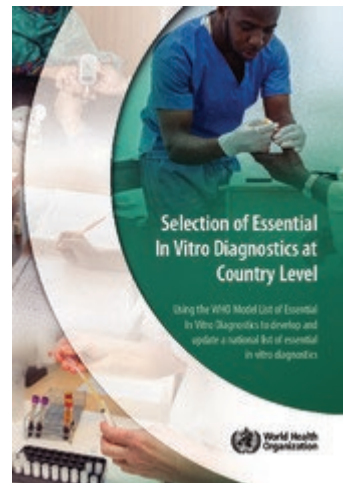
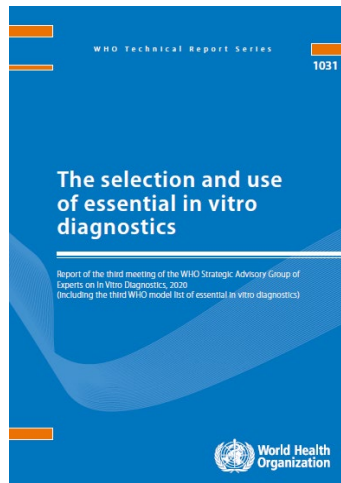
Review and updating of the list

- The EDL is updated regularly, with periodic calls for submission of applications
- Applications can be submitted by:
 - WHO HQ departments
 - WHO regional or country offices
 - Other stakeholders, such as Member States, academia, NGOs or companies in the IVD industry
- The EDL secretariat oversees submissions, and the **SAGE IVD** is responsible for reviewing applications and making recommendations



Additional tools to support countries

1. WHO Technical Report Series The selection and use of essential IVDs
2. **Electronic EDL (eEDL)**
3. Selection of essential in vitro diagnostics at country level: using the WHO Model List of Essential In Vitro Diagnostics to develop and update a national list of essential in vitro diagnostics
4. Technical specifications to support selection and procurement of IVD products



Planning for the EDL 4

Timeline

- Call for submissions is open from 19 January until July 31, 2022
- May to August 2022: review of submissions
- September 2022: public consultation
- October 2022: review of input from public consultation
- November 2022: SAGE IVD meeting, date and modality to be confirmed
- November – December 2022: development of the report of the SAGE IVD meeting, including the EDL 4
- January 2023: EDL 4 launch

High priority IVDs categories for EDL 4

For the addition of new IVD categories for EDL4 we are specially inviting applications for the following IVD categories:

1. Therapeutic drug monitoring (TDM) Amikacin
2. TDM Gentamicin
3. TDM Phenytoin
4. TDM Lithium
5. TDM Methotrexate
6. Nucleic acid testing, *N. meningitidis*
7. Antigen, Entamoeba
8. Testosterone total
9. Protein electrophoresis (in serum and urine)
10. Immunofixation electrophoresis
11. Free light-chain test (in serum)
12. Antibodies against Scrub Typhus (IgM)
13. Antibodies against Leptospira (IgM)
14. Serology, Yellow fever
15. Nucleic acid testing, Diphtheria
16. IVDs for Bordetella pertussis
17. IVDs for Poliovirus
18. IVDs for Rotavirus
19. Lead
20. Hepatitis Delta (RDTs, EIA and RNA PCR)
21. Hepatitis E (RDTs, EIA and RNA PCR)
22. 17 hydroxyprogesterone
23. Parathyroid hormone

The EDL Secretariat will also consider submissions for IVD categories not mentioned in the above list.

EDL4 call for submissions

Expressions of interest

- Department of Public Health Syracuse University: Hepatitis E virus
- International Myeloma Working Group: Protein electrophoresis (in serum and urine), immunofixation electrophoresis and free light-chain test (in serum)
- Queensland Children's Hospital: 17-hydroxyprogesterone, testosterone and PTH
- The Ohio State University: Parathyroid hormone
- WHO: yellow fever, rotavirus and diphtheria
- FIND and Life for a Child: glucose (edits)
- International Federation of Biomedical Laboratory Science
- Uganda National Health Laboratories and Diagnostics
- Manufacturers: blood typing dry format card testing

Additional Information

- **EDL Secretariat contact:** EDLsecretariat@who.int
- **EDL 4 Call for submissions:** [https://www.who.int/news-room/articles-detail/call-for-submission---submissions-for-the-fourth-who-model-list-of-essential-in-vitro-diagnostics-\(edl-4\)](https://www.who.int/news-room/articles-detail/call-for-submission---submissions-for-the-fourth-who-model-list-of-essential-in-vitro-diagnostics-(edl-4))
- **EDL Submission portal:** <https://submissions.who-healthtechnologies.org/>
- **WHO IVD web page:** https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1
- **WHO web page on the EDL:** <https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/selection-access-and-use-in-vitro>
- **Electronic eEDL (beta version):** <https://edl.who-healthtechnologies.org/>
- **WHO Medical Devices web page:** https://www.who.int/health-topics/medical-devices#tab=tab_1