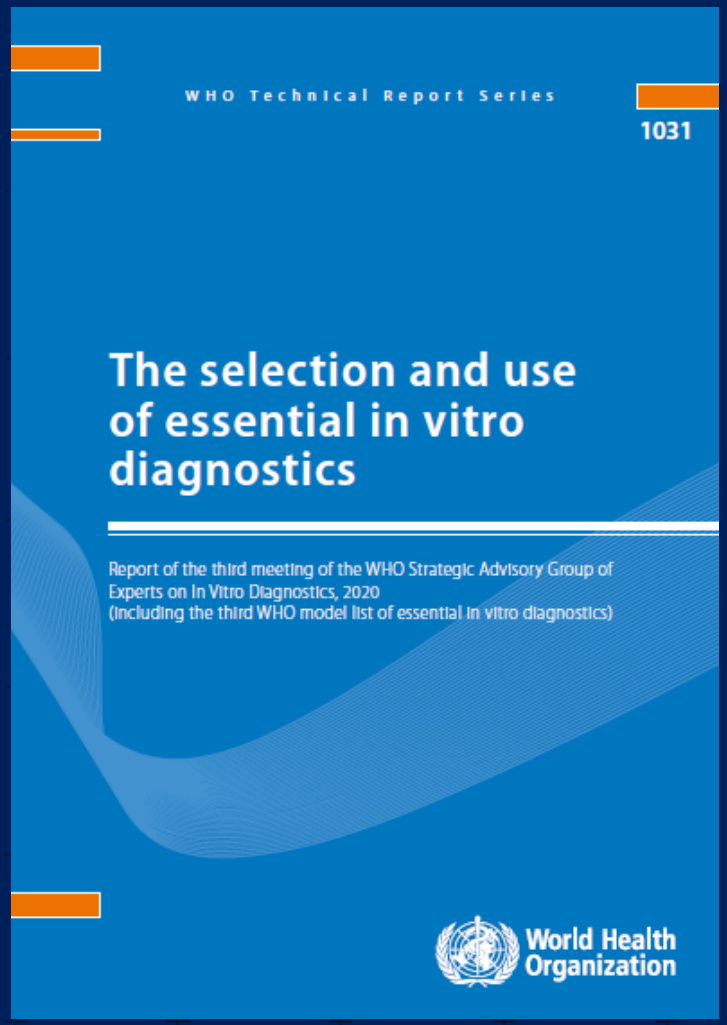
Updates on the WHO model list of essential in vitro diagnostics (EDL)



24th WHO Expert Committee on the Selection and Use of Essential Medicines – Open session

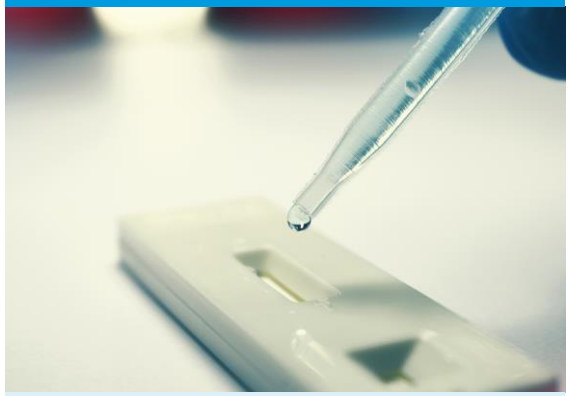
World Health Organization

24th April 2023

Presentation of the EDL

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

I. Community settings and health facilities without laboratories



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

II. 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

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Scope of EDL

The **EDL 3** includes 142 unique IVD tests encompassing general and disease-specific test for non-communicable diseases (NCD) and infectious diseases.

For the **EDL 4** (expected publication by the end of May 2023), eight IVD tests will be added to the list and several edits will be implemented for IVDs recommended for TB, HIV, HBV and HCV.

EDL 4 will include two new disease-specific sections: **Hepatitis E** and **Cardiovascular 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

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Following recommendations from the EML Cancer Medicines Working Group and WHO technical team in cancer, SAGE IVD recommended the inclusion of 13 tests for Cancer

Alpha-fetoprotein	Human chorionic Gonadotrophin (hCG)/Total beta-hCG
Basic panel for immunohistochemical (IHC) testing for diagnosis of lymphoma	Lactate dehydrogenase (LDH)
Basic panel of immunohistochemical (IHC) markers for diagnosis of solid tumours	Estrogen (ER) and progesterone (PgR) receptors
BCR-ABL1 and ABL1 transcripts	Papanicolaou (Pap) smear test
Epidermal growth factor receptor (EGFR) gene mutation	Prostate specific Antigen (PSA)
Basic flow cytometry panel of antibodies for leukemia	Tyrosine-protein kinase receptor (erbB-2) or human epidermal growth factor receptor 2 (HER-2) overexpression
Faecal Immunochemical test (FIT)	

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WHO TRS 1031/EDL3, 2021 available in: https://www.who.int/publications/i/item/9789240019102

Planning for the EDL 4 and future editions

What tests are missing? Identifying **high priority IVDs** for the EDL

From the review of WHO publications, past SAGE IVD recommendations and published work on IVDs for the medicines listed in the WHO EML, we identified 71 candidate tests to inform EDL 4 call for submissions, additional discussions took place and the SAGE IVD reach consensus on the following 23 tests categories:

1. therapeutic drug monitoring Amikacin
2. therapeutic drug monitoring Gentamicin
3. therapeutic drug monitoring Phenytoin
4. therapeutic drug monitoring Lithium
5. therapeutic drug monitoring 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

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EDL 4 applications

Addition of new IVD categories:

1. High-sensitivity Troponin I test (hs-cTnI)
2. RDT to anti-Hepatitis E Virus IgM
3. Hepatitis E Virus NAT
4. ELISA to anti-Hepatitis E Virus IgM
5. 17-Hydroxyprogesterone
6. Kleihauer-Betke acid-elution test
7. Parathyroid hormone
8. Meningitis/Encephalitis Multiplex PCR Panel
9. ABO and Rh factor POC dry format card

Edits:

10. Glucose (SMBG)
11. M. tuberculosis DNA (POC)

Do Not Do Recommendations

12. Typhoid serological tests

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Review and updating of the EDL

- The EDL is updated regularly, with periodic calls for submission of applications
- Applications can be submitted by:
  - Stakeholders, such as Member States, academia, professional organizations, NGOs or companies in the IVD industry
  - WHO regional or country offices
  - WHO HQ departments

- The EDL secretariat oversees the submission process, and the **SAGE IVD** is responsible for reviewing applications and making recommendations

- **Type of applications:** addition of new IVD categories, do not do recommendations, edits, additional evidence in support of previous applications (conditional listing) and delisting

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- The EDL Secretariat acknowledges the challenges related to the limited diagnostic capacity in LMICs, specially for Cancer, and agrees with the doubts about the diagnostic feasibility of some high-skilled molecular IVD required for certain cancer medicines.
- The EDL Secretariat concurs with WHO Cancer team views that more data on clinical benefits, diagnostic feasibility and cost-effectiveness, specially from LMICs, would help to consider future inclusion of cancer medicines requiring accompanying diagnostics.
- The EDL Secretariat offers its great appreciation to the EML Expert Committee for their valuable work and for the recommendations related to in vitro diagnostic tests.

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Thank you

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