WHO model list of essential in vitro diagnostics

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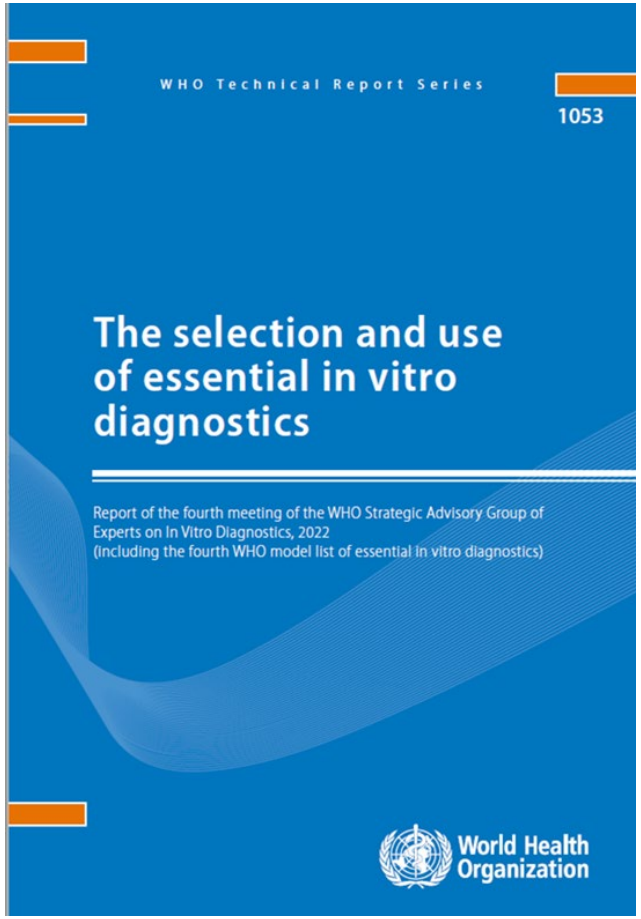
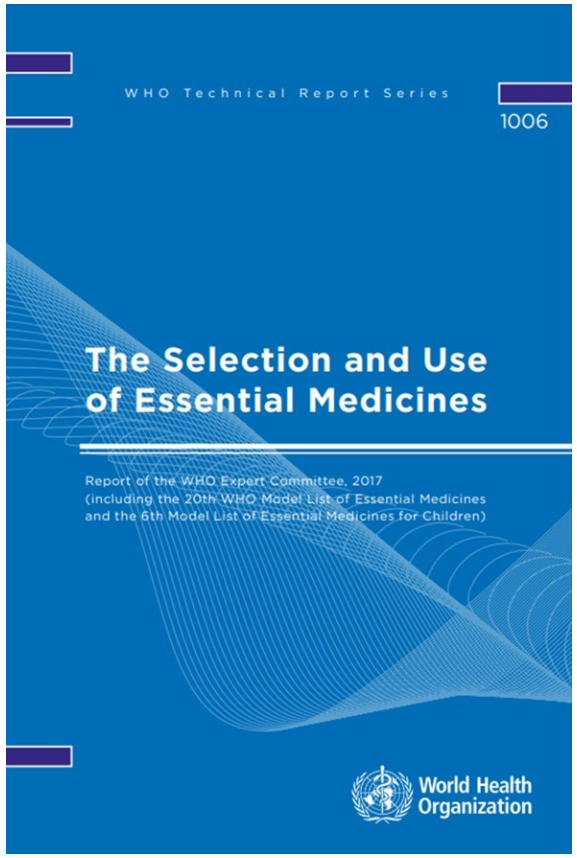
The model list of essential in vitro diagnostics (EDL)

- List of IVD tests categories and recommendations on the assay format, test purpose, specimen type and health care setting
- Health policy document, based on scientific evidence
- The EDL 5 is currently being drafted and will be launched in Q2 2025.



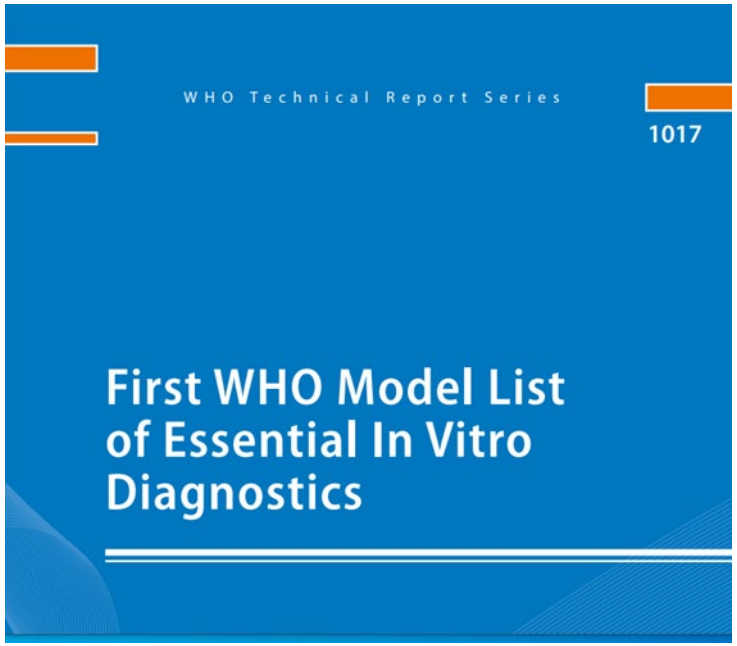
The evolution of the EDL



3.5: Proposal for a WHO list of essential in vitro diagnostics

The recommendations and comments of the Expert Committee in relation to a proposed WHO list of essential in vitro diagnostics were as follows:

- The Committee acknowledged that specific tests are essential to diagnose the disease or identify the subpopulation for which certain medicines may be indicated, and to monitor the effectiveness or toxicity of medications. Moreover, diagnosis often has important implications for prognosis.
- The Committee recognized that countries might seek advice about the technologies to prioritize, how to shift from one technology to another, and which technologies should accompany essential medicines since they are strongly interconnected.
- The Committee recognized that the idea of a model list of essential in vitro diagnostics, developed and maintained by WHO, merits exploration, basing its process, methodology and transparency on the Model List of Essential Medicines.
- The diagnostics list may initially focus on in vitro diagnostics.
- The initial proposed priority areas (tuberculosis, malaria, HIV, and hepatitis B and C) may be appropriate for the first iteration of the list but the scope should extend to other areas, including other antimicrobials and noncommunicable diseases, as soon as possible.
- The Committee recommended that strong links should be maintained between the planned Strategic Advisory Group of Experts on In Vitro Diagnostics, which will oversee the diagnostics list, and the Expert Committee on Selection and Use of Essential Medicines.
- The diagnostics list should be integral to the development of both medical guidelines and laboratory accreditation schemes.

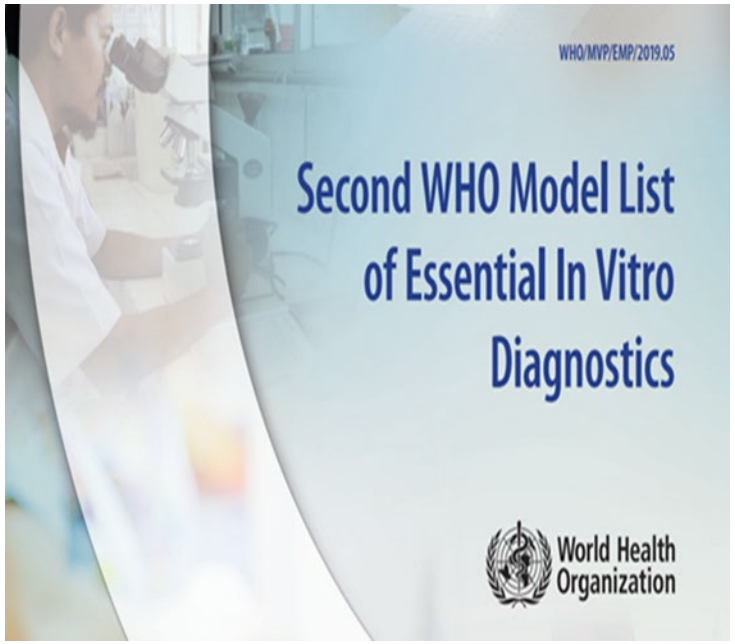


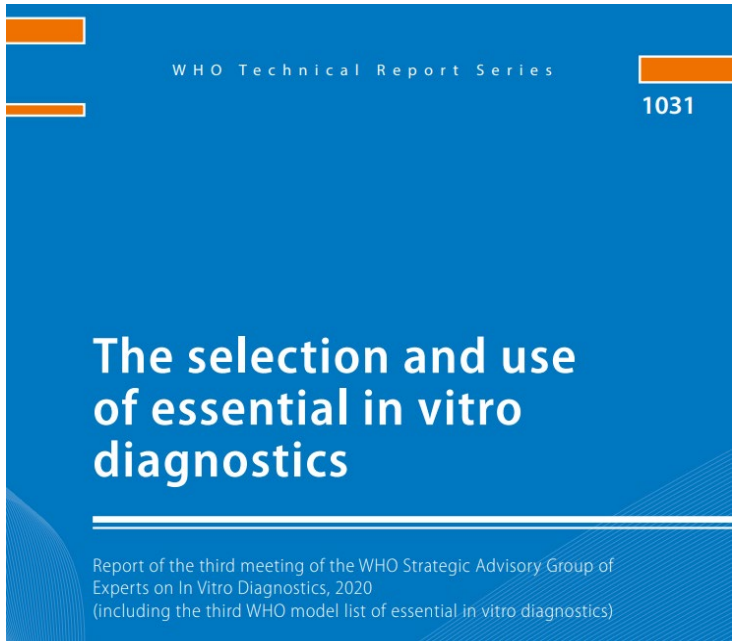
EDL 1: published in May 2018,
113 IVD tests categories
General tests, HIV, TB, malaria, hepatitis, HPV and syphilis

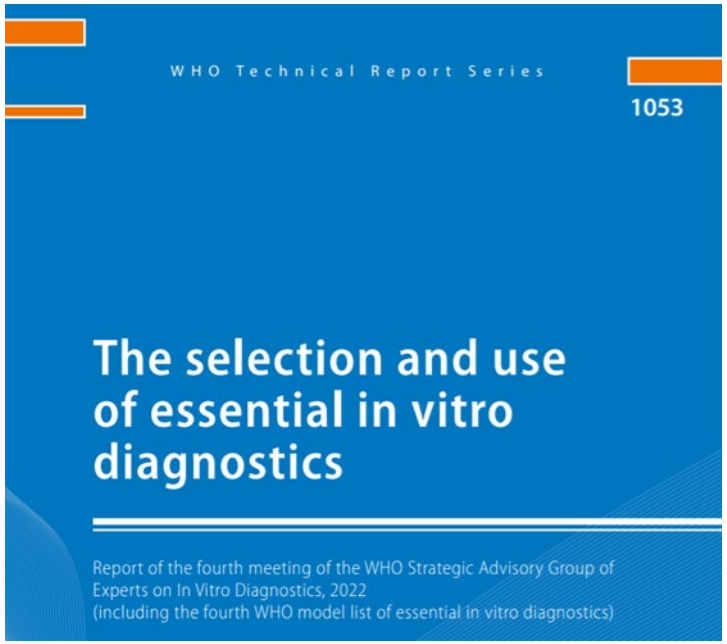
2017

2018

The evolution of the EDL







EDL 2: published in July 2019,
122 IVD tests categories
II.c. Blood screening labs
Cancer, anemia, NTD

EDL 3: published in January 2021,
145 IVD tests categories
Do not do recommendations
COVID-19, endocrine disorders

EDL 4: published in October 2023,
156 IVD categories
Cardiovascular health
HEV, Glucose meter self-monitoring

2019 → 2021 → 2023

5th SAGE IVD meeting from 25 to 29 November 2024 at Geneva

- 18 applications: 11 additions of new IVD categories, 5 additions of new assay formats, and 2 edits

- 8 from NGOs
- 6 from academia
- 2 IVD manufacturer
- 1 WHO
- 1 NSA

Scope of EDL 4

- The EDL does not list commercial products but categories of IVD tests
- The EDL includes general tests and disease-specific tests for non-communicable diseases (NCD) and infectious diseases
- Most tests are recommended for medical care
- Some tests for surveillance and for use in public health labs

General tests	Disease-specific
Anatomical pathology	Aspergillosis
Blood typing	**Cancer** (hepatocellular carcinoma, germ cell tumours, hepatoblastoma, lymphoma, solid tumours, chronic myelocytic leukaemia, acute lymphoblastic leukaemia, non-squamous non-small cell lung carcinoma, acute leukaemia, colorectal cancer, gestational trophoblastic disease, breast cancer, cervical cancer, prostate cancer)
Clinical chemistry	Cardiovascular disease
Clinical microbiology	Chagas disease
Clinical pathology	Cholera
Haematology	COVID-19
Pregnancy testing	Diabetes mellitus
	Endocrine disorders (Addison's disease, Cushing's syndrome, gonadal dysfunction, infertility, calcium homeostasis disorders, hyperprolactinaemia, hypothyroidism, hyperthyroidism, congenital adrenal hyperplasia)
	Hepatitis B, C and E
	HIV
	Human papillomavirus
	Influenza
	Malaria
	Neglected tropical diseases (Dengue, soil-transmitted helminthiases and schistosomiasis, *Trypanosoma cruzi* infection and Chagas disease, visceral leishmaniasis)
	Pneumocystis pneumonia
	Primary immunodeficiencies
	Streptococcal pharyngitis
	Sickling disorders
	Sexually transmitted infections (chlamydial and gonorrheal urogenital disease and extragenital infection, syphilis)
	Tuberculosis
	Vaccine preventable diseases (measles infection, rubella infection)
	Zika virus

Example of EDL 4 listing

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

Disease	IVD test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Diabetes mellitus	Glucose	To diagnose and monitor[39] type 1 and type 2 diabetes mellitus To diagnose impaired fasting glucose/ impaired glucose tolerance To screen for type 2 diabetes mellitus and impaired fasting glucose/impaired glucose tolerance *Note: When used for emergency or critical care, results are time-sensitive.*	Optical methods, automated chemistry analyser if available	Serum Plasma	N/A	HEARTS-D: diagnosis and management of type 2 diabetes (2020) https://apps.who.int/iris/handle/10665/331710
	Haemoglobin A1c (HbA1c)	To diagnose and monitor diabetes mellitus	Immunoassay	Venous whole blood	N/A	HEART-D: diagnosis and management of type 2 diabetes (2020) https://apps.who.int/iris/handle/10665/331710

Objective of the EDL and recommended uses

- The objective of the EDL is to support IVD policy development
- The EDL is being used to prioritize and select IVD tests, and to support the development and update of national EDLs (NEDL) at country level
- EDL and NEDLs can inform universal health coverage-priority benefits packages (UHC-PBP)
- EDL and NEDL can help decision makers define the tests that should be available at different levels of the health system as per the context and needs of each country
- Ideally, the EDL should be used within the scope of integrated clinical laboratory testing services and laboratory networks ⇒ With the proper implementation of a NEDL, patients can have better and greater access to IVD tests

NEDL development and implementation efforts

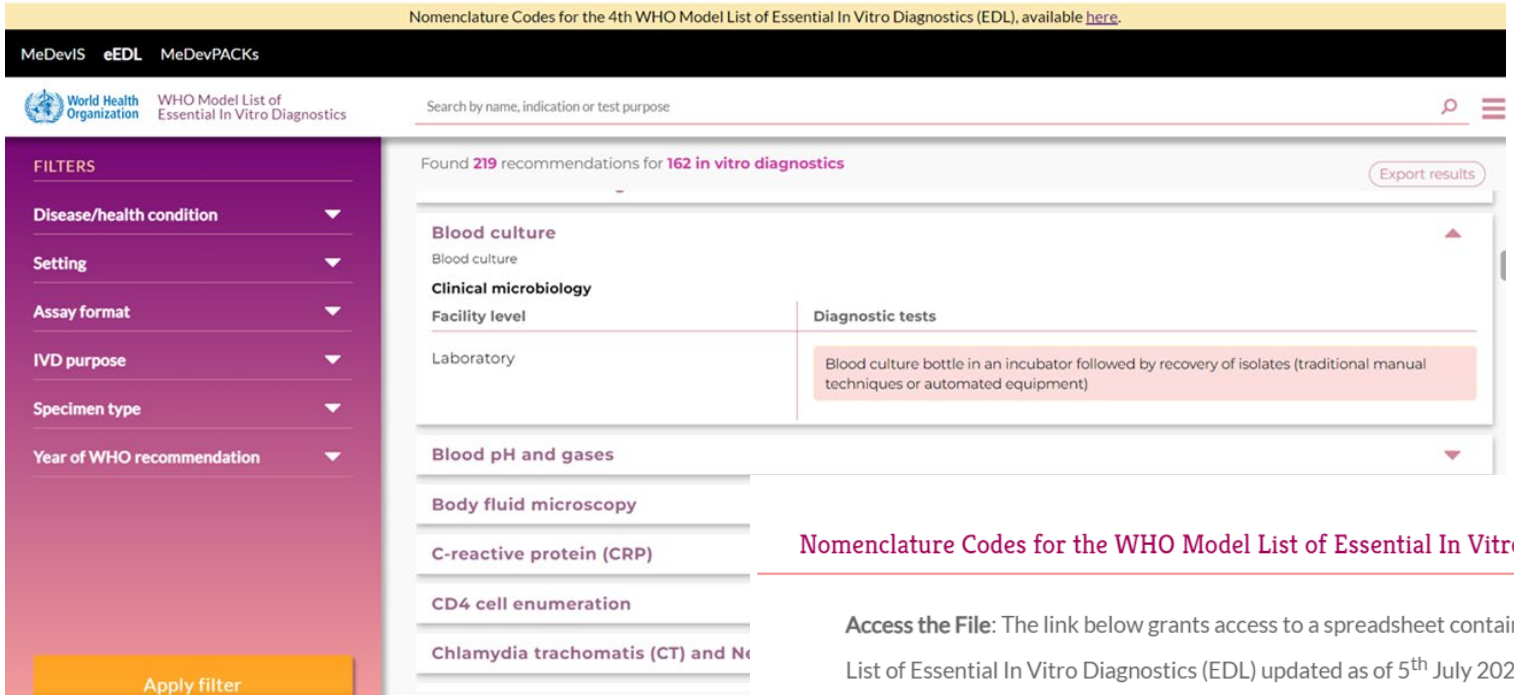
- India and Nigeria currently working in implementation
- Nepal and Ethiopia have recently finalized their NEDL
- Pakistan and Timor Leste: NEDL final development phase
- Honduras has recently started NEDL development
- NEDLs under development in Kenya, Malawi, South Africa, the Gambia, Zimbabwe, Viet Nam and Indonesia

Kao K, Kohli M, Gautam J, Kassa H, Acellam S, Ndungu J, Albert H. Strengthening health systems through essential diagnostic lists and diagnostic network optimization. PLOS Glob Public Health. 2023 Mar 30;3(3):e0001773. doi: 10.1371/journal.pgph.0001773. PMID: 36996019; PMCID: PMC10062591.

- Burkina Faso, Madagascar, South Sudan: have also finalized NEDL development

What is new for EDL 5?

- Clinical microbiology tests will be re-named to provide greater level of detail and to align better with the “WHO essential diagnostic tests for bacterial and fungal infections and AMR”
- Subset of the EDL tailored to emergency situations as per the mandate of the resolution WHA 76.5 on Strengthening diagnostics capacity
- Updates to the STI section (internal edits by STI programme)
- Electronic EDL (eEDL) will include codes from the European Medical Device Nomenclature (EMDN) system and the Global Medical Device Nomenclature (GMDN) system, in accordance with the WHA75(25) decision on nomenclature of medical devices
- The eEDL will include a new filter to facilitate the search of technical specifications included in the eEDL



Spreadsheet containing GMDN codes associated with the IVD tests listed in the eEDL

In 2025 the eEDL will include GMDN and EMDN codes embedded in it, updated as per the EDL 5.

Nomenclature Codes for the WHO Model List of Essential In Vitro Diagnostics (EDL)

Access the File: The link below grants access to a spreadsheet containing some GMDN Codes associated with the test formats of the 4th WHO Model List of Essential In Vitro Diagnostics (EDL) updated as of 5th July 2024.

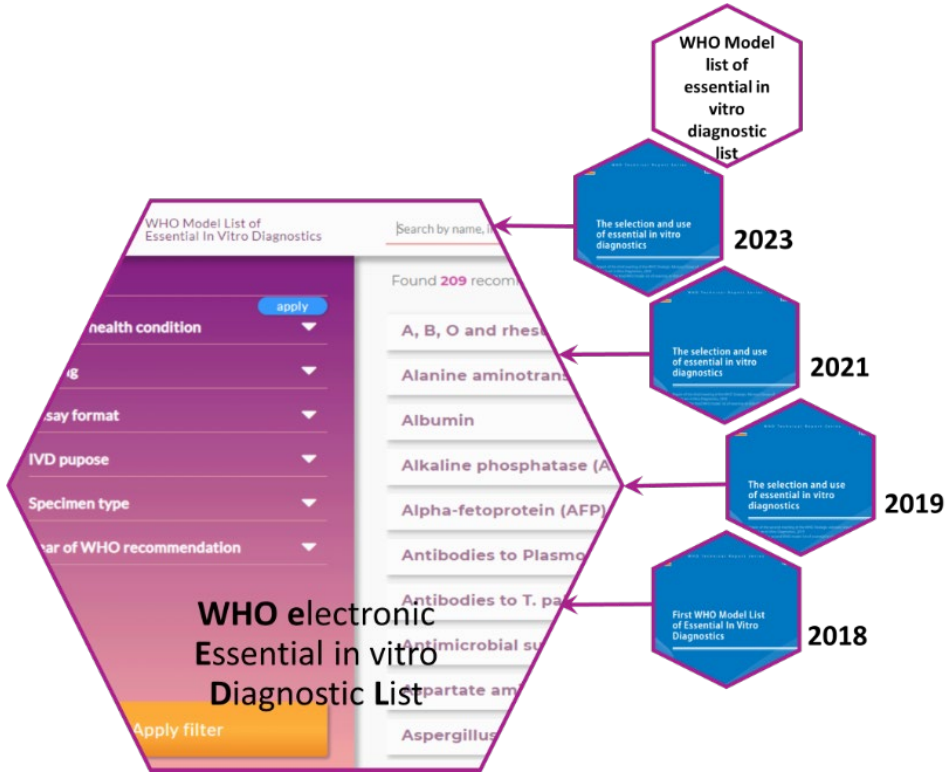
Please kindly read the notices disclaimers in the first tab, indicating that this table will help you identify the GMDN Term that is considered to be the most appropriate for each EDL test, but please note neither the GMDN Agency, nor WHO has any responsibility or liability to you for use of any GMDN Term that is identified by this service. For more information on GMDN, please consult https://gmdnagency.org GMDN ®. © GMDN Agency 2005-2024.

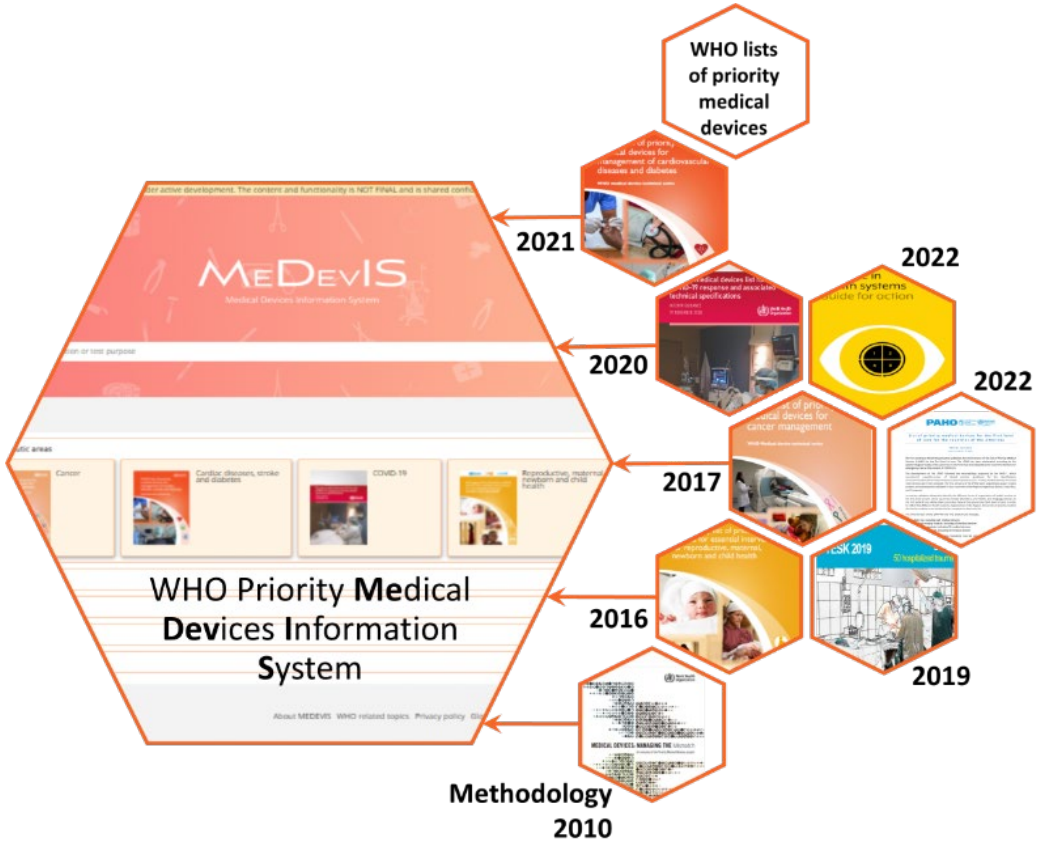
Download the file

Trial Version: The current version is a reference table of the codes related to the IVD tests of the WHO essential in vitro list.

Noting that the codes, term and definitions are not yet embedded in each of the type of tests description page. However, future developments will associate each diagnostic category with a GMDN Code and eventually a European Medical Device Nomenclature (EMDN) code as well, directly in the test type profile.

WHO electronic platforms including MDs nomenclature systems





The resolution WHA76.5 on Strengthening diagnostics capacity requests to provide cross-references between the WHO EDL and the diagnostic devices already included in MeDevIS.

To remember…

- In countries and settings where resources are scarce, the EDL can help to identify and prioritize the IVD tests that should be available in the country
- The EDL can inform UHC-PBPs and national diagnostic guidelines
- The EDL is a useful tool to develop, update and implement a NEDL according to each country's needs and priorities
- With a proper implementation of a NEDL, lab professionals and health care providers can have the appropriate IVD tests available in the settings needed, and the population will have increased and timely access to IVD testing

Thank you

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