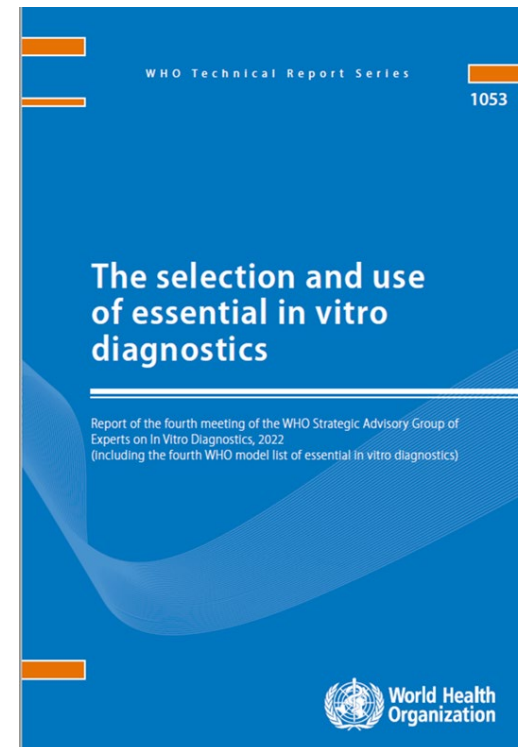


# Fourth WHO model list of essential in vitro diagnostics (EDL 4)

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# WHO Model list of essential in vitro diagnostic (EDL)

The EDL is a health policy document, based on scientific evidence, consisting of a list of categories of IVD tests and recommendations for using those tests in relation to the assay format, test purpose, specimen type and health care setting



# Scope of EDL 4

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

The EDL does not list branded products but rather categories of IVD tests

General tests	Disease-specific
Anatomical pathology	Aspergillosis
Blood typing	Cancer
Clinical chemistry	Cardiovascular diseases
Clinical microbiology	Chagas disease
Clinical pathology	Cholera
Haematology	COVID-19
Pregnancy testing	Diabetes mellitus
	Endocrine disorders
	Hepatitis B, C and E
	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

# Structure of the EDL

- The EDL is organized in two tiers based on levels of care within the health system
- The list also includes a special section titled Do Not Do recommendations

## 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

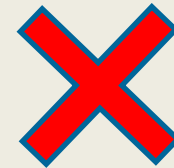


**II.a** General tests (arranged by discipline)

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

**II.c** Bloods screening tests

## Do Not Do recommendations



Refer to test categories recommended for discontinuation based either on evidence of harm or lack of benefit

# Example of EDL 4 listing

II.b. Disease-specific IVDs recommended for use in clinical laboratories <i>continued</i>						
Disease	IVD test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Diabetes mellitus	Glucose	<p>To diagnose and monitor<sup>39</sup> type 1 and type 2 diabetes mellitus</p> <p>To diagnose impaired fasting glucose/ impaired glucose tolerance</p> <p>To screen for type 2 diabetes mellitus and impaired fasting glucose/impaired glucose tolerance</p> <p><i>Note: When used for emergency or critical care, results are time-sensitive.</i></p>	Optical methods, automated chemistry analyser if available	Serum Plasma	N/A	<p>HEARTS-D: diagnosis and management of type 2 diabetes (2020)</p> <p><a href="https://apps.who.int/iris/handle/10665/331710">https://apps.who.int/iris/handle/10665/331710</a></p>
	Haemoglobin A1c (HbA1c)	To diagnose and monitor diabetes mellitus	Immunoassay	Venous whole blood	N/A	<p>HEART-D: diagnosis and management of type 2 diabetes (2020)</p> <p><a href="https://apps.who.int/iris/handle/10665/331710">https://apps.who.int/iris/handle/10665/331710</a></p>

# Objectives of the EDL

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

- Provision of evidence-based guidance to countries to create/update their national EDL (NEDL)
- Prioritization of IVD tests that should be available at different levels of the healthcare system
- Provision of information to United Nations agencies and NGOs that support the selection, procurement, supply or donation of IVDs
- Provision of guidance to the private health technology and manufacturing sectors about the IVD priorities required to address global health issues

## Recommended use

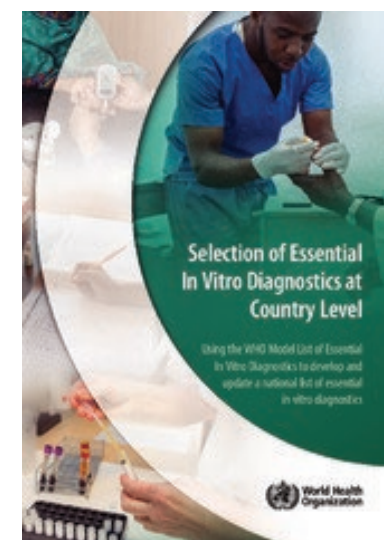
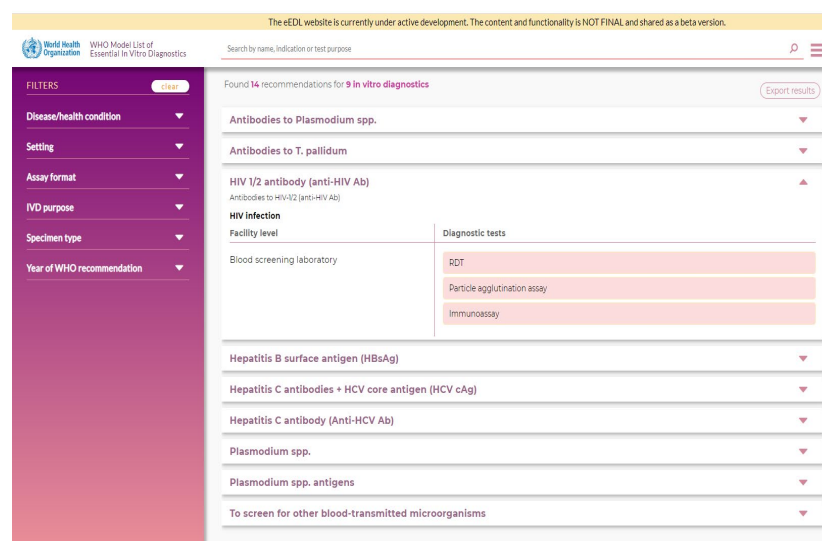
- The EDL is used to prioritize and select IVD tests that are indispensable for a country, which can be grouped into a "national list of essential in vitro diagnostic tests" (NEDL), and in turn, this national list helps decision makers define the tests that should be available at each level of the health system in their country
- To support the scale-up of Universal Health Coverage (UHC) and improve access to diagnostics at country level
- The EDL should not be used in isolation but within the scope of integrated clinical laboratory testing services that meet the clinical needs and expectations of each country through its laboratory networks





# Tools to support countries

1. WHO Technical Report Series The selection and use of essential IVDs
2. Electronic EDL (eEDL): *currently being updated, will be available in December 2023.*
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, available in the eEDL





## Additional information

- 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>
- WHO IVD web page: [https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab\\_1](https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1)
- Electronic EDL (eEDL) <https://edl.who-healthtechnologies.org/>

# Thank you

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