WHO model list of essential in vitro diagnostics (EDL) and IVDs for C-TAP.

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What is the EDL?

The WHO model list of essential in vitro diagnostics (EDL) is a policy document, based on scientific evidence, consisting of a register of categories of IVD tests and recommendations for those test (assay format, test purpose, specimen type, healthcare setting).

- First edition (May 2018)
- Second edition (November 2019)
- Third edition (January 2021)
- Fourth edition (early 2023)

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Objectives of the EDL

- **The EDL is intended to support IVD policy development to improve people access to IVD testing and clinical laboratory services through:**
- Provision of evidence-based guidance for countries to create or update their national EDL
- 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 IVDs priorities required to address global health issues

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The update of the EDL is a rigorous evidence-based process

Step 1	Pre-submission for addition of a new test category assessed for completeness by the EDL secretariat and circulated to relevant WHO departments. A full submission is invited if appropriate.
Step 2	EDL secretariat reviews for completeness all **type of submissions**: full submissions for **addition of a new test category**, and submissions for **edits**, **delisting**, **additional evidence** for IVDs conditionally listed **and Do Not Do recommendations**.
Step 3	Each submission is peer-reviewed by at least two members of the SAGE IVD, who formulate draft recommendations for consideration by the full SAGE IVD during meeting(s) for selection.
Step 4	The evidence provided in each submission is reviewed and assessed for its strength and quality by a methodologist.
Step 5	All applications and expert reviews are published on the WHO website for full transparency and public comment at least 1 month before the selection meeting(s).
Step 6	**SAGE IVD meeting**: SAGE IVD members and methodologists present their recommendations for each application to the full SAGE IVD for discussion.
Step 7	The SAGE IVD reaches a decision for each submission by consensus, documents the reasons for its decision and makes a recommendation to the WHO Director-General.
Step 8	The Director-General approves the list.

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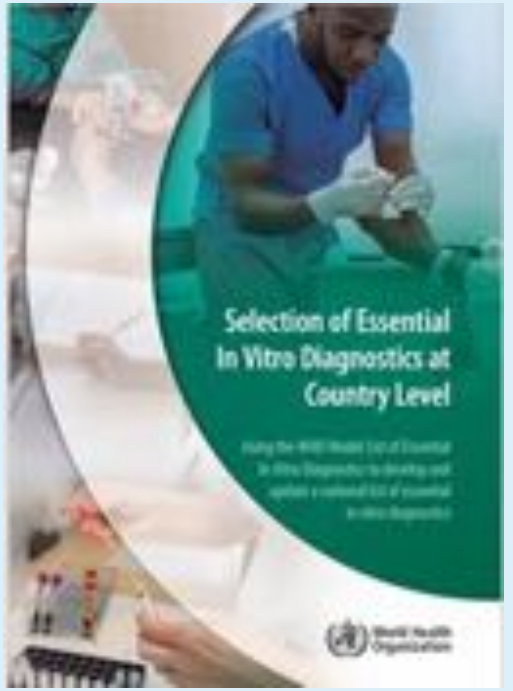
How to develop a national list of essential in vitro diagnostics

To make best use of the WHO EDL, countries may consider adapting the WHO EDL to their own national context and needs

A guidance document to help countries to adapt the WHO EDL into national EDLs has been published in 2021



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How to develop a national list of essential in vitro diagnostics

Guiding principles

- **Political commitment** of the ministry of health for promoting better access to IVDs, supported by formulation of a national IVD policy and allocation of adequate resources to ensure the availability of the tests listed in the NEDL
- **Committee-led process**
- **Standardized, rigorous evidence-based evaluation** for developing and updating the NEDL
- **Inclusion and participation** of relevant stakeholders through a public consultation phase and an open, transparent application process widely disseminated throughout the country
- **Periodic review and updating of the NEDL** according to an institutional process

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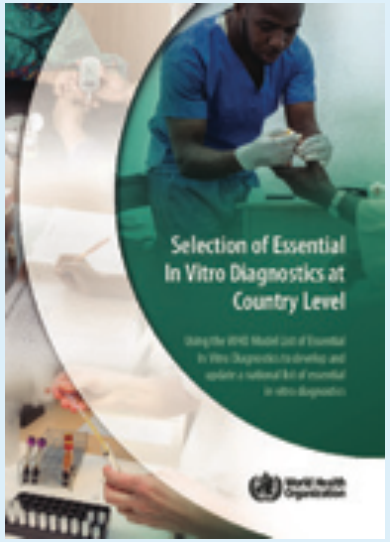
Tools to support countries

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 (under development, tech specs will be added to the eEDL)



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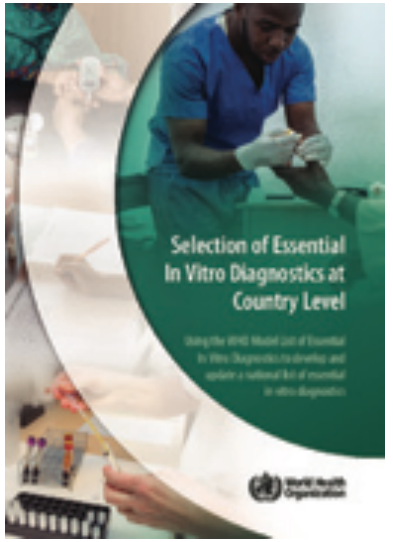
IVD - In Vitro Diagnostic Medical Device – Definition

Devices intended by the manufacturer for the examination of specimens derived from the human body solely or principally to provide information for:

- diagnosis, aid to diagnosis,
- screening, monitoring,
- predisposition, prognosis,
- prediction, determination of physiological status



Includes reagents, calibrators, control materials, specimen receptacles,

software, and related instruments or apparatus or other articles

- Note: In some jurisdictions, certain IVD medical devices may be covered by separate regulation.

(GHTF/SG1/N071:201Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' Study Group 1 Final Document GHTF/SG1/N071:2012 (http:// www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf, accessed October 2022).

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Classification of IVDs

Criteria for classification used worldwide:

- the intended use / indications for use
- the expertise of the intended user (lay person or healthcare professional),
- the importance to the diagnosis (sole determinant or one of several),
- natural history of disease/symptoms
- the impact of the result (true or false) to the individual and/or to public health.

Classification is always **risk based**

By Member States:

- Either Four Categories
- Or Three Categories

For the **lowest class IVDs – Class 1**

- the impact of the incorrect result of the IVDs test could cause **minimal public or individual health risk.**

For the **highest class IVDs – Class (4/3):**

- the impact of the incorrect result of IVDs test could cause **high public health risk.**

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IVD testing for COVID-19

To detect if a person has, or have had COVID-19, the tests can either detect:

- Presence of the SARS-CoV-2 virus in the body.
  - Usually by testing if the virus is present in the throat, nose, nasal secretions (snot) or sputum (saliva/spit)
  - Tests to detect the presence of the SARS-CoV-2 virus, used as screening/diagnostic tests are:
    - Nucleic acid test (PCR, LAMP..) – highly sensitive laboratory tests
    - Rapid antigen tests – PoC (by health professional), or self-test (at home use)
- Presence of antibodies to the SARS-CoV-2 virus.
  - This is usually done by taking sample to test for **presence of SARS-CoV-2 antibodies**
    - developed in response to the virus (COVID 19 disease) or
    - developed in response to the vaccine.

    (Immunoassays, e.g. well known ELISA, less known RIA, FIA, CLIA, CIA)

Realizing Equitable Global Access
COVID-19 Technology Access Pool (C-TAP)

Making the response to COVID-19 a public common good
Solidarity Call to Action

To realize equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data.

44 Member States have joined the Solidarity Call to Action so far

Argentina; Bangladesh; Barbados; Belgium; Belize; Bhutan; Bolivia; Brazil; Chile; Costa Rica; Dominican Republic; Ecuador; Egypt; El Salvador; Guatemala; Honduras; Indonesia; Kenya; Lebanon; Luxembourg; Malaysia; Maldives; Mexico; Mongolia; Mozambique; Norway; Oman; Pakistan; Palau; Panama; Paraguay; Peru; Portugal; Saint Vincent and Grenadines; South Africa; Spain; Sri Lanka; Sudan; The Netherlands; Timor-Leste; Tunisia; Turkmenistan; Uruguay; Zimbabwe

C-TAP – Objectives

- To promote open science in order to accelerate product development by pooling intellectual property, data and know-how.
- To accelerate the scale-up of manufacturing and facilitate speedy and equitable access to new technologies, through transparent, non-exclusive, and public health-driven licensing and enhanced technology transfer.
- To foster active engagement of key partners including funders, research institutions and governments to facilitate sharing of knowledge, data and the licensing of products, in order to maximize global access.

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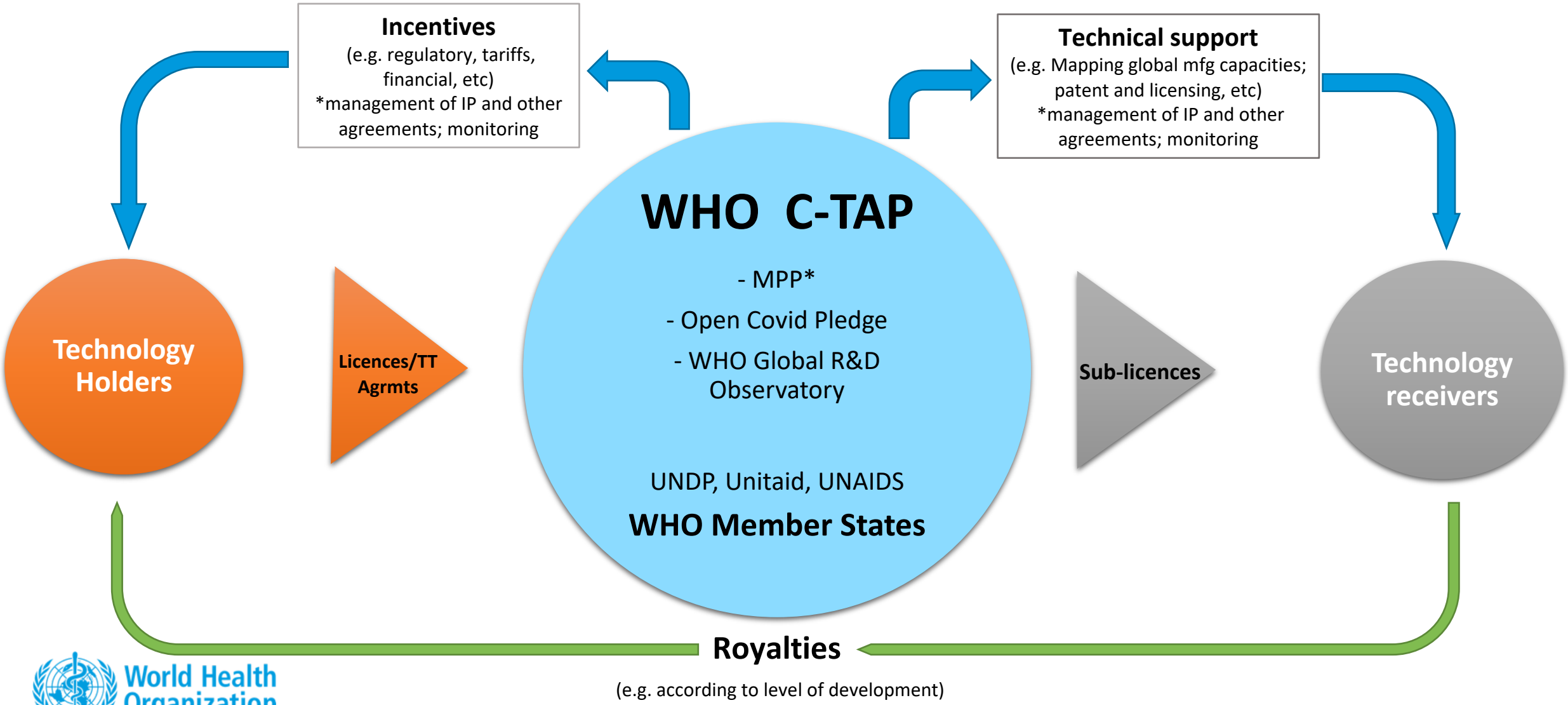
How C-TAP works to facilitate technology sharing and increase scale up?



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C-TAP mandate for IVDs

- Why is C-TAP important in IVD space?
  - Share voluntarily relevant knowledge, IP and data to enable scaled-up production, distribution and use of Covid-19 IVDs
  - C-TAP only works through non-exclusive voluntary licensing
  - Licences are global with the aim of focusing on LMIC manufacturers

  - C-TAP performs
    - in depth assessment of technologies to be transferred and
    - equally detailed assessment of TT acceptor – sublicensee
    - early assistance with TT ensuring readiness for regulatory submission -> EOIs can be granted in the WHO target timeframe
    - monitoring/evaluation of TT and transferred product quality.

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Key License-in activities outcomes since Nov 2021

- One IVD license for a serological antibody COVID 19 test signed with CSIC
- Multi product license signed with NIH
- Additional licenses are being negotiated for IVD, Vx and other technologies

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Key recent licence-out activities

- The first IVD sublicense signed and
- Technical Transfer to a LMIC IVD manufacturer started
- Based on the assessment of information supplied under EOI, two LMIC manufacturers of IVDs were categorized as suitable, ready, and willing to manufacture for supply to LMIC.
- Ongoing responses to formal and informal enquiries and technical discu s with potential sublicensees

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Way forward

- In vitro diagnostics are required in all health systems for: emergencies, universal health coverage and wellness.
- The IVDs need to be: good quality, available, affordable , accessible, safe.
- WHO will continue to develop guidance for MS
- MS to support access to target population
- C-TAP systems are in place, developed, documented and currently being utilized.
    - System for evaluation and monitoring of the effectiveness will provide a feedback loop for further system improvements.

The final goal is not the technology per se but the effective and promptly diagnosis to patients, to allow treatment accordingly.

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Gracias
Thank you
Merci
Shokran
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EDL website:
http://www.who.int/medical_devices/diagnostics/Selection_in-vitro_diagnostics/en/

Additional Information

- **EDL Secretariat contact:** EDLsecretariat@who.int
- **Electronic eEDL (beta version):** https://edl.who-healthtechnologies.org/
- **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
- **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)
- **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 Medical Devices web page:** https://www.who.int/health-topics/medical-devices#tab=tab_1

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