The EDL is intended to support IVD policy development, to support patients having diagnostics-informed treatment.

The EDL lists a set of priority IVD types of tests for use at various levels of the healthcare system.

The EDL is expected to:

1. Provide evidence-based guidance to Member States for the development of local/national essential in vitro diagnostics lists

2. Inform United Nations (UN) agencies and non-governmental organizations (NGOs) who support selection, procurement, supply, donations or provision of in vitro diagnostics

3. Provide guidance to the medical technology private sector on diagnostics priorities needed to address global health issues
Context of the Essential Diagnostics List

WHO recognises that IVDs are an essential component to the 3 strategic priorities of the WHO 13 General Programme of Work (2019-2023):

- Advance universal health coverage
- Address health emergencies
- Promote healthier populations

Source: Image from iStock.com
Inclusion Criteria for 1\textsuperscript{st} EDL

Criteria:

- Primary care: For patients at entry level care facilities
- Public health relevance: High burden diseases, affordable, quality
- Evidence based: Supported by WHO guidelines & guidance.
- Free of conflict of interests
- Have regulatory approval
- Be available worldwide

Similar process to the EMLs but adapted for IVDs

Priority disease areas for the 2\textsuperscript{nd} Ed of the EDL are: public health emergencies, AMR, NCD’s & NTD’s, Influenza, reproductive health and fungal disease
Content of 1st edition of EDL

May 2018

Section I
Primary Health Care
(No lab available)

Section II
Facilities with Laboratories

Section I.a & II.a
General IVDs

Section I.b & II.b
Disease Specific IVDs

12 Test Categories

11 Test Categories

62 Test Categories

23 Test Categories

16 Test Categories
### Differences between the WHO EDL and WHO IVD prequalification

The EDL is policy oriented and PQ lists quality assessed individual products.

<table>
<thead>
<tr>
<th>Model list of Essential IVDiagnóstics</th>
<th>List of WHO Prequalified IVDs</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Evidence based selection for policy</td>
<td>• Specific product assessment</td>
</tr>
<tr>
<td>• <strong>Product categories by type:</strong> no manufacturer names, no brand names.</td>
<td>• <strong>Specific IVDs</strong> assessed for quality, safety and performance, listed by product manufacturer, model, brand name.</td>
</tr>
<tr>
<td>• <strong>Larger scope:</strong> Infectious, Non Communicable diseases and general laboratory tests.</td>
<td>• <strong>Limited scope:</strong> HIV, malaria, syphilis, G6PD, HPV, HCV, HBV, cholera.</td>
</tr>
<tr>
<td>• <strong>Outcome:</strong> List of types of tests to be considered essential for UHC, emergencies and wellness.</td>
<td>• <strong>Outcome:</strong> a list of quality assured branded products that are eligible for procurement by UN agencies, NGOs, donors or Member States.</td>
</tr>
<tr>
<td>• Note: EDL includes references to WHO guidelines, WHO documents and Prequalified products that correspond to certain categories of test.</td>
<td>• PQ by product is time bounded to assessment performed to the specific brand/model.</td>
</tr>
</tbody>
</table>
For First Time, W.H.O. Names Some Lab Tests ‘Essential’

The World Health Organization (WHO) published Tuesday its first catalogue of tests needed to diagnose the most common health conditions as well as a number of priority diseases to improve diagnosis and treatment outcomes.

The Essential Diagnostics List concentrates on in vitro tests, which are tests of human specimens like blood and urine.

Taking blood for an H.I.V. test at a mobile clinic in KwaZulu Natal, South Africa. The World Health Organization has recommended 113 diagnostic tests it considers essential to every health care system in the world. Credit Stephane De Sakutin/Agence France-Presse — Getty Images
Advocacy and media coverage for 1EDL

More than 30 articles on EDL launch around the world:

More than 5 editorial articles:

Advocacy by SAGE members, WHO and network:
USFDA, Labs, pathologists and clinicians around the world

Presentation on international forum:
Int. Society for Neglected tropical Diseases (ISNTD) – June 2018
International conference on laboratory medicine (ICLM) – Sept 2018
9th Advanced Course on Diagnostics (ACDx) – Sept 2018
African Society of Laboratory Medicine (ASLM) – Dec 2018
Fourth Global Forum on Medical Devices (4GFMD) – Dec 2019
After release: statements from various stakeholders....

Global Health NGO’s:
- MSF, FIND, PATH, ASLM, EFLM, BMGF, GAFFI

Academia:
- Fiocruz, U. of Michigan, Johns Hopkins, McGill,

Professional Societies:
- Infectious Diseases Society of America

Disease Advocacy Groups:
- ACTION Global Health Advocacy Partnership
- The Global Coalition of TB Activists
- The European AIDS Treatment Group
- The Global TB Community Advisory Board
- TB Proof, Treatment Action Group,
- Global Health Technologies Coalition

Industry:
- Diagnostics Companies/AdvaMedDx
- McGill University Survey: Paulami Sen et al,

Source: Image from iStock.com
1. High priority tests for future editions of the EDL
2. Prepare detailed preface to support the EDL
3. Emphasize the infrastructure and processes required to support IVD utilization
4. Set up an EDL website
5. Update WHO technical documents
6. Implement the EDL globally
7. Broaden WHO PQ programme to high priority tests
# 1. High Priority Tests for Future Editions

<table>
<thead>
<tr>
<th>High Priority Test Recommendations</th>
<th>Activities &amp; Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimicrobial Resistance Testing (AMR)</td>
<td>Added language to the Microbiology AST section noting priority organisms for AMR surveillance</td>
</tr>
<tr>
<td>Neglected Tropical Diseases (NTD’s)</td>
<td>Submissions received for: Dengue fever, Leishmaniasis, Soil Transmitted Helminths/Schistosomiasis</td>
</tr>
<tr>
<td>Non-Communicable Diseases (NCD’s)</td>
<td>Cancer: Submissions received for 13 test categories New Anatomical Pathology section under General Lab Tests Diabetes: Reviewed EDL 1.0 – all required tests were already included Cardiology: Reviewed EDL 1.0 – Coagulation tests added Emergency Medicine: Designated tests that are time sensitive in Emergency &amp; Critical care</td>
</tr>
<tr>
<td>Public Health Emergencies</td>
<td>Submissions received for Zika virus &amp; cholera tests</td>
</tr>
<tr>
<td>Influenza</td>
<td>Submissions received for point-of-care flu tests (not for surveillance)</td>
</tr>
<tr>
<td>Reproductive Health</td>
<td>Submission received for CT/NG test</td>
</tr>
<tr>
<td>Fungal disease</td>
<td>Submission received for histoplasmosis</td>
</tr>
</tbody>
</table>
2 & 3. Detailed Preface Incl. Emphasis on EDL Supporting Factors

Preface to the EDL was prepared and published with the 1st Edition of the EDL. Topics covered were:

1. Objectives
2. Scope of the 1st Edition
3. Content and Format
4. Recommended Use
6. Selection of IVD’s for inclusion in the 1st Edition
7. Process of Updating the EDL Going Forward
8. Relationship between the EDL and the List of Prequalified IVDs

“…it is important to note that the EDL itself cannot have an impact without an integrated, connected, tiered laboratory system, with well qualified primary care and laboratory personnel, laboratory infrastructure, regulatory & quality assurance systems and IVD supply chain.”
4. EDL Website Launched Nov ‘18


1. Headings identified by EDL Secretariat & WHO programmes
2. WHO document library, IRIS, was searched for relevant WHO publications under agreed topics
3. Documents listed under each topic
4. Lists were reviewed by WHO programme staff & SAGE IVD
5. Website information was compiled with final agreed list of documents
6. Information gaps identified – recommendations made to EDL Secretariat

**FUTURE:**
EDL Secretariat and Disease Programme staff responsible for ensuring new documents are added
5. Technical Document Update

Lab Manual in progress

**Aim of the manual:**
*For use in Developing Countries particularly in peripheral labs and rural health centres where the lab technician often has to work alone.*

**Early steps:**
1. Researched open source materials online for training and support of lab personnel
2. Found various resources e.g.:
   - Lab techniques from US CDC, Merlot.org, ASM
   - Good Clinical Lab Practice from Global Health Network
   - Lab Accreditation from CLSI

**Proposal:**
Develop new, high impact, digital training materials for IVD support – potentially in collaboration with Academia, NGO’s and WHO Collaborating Centres, and SAGE IVD members
6. Global Implementation
From EDL to access of IVDs

WHO HQ

Call for new tests to be added general and disease specific

Review by WHO
Public consultation
Recommendations by SAGE IVD

Publication of a list including test type, test purpose and link to WHO guidance

WHO EDL

Local needs: epidemiology, resources, committee

Prioritized national list

Country and health facilities

Final users

National reference lab

2 and 3er level

Primary health care PHC (self testing)
Guidance for country implementation

Next steps after EDL, to develop/integrate

1. Develop good quality EDL tests for viable markets
2. Sell/lease products
3. Get regulatory approval for market in regions or countries
4. Provide ongoing support, training, consumables, affordable and good quality

Technical specifications for procurement or leasing
New WHO nomenclature, codes, definitions
Procurement / leasing / payment mechanisms / reimbursement
Installation/ user training / Operating costs- (consumables and reagents)

Role of industry
7. Broaden WHO PQ programme to high priority tests

Presented in the Open Session by WHO PQ Team

1. After SAGE IVD 2018, there was a consultation process to identify the highest priority tests to be added to the WHO PQ programme

2. EDL Secretariat supported this process

3. Report was presented includes a list of IVDs for which prequalification is most needed
2018 SAGE IVD Recommendations

1. High priority tests for future editions of the EDL
2. Prepare detailed preface to support the EDL
3. Emphasize the infrastructure and processes required to support IVD utilization
4. Set up an EDL website
5. Update WHO technical documents
6. Implement the EDL globally
7. Broaden WHO PQ programme to high priority tests

Source: Image from iStock.com
117 suggestions for changes were received after the release of the first edition of the EDL

1. General laboratory tests in the 2018 EDL were reviewed by the EDL secretariat and SAGE-IVD members.
2. Various clarifications, corrections, updates, and expansions of test categories were considered.
3. Changes were then reviewed by the General Laboratory Working Party.
4. List then reviewed by the full SAGE-IVD.
5. Final list of changes posted on EDL web site Feb 2019.
Results of consultation on the use and impact of WHO lists

January 2019

Input 4 WHO lists:

- List of Essential Medicines;
- List of Essential In vitro Diagnostics;
- Lists of Priority Medical Devices; and
- Priority Assistive Products List.

Outcomes:

- **Integrate the four lists**
  - Establish common nomenclature
  - Ensure cross-sector representation
  - Align timing and eliminate duplication
  - Integrate information exchange

- **Improve communications**
  - Use communications strategies
  - Integrate communications across lists
  - Reach the grassroots
  - Encourage bottom-up communications

- **Help adapt the lists**
  - Add granularity and expand scope
  - Classify lists by context
  - Support prioritization
  - Develop downstream tools and guidance
  - Build in-country capacity
  - Promote the process

- **Raise awareness and engagement**
  - Increase awareness of lists themselves
  - Promote ancillary products
  - Target key influencers
  - Emphasize links to SDG 3 and UHC
  - Leverage networks for dissemination

- **Make a bigger impact**
  - Focus on end goal of improving access
  - Look beyond selection
  - Showcase success stories

- **Improve accessibility**
  - Develop an online database
  - Contribute to the UHC Menu
  - Support national data management needs

- **Tackle the finance dimension**
  - Find a way to address cost effectiveness

- **Monitor progress**
  - Develop indicators for implementation, availability & access

- **Share learning**
  - Review and refine tools through feedback
  - Establish taskforce
  - Foster knowledge exchange

- **Leverage strengths**
  - Leverage existing brands
  - Harness partner and regional expertise
IVDs for PHC to be considered in the package of essential supplies

Now a WHO Technical Report Series
Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

WHO
20, Avenue Appia
1211 Geneva
Switzerland

EDL Secretariat
Email: edlsecretariat@who.int

EDL website: