

# First WHO Model List of Essential In Vitro Diagnostics

---



The World Health Organization was established in 1948 as a specialized agency of the United Nations serving as the directing and coordinating authority for international health matters and public health. One of WHO's constitutional functions is to provide objective and reliable information and advice in the field of human health, a responsibility that it fulfils in part through its extensive programme of publications

The Organization seeks through its publications to support national health strategies and address the most pressing public health concerns of populations around the world. To respond to the needs of Member States at all levels of development, WHO publishes practical manuals, handbooks and training material for specific categories of health workers; internationally applicable guidelines and standards; reviews and analyses of health policies, programmes and research; and state-of-the-art consensus reports that offer technical advice and recommendations for decision-makers. These books are closely tied to the Organization's priority activities, encompassing disease prevention and control, the development of equitable health systems based on primary health care, and health promotion for individuals and communities. Progress towards better health for all also demands the global dissemination and exchange of information that draws on the knowledge and experience of all WHO's Member countries and the collaboration of world leaders in public health and the biomedical sciences.

To ensure the widest possible availability of authoritative information and guidance on health matters, WHO secures the broad international distribution of its publications and encourages their translation and adaptation. By helping to promote and protect health and prevent and control disease throughout the world, WHO's books contribute to achieving the Organization's principal objective – the attainment by all people of the highest possible level of health.

The WHO *Technical Report Series* makes available the findings of various international groups of experts that provide WHO with the latest scientific and technical advice on a broad range of medical and public health subjects. Members of such expert groups serve without remuneration in their personal capacities rather than as representatives of governments or other bodies; their views do not necessarily reflect the decisions or the stated policy of WHO.

For further information, please contact: WHO Press, World Health Organization, 20 avenue Appia, 1211 Geneva 27, Switzerland (tel. +41 22 791 3264; fax: +41 22 791 4857; email: [bookorders@who.int](mailto:bookorders@who.int); order on line: [www.who.int/bookorders](http://www.who.int/bookorders)).

WHO Technical Report Series  
1017

# First WHO Model List of Essential In Vitro Diagnostics

---



World Health  
Organization

First WHO Model List of Essential In Vitro Diagnostics  
(WHO Technical Report Series, No. 1017)  
ISBN 978-92-4-121026-3  
ISSN 0512-3054

© World Health Organization 2019

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

**Suggested citation.** First WHO Model List of Essential In Vitro Diagnostics. Geneva: World Health Organization; 2019 (WHO Technical Report Series, No. 1017). Licence: CC BY-NC-SA 3.0 IGO.

**Cataloguing-in-Publication (CIP) data.** CIP data are available at <http://apps.who.int/iris>.

**Sales, rights and licensing.** To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

**Third-party materials.** If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

**General disclaimers.** The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Printed in Switzerland

# Contents

<b>Abbreviations and acronyms</b>	iv
<b>1. Introduction</b>	1
<b>2. First WHO Model List of Essential In Vitro Diagnostics</b>	3
2.1 Explanatory notes	3
2.1.1 Scope of the first EDL	3
2.1.2 Content and format	3
2.1.3 Recommended use of the EDL	4
2.1.4 Glossary	5
2.2 Model List of Essential In Vitro Diagnostics	6
I. For primary health care	6
I.a General IVDs for primary health care	8
I.b Disease-specific IVDs for primary health care	11
II. For health care facilities with clinical laboratories	18
II.a General IVDs for health care facilities with clinical laboratories	19
II.b Disease-specific IVDs for health care facilities with clinical laboratories	25
<b>3. Methods used to establish the List</b>	43
3.1 Strategic Advisory Group of Experts on In Vitro Diagnostics	43
3.2 Selection of IVDs for inclusion in the first EDL	44
3.3 Principles that should guide preparation of the EDL	45
3.4 Draft first EDL proposed by the Secretariat	46
3.4.1 Method for assessing IVDs for inclusion or deletion	47
3.4.2 Identification of high-priority IVDs for the EDL	48
<b>4. Integration of the EDL with other WHO initiatives</b>	51
<b>5. Procedures for revising the EDL</b>	54
<b>6. Adaptation of the EDL for national lists</b>	56
<b>7. Recommendations</b>	57
<b>References</b>	59
<b>WHO sources used to select the general laboratory tests</b>	60
<b>Acknowledgements</b>	61
<b>Annex 1</b>	
Participants in the first meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics	62
<b>Annex 2</b>	
Declarations of interest of SAGE IVD members	65

## Abbreviations and acronyms

CLIA	chemiluminescence immunoassay
ECL	electrochemiluminescence
EDL	Model List of Essential In Vitro Diagnostics
EIA	enzyme immunoassay
G6PD	glucose-6-phosphate dehydrogenase
GLASS	Global Antimicrobial Resistance Surveillance System
HBV	hepatitis B virus
HCV	hepatitis C virus
IVD	in vitro diagnostic
MSF	Médecins Sans Frontières
RDT	rapid diagnostic test
SAGE	Strategic Advisory Group of Experts
TB	tuberculosis
USCDC	Centers for Disease Control and Prevention (USA)
USFDA	Food and Drug Administration (USA)

# 1. Introduction

The three strategic priorities of WHO stated in its Thirteenth General Programme of Work 2019–2023 are to advance universal health coverage, address health emergencies and promote healthier populations (1). The WHO Model List of Essential Medicines contains the medications considered to be the most effective and safe to meet the most important needs in a health system, thus advancing these strategic priorities. Access to good-quality, affordable in vitro diagnostics (IVDs) that allow health providers to make timely diagnoses and offer the most appropriate treatment is also essential for reaching these goals. The WHO Model List of Essential Medicines published in 2017 (2) included a recommendation by the Expert Committee on the Selection of Essential Medicines that WHO prepare a list of essential in vitro diagnostics, which will make an important contribution to universal health coverage.

Like the Model List of Essential Medicines, the Model List of Essential In Vitro Diagnostics (“essential diagnostics list”, EDL) is intended to provide evidence-based guidance to countries for creating their own lists of essential in vitro diagnostic tests. National essential medicines lists have been successful in facilitating access to treatment, particularly in low-resourced countries, by prioritizing the most important medicines all countries should make available to their populations. It is expected that national EDLs will provide the same benefits for in vitro diagnostic tests. It should be noted that EDLs may be included in national lists of essential / priority medical devices that are used for public procurement, reimbursement or for universal health coverage (3).

The EDL comprises a group of IVDs that are recommended by WHO for use at various levels of a tiered national health care system (4). The List is not intended to be prescriptive with respect to the IVDs nor the levels at which they can or should be used. Countries should make their own decisions about which IVDs to select and where they are to be used on the basis of the national or regional burden of the disease, unmet needs, available resources and priorities.

The EDL will provide guidance and serve as a reference to ministries of health, programme managers, users such as laboratory managers, procurement officers and reimbursement systems in Member States, who are establishing or updating national lists of essential IVDs for universal health coverage. It will also inform United Nations agencies and nongovernmental organizations that support the selection, procurement, supply, donations or provision of IVDs. Finally, it will inform and guide the private sector for medical technology on IVD priorities and the IVDs needed to address global health issues.

While the EDL provides a list of tests required at various levels of the health care system, the EDL cannot be useful without an integrated, connected, tiered laboratory system, with adequate human resources, training, laboratory

infrastructure and regulatory and quality-assurance systems (5). Its impact also requires adoption and adaptation of the EDL by Member States, establishment of national and regional EDLs and the selection and supply mechanisms necessary to ensure access to the IVDs.

This report presents the first EDL and describes the process by which it was established and proposed next steps.

预览已结束，完整报告链接和

<https://www.yunbaogao.cn/report/index/report>