

The selection and use of essential in vitro diagnostics

Report of the second meeting of the WHO Strategic Advisory Group of
Experts on In Vitro Diagnostics, 2019
(including the second WHO model list of essential in vitro diagnostics)



**World Health
Organization**

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; order on line: www.who.int/bookorders).

The selection and use of essential in vitro diagnostics

Report of the second meeting of the WHO Strategic Advisory Group of
Experts on In Vitro Diagnostics, 2019
(including the second WHO model list of essential in vitro diagnostics)



**World Health
Organization**

The selection and use of essential in vitro diagnostics: report of the second meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics, 2019 (including the second WHO model list of essential in vitro diagnostics).

(WHO Technical Report Series, No. 1022)

ISBN 978-92-4-121031-7

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. The selection and use of essential in vitro diagnostics: report of the second meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics, 2019 (including the second WHO model list of essential in vitro diagnostics). Geneva: World Health Organization; 2019 (WHO Technical Report Series, No. 1022). 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.

This publication contains the collective views of an international group of experts and does not necessarily represent the decisions or the policies of WHO.

Printed in Italy

Contents

Abbreviations and acronyms	v
List of participants	vii
Declarations of interests of the Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD), observers, reviewers and consultants	xi
Acknowledgements	xii
Executive summary	xiii
1. Introduction	1
2. Open session	2
3. General items	7
3.1 Methods used to establish the second EDL	7
3.1.1 Changes to entries in the first EDL	8
3.1.2 Submissions for new product categories	8
3.1.3 Proposals for general and anatomical pathology tests	10
3.1.4 Proposal for inclusion of therapeutic drug monitoring tests	10
3.1.5 Public consultation	11
3.1.6 Process for decision-making	11
3.2 Changes to the structure of the List	11
3.3 Country implementation plans	12
3.4 Integration of the List within other WHO initiatives	13
3.4.1 Integration with the Essential Medicines List	13
3.4.2 Integration with the WHO Expert Committee on Biological Standardization	14
3.5 Eligibility for prequalification	14
4. Summary of recommendations	16
4.1 General recommendations	16
4.2 Additions to the List	20
4.3 Deletions from the List	25
4.4 Changes to listings	25
4.5 Rejected proposed changes	25
4.6 Rejected applications	28
5. Accepted applications for the second Model List of Essential In Vitro Diagnostics	29
Section I.b. Disease-specific tests for use in community settings and health facilities without laboratories	29
<i>Leishmania</i> rk39 antigen: rapid diagnostic test	29
<i>Vibrio cholerae</i> antigen: rapid diagnostic test	33
Section II.a General in vitro diagnostics for clinical laboratories	38
Clinical chemistry	38
Procalcitonin in serum and plasma: immunoassay	38
Section II.b Disease-specific in vitro diagnostics for clinical laboratories	43
Cancer	43
Alpha fetoprotein immunoassay for diagnosis of liver and germ-cell tumours	43

Basic panel of immunohistochemical tests for diagnosis of lymphoma	48
Basic panel of immunohistochemical tests for diagnosis of solid tumours	53
<i>BCR-ABL1</i> and <i>ABL1</i> transcripts for diagnosis of chronic myelogenous leukaemia (CML) and CML variants and prognosis of acute lymphoblastic leukaemia (ALL)	57
Essential panel of antibodies for flow cytometry for leukaemia	62
Faecal immunochemical test (FIT) for screening for colorectal cancer	66
Guaiac faecal occult blood test	71
Human chorionic gonadotrophin plus β -human chorionic gonadotrophin immunoassay to aid in the diagnosis of and surveillance for germ-cell tumours and gestational trophoblastic disease	76
Human epidermal growth factor receptor 2 (HER2) or tyrosine-protein kinase receptor (erbB-2) or overexpression: immunohistochemical tests to aid in diagnosis, prognosis and treatment of breast cancer	80
Lactate dehydrogenase activity to aid in the prognosis and monitoring of haematological malignancies and germ-cell tumours	84
Oestrogen and progesterone receptors in breast cancer: immunohistochemical test	88
Papanicolaou smear test	92
Prostate-specific antigen	96
HIV infection	100
Histoplasma antigen enzyme immunoassay	100
Influenza	104
Influenza antigen: rapid immunoassay to aid in diagnosis of seasonal influenza	104
Influenza A and B: nucleic acid test for diagnosis of seasonal influenza	108
Neglected tropical diseases	112
Dengue virus antibody enzyme immunoassay or rapid diagnostic test	112
Dengue virus antigen (NS1) enzyme immunoassay or rapid diagnostic test	116
Dengue virus nucleic acid test	120
Kato-Katz test for soil-transmitted helminths and intestinal schistosomes	125
Primary immunodeficiency disorders	128
Lymphocyte subtypes (CD4, CD8, CD20 and CD16/56 cells, B cells and NK cells)	128
Plasma levels of immunoglobulins G, A and M	133
Plasma and urine protein electrophoresis and immunofixation	138
Response to tetanus and pneumococcus vaccines	143
Sexually transmitted infections	147
<i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> genomic DNA	147
<i>Treponema pallidum</i> antibodies: rapid diagnostic test for diagnosis or as an aid in diagnosis of syphilis	151
Zika virus infection	154
Zika virus: enzyme-linked immunoassay for immunoglobulin M	154
Test for Zika virus nucleic acid	158

Annex 1

Second Model List of Essential In Vitro Diagnostics (EDL)	163
---	-----

Index

215

Abbreviations and acronyms

AFP	alpha-fetoprotein
ALL	acute lymphoblastic leukaemia
CML	chronic myelogenous leukaemia
DALY	disability-adjusted life-year
DENV	dengue virus
ECLIA	electrochemiluminescence immunoassay
EDL	Essential In Vitro Diagnostics List
eEDL	electronic EDL
EIA	enzyme immunoassay
ELISA	enzyme-linked immunosorbent assay
EML	Essential Medicines List
ER	oestrogen receptor
FDA	Food and Drug Administration (USA)
FIT	faecal immunochemical test
gFOBT	guaiac faecal occult blood test
hCG	human chorionic gonadotrophin
HER2	human epidermal growth factor receptor 2
HPV	human papillomavirus
IARC	International Agency for Research on Cancer
Ig	immunoglobulin
IHC	immunohistochemistry
IHR	International Health Regulations (2005)
IPOPI	International Patient Organisation for Primary Immunodeficiencies
IU	international units
IVD	in vitro diagnostic
LDH	lactate dehydrogenase
LMICs	low- and middle-income countries

NAAT	nucleic acid amplification test
NAT	nucleic acid test
NGO	nongovernmental organization
PCR	polymerase chain reaction
PgR	progesterone receptor
PHC	primary health care
PHEIC	public health emergency of international concern
PSA	prostate-specific antigen
QALY	quality-adjusted life-year
RDT	rapid diagnostic test
RT-PCR	reverse transcriptase PCR
SAGE	Strategic Advisory Group of Experts
TPHA	<i>Treponema pallidum</i> haemagglutination assay
TPPA	<i>Treponema pallidum</i> particle agglutination
UHC	universal health coverage
VDRL	Venereal Disease Research Laboratory
ZIKV	Zika virus

预览已结束，完整报告链接和

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