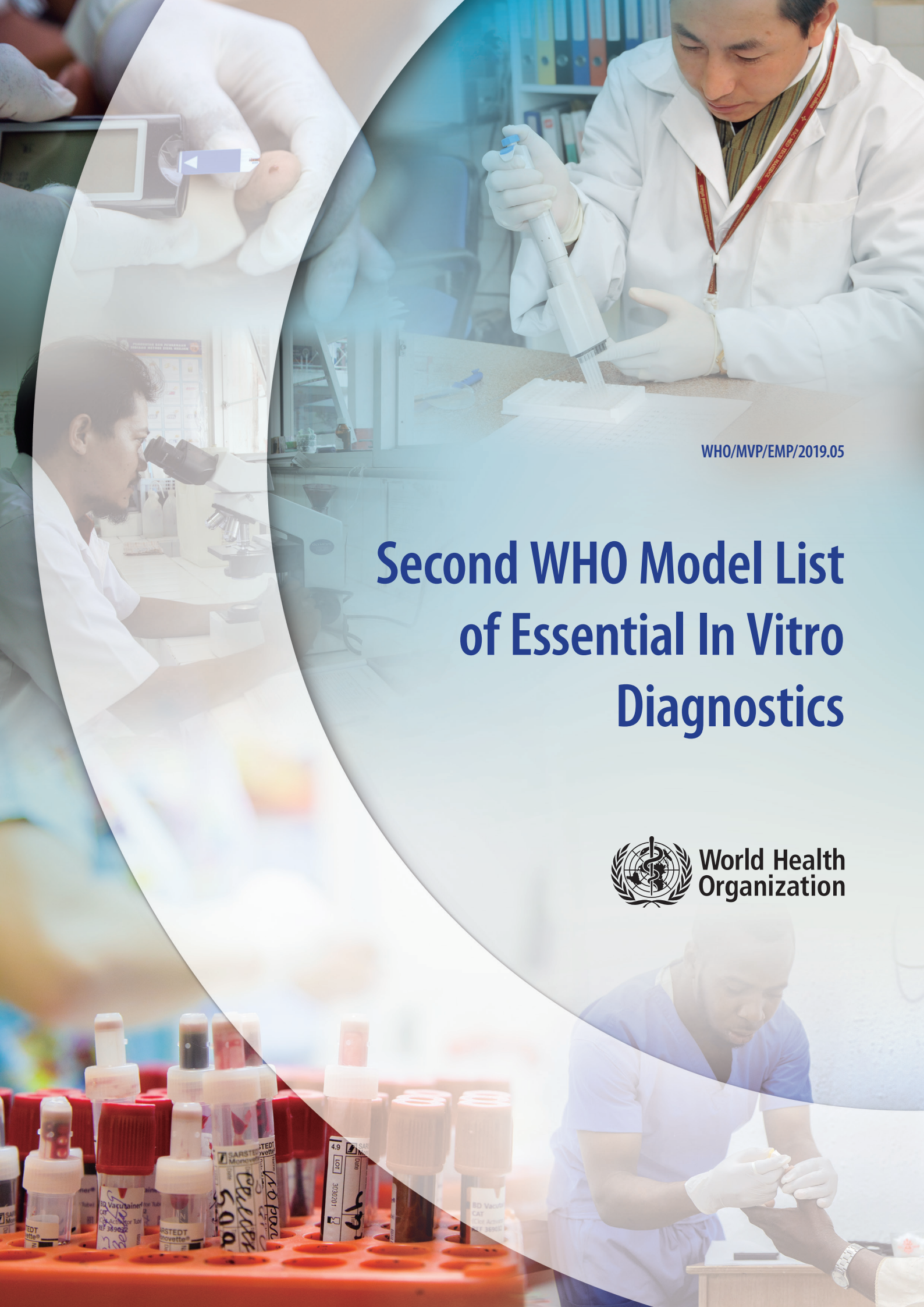

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Second WHO Model List of Essential In Vitro Diagnostics

World Health Organization

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Second WHO Model List of Essential In Vitro Diagnostics

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Contents

Preface

This document is intended to provide a convenient reference to the second edition of the WHO Model List of Essential In Vitro diagnostics (EDL). The EDL presented here provides abbreviated information including the EDL table itself and should be read and interpreted with reference to the report of the second meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics, 2019.

The full report of the Second meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD) presents a full description of the methodologies, reviews, evidence, references and recommendations of the SAGE IVD members and is available under: https://www.who.int/medical_devices/publications/TRS_1022_SAGE_IVD_Second_WML_of_Essential_In_Vitro_Diagnostics/en/.

The second meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD) was held from 18 to 22 March 2019 in Geneva. The objectives of the meeting were among others: to review the first WHO Model List of Essential In Vitro Diagnostics (EDL), to consider submission of new tests and general input from stakeholders, to review and make recommendations for the Second EDL and to discuss on eligibility criteria for prequalification of IVDs.

WHO secretariat prepared a working draft of the second EDL for open consultation and for review by the SAGE IVD members. The proposed Second list was developed based on changes proposed to the first EDL, submissions for new product categories, a suggested list of general laboratory and anatomical pathology tests.

All the procedures were transparent and based on input from internal and external stakeholders, SAGE IVD members and members of the public interested in policy or implementation of the EDL. All the suggested changes, submissions, reviews and responses to the reviews were published on the WHO website for comment, and all public comments received were acknowledged.

The agenda and members of the SAGE IVD as well as all background documents, were posted under: https://www.who.int/medical_devices/diagnostics/selection_in-vitro/selection_in-vitro-meetings/sage-ivd-2nd-meeting/en/.

All information regarding the selection and use of in vitro diagnostics can be found at https://www.who.int/medical_devices/diagnostics/selection_in-vitro/en/.

The introduction below explains the background and context to the 2nd Edition of the EDL.

1. Explanatory notes

1.1 Introduction

WHO presents the second Model List of Essential In Vitro Diagnostics (EDL), which extends the first List, published in May 2018.[1] The List recognizes that in vitro diagnostics (IVDs) are essential for advancing universal health coverage, addressing health emergencies and promoting healthier populations, which are the three strategic priorities of the Thirteenth WHO General Programme of Work, 2019–2023.[2]

1.2 Objective

The EDL lists IVDs that are recommended by WHO for use in countries. The EDL is not intended to be prescriptive with respect to the IVDs listed or the levels at which they can or should be used; rather, countries should decide which IVDs to select and where to use them, depending on their epidemiology, human resources and infrastructure.

The EDL is expected to provide guidance and serve as a reference for Member States (programme managers, laboratory managers, procurement officers and reimbursement officers) that are developing and/or updating national EDLs for interventions within universal health coverage and for selecting and using IVDs. It will also be informative for United Nations agencies and nongovernmental organizations that support selection, procurement, supply, donation or provision of IVDs and will inform the private medical technology sector about the diagnostic priorities and the IVDs necessary to address global health issues.

1.3 Scope of the second EDL

The EDL consists of 122 test categories presented as follows:

- 46 general IVD tests that can be used for routine patient care as well as for the detection and diagnosis of a wide array of disease conditions;
- 69 IVDs intended for the detection, diagnosis and monitoring of specific diseases. The first EDL listed tests for the following WHO priority disease areas: HIV infection, tuberculosis, malaria and hepatitis B and C as well as syphilis and human papillomavirus infection. The second EDL extends the diseases to include noncommunicable diseases, with an extensive new section covering cancer tests as well as a set of general tests, including a new anatomical pathology section; and
- 7 test categories intended for screening of blood donations.

The EDL does *not* name specific test brands but rather consists of test categories described according to their biological targets. When specific products in categories of tests on the EDL have been prequalified by WHO or are recommended by a WHO disease programme, a link is provided to that information, which is updated regularly.

The EDL comprises test types or categories and is not intended for use as a guideline for use of the types of test. The purpose of each test category is stated briefly, and links to WHO guidelines are provided when available. Many tests are used in the context of broader testing strategies, and the results might have to be confirmed or interpreted in accordance with defined clinical signs and symptoms.

The EDL does not specify the desirable minimal performance characteristics for each test category, nor does it state the minimum quality standards to be considered in selecting specific brands of the test types listed. The quality of tests in each category that are on the market in different regions of the world may vary widely, and this should be taken into account when selecting tests for procurement. Some regulatory agencies define the minimum performance standards required for specific tests in order to avoid false results and the consequent treatment decisions.

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[1] First WHO model list of in essential vitro diagnostics. Geneva: World Health Organization; 2019 (WHO Technical Report Series, No. 1017) (https://apps.who.int/iris/handle/10665/311567, accessed May 2019).

[2] Draft thirteenth general programme of work, 2019–2023 (document A71/4). Geneva: World Health Organization; 2018 (http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_4-en.pdf, accessed May 2019).

Test safety and performance guidelines and quality standards should be taken into account in selecting diagnostic tests for procurement, when available, and only tests validated for the intended purpose and with regulatory approval from national authorities should be procured.

1.4 Content and presentation

The second EDL is presented by health care facility level in two tiers:

I. Community and health settings without laboratories, with two sections:
   a. General IVDs for community and health settings without laboratories
   b. Disease-specific IVDs for community and health settings without laboratories

II. Health care facilities with clinical laboratories, with three sections:
   a. General IVDs for clinical laboratories
   b. Disease-specific IVDs for clinical laboratories
   c. Disease-specific IVDs for blood screening laboratories

Community and health settings without laboratories are defined as community and health facilities such as health posts and centres, doctors' offices, outreach clinics, ambulatory care and home-based and self-testing. If laboratory facilities are not available, specimens may be collected, transported to and processed at a higher tier of the health system; specimens must be shipped under appropriate conditions in order to obtain reliable results. The tests in this section of the EDL are also assumed to be available, in combination with the extended list in Section II, at healthcare facilities with laboratories.

The title of tier I was changed from that in the first EDL, where it was "Primary health care". The change was made to differentiate between tests that do not require a laboratory (whether basic or not) and those that must be performed in a laboratory. This change resulted in the deletion of some tests from the original first tier, as their performance was deemed by SAGE IVD to require qualified personnel and a basic laboratory.

Health care facilities with clinical laboratories are defined as district, regional, provincial or specialized hospitals or laboratories and national reference laboratories. It is assumed that trained laboratory technologists, laboratory scientists and pathologists, as well as laboratory infrastructure and equipment, are available as required at the appropriate level. All diagnostic tests available at primary care level are assumed to be available at higher levels, as appropriate.

General IVDs are grouped by test discipline – e.g. clinical chemistry, serology, haematology, microbiology; and specific test types within each discipline are listed in alphabetical order – e.g. bilirubin, complete blood count. Disease-specific IVDs are grouped by disease area in alphabetical order.

For each specific test category on the EDL, the following are described:

Test purpose: Intended use of the test

Assay format: The technique on which the test is generally based, e.g. immunoassay, nucleic acid test

Specimen type: The types of specimens that can be used for the test. Although all validated specimen types are listed for each test category, not all tests on the market are validated for all specimen types. Users are requested to always follow the manufacturer's instructions for specimen preparation and storage.

WHO prequalified or recommended products: For each test for which there are name brand products either prequalified or otherwise recommended by WHO, a link is provided.

Link to WHO guidance: If there is WHO guidance on use of the test category, a link is provided to the appropriate site on the WHO website.

In general, the following terms were used for the different test purposes:

- Screening test:[3] Screening tests are used to determine the status of a disease, disorder or other physiological state in an asymptomatic individual. Depending on the nature of the condition and the targeted patient population, screening tests may be used routinely or may be restricted to 'at risk' patients. These tests are designed to evaluate an individual's current state.
- Diagnostic test:[3] Diagnostic tests are used to determine, verify or confirm a patient's clinical condition as a sole determinant. This type of testing also includes sole confirmatory assays (to verify results of previous testing) and sole exclusion assays (to rule out a particular condition). These tests are designed to evaluate a patient's current state.
- Aid to diagnosis:[3] Tests that are used as aids to diagnosis provide additional information to assist in the determination or verification of a patient's clinical status. The test is not the sole determinant. These tests are designed to evaluate a patient's current state.
- Monitoring test:[3] Monitoring tests are used for measuring levels of analytes for the purpose of adjusting treatments or interventions as required. Monitoring tests include:
  - Assays which are used to ensure that an analyte remains within physiological levels or within an established therapeutic drug range. These types of monitoring tests are designed to evaluate an individual's current state.
  - Assays which are used for serial measurement, whereby multiple determinations are taken over time. These types of monitoring tests are typically used for the detection/assessment of disease progression/regression, disease recurrence, minimum residual disease, response/resistance to therapy, and/or adverse effects due to therapy. These types of monitoring tests are designed to evaluate changes in an individual's state.
- Prognostic tests:[3] These tests are used to measure factors linked to clinical outcome irrespective of treatment. Such tests may be used to estimate the natural progression of a disease (i.e. outcome in the absence of treatment), or to determine the likelihood of a clinical outcome irrespective of therapeutic intervention. These tests are designed to evaluate a patient's future state.
- Surveillance test: Performed on populations of interest to track the progression of disease incidence and/or prevalence.
- Staging test: Performed on patients with a confirmed disease or condition to determine its state at the time of diagnosis and establish a baseline to make relevant treatment decisions.

1.5 Recommended use of the EDL

- WHO recognizes that, in order to use the EDL effectively and adapt it to national needs, Member States should consider a variety of factors. These include: local demographics and pattern of diseases; treatment