

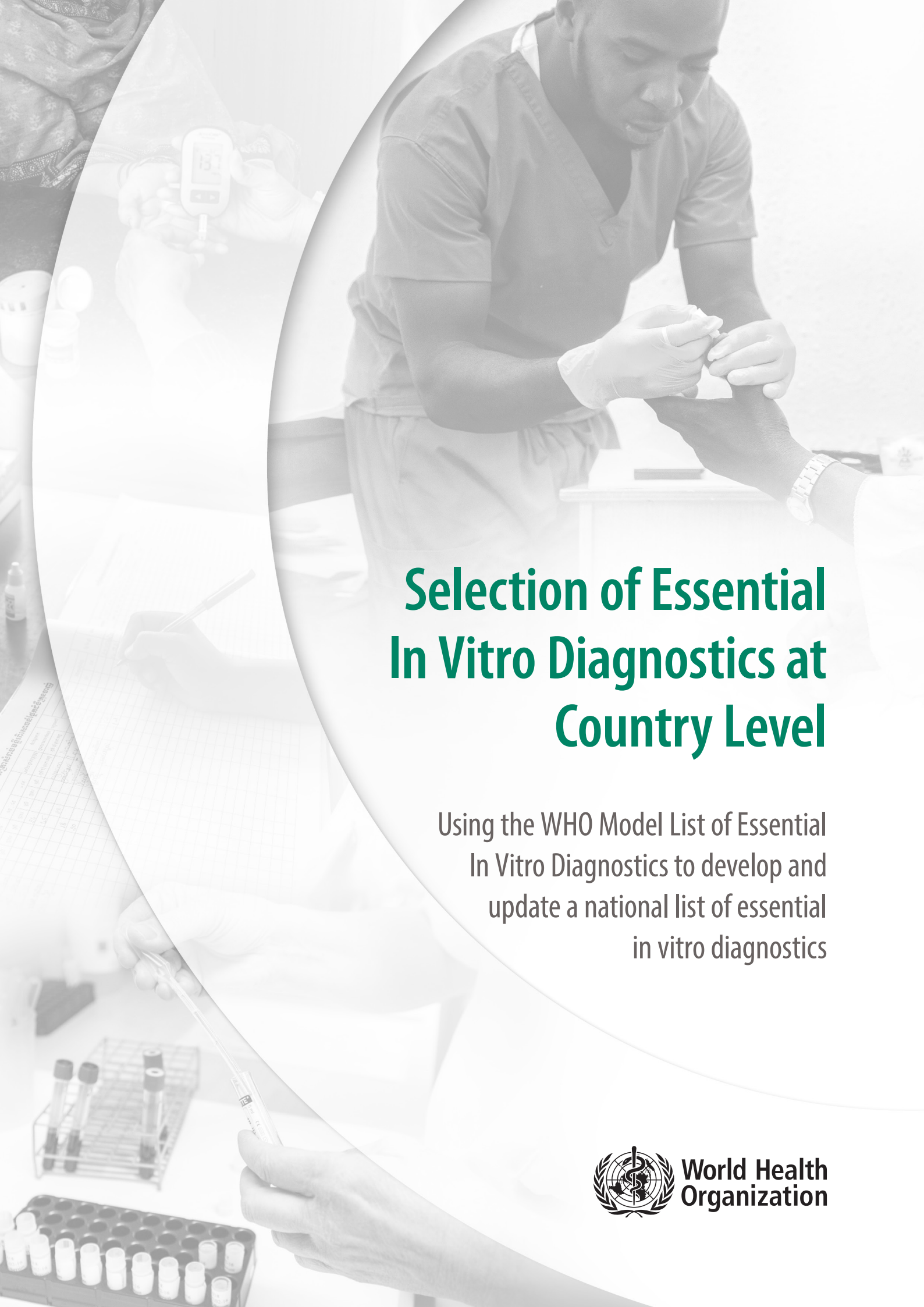
# Selection of Essential In Vitro Diagnostics at Country Level

Using the WHO Model List of Essential  
In Vitro Diagnostics to develop and  
update a national list of essential  
in vitro diagnostics



**World Health  
Organization**





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## Abbreviations and acronyms

Ag-RDT	antigen rapid diagnostic test
COVID-19	coronavirus-19 disease
EDL	Essential In Vitro Diagnostics List
EML	Essential Medicines List
IVD	in vitro diagnostic
NAAT	nucleic acid amplification test
NEDL	National Essential In Vitro Diagnostics List
RDT	rapid diagnostic test
SAGE	Strategic Advisory Group of Experts
SARS-CoV-2	severe acute respiratory syndrome coronavirus-2
UHC	universal health coverage
WHO	World Health Organization

## Executive Summary

WHO published the first edition of the Model List of Essential In Vitro Diagnostics (EDL) in May 2018. This was followed by two further editions, in 2019 and 2021. The aim of the WHO EDL is to ensure the availability of tests for universal health coverage (UHC) and health emergencies and to promote healthier populations, which are the three strategic priorities of the WHO Thirteenth General Programme of Work (2019–2023).

Since the first edition of the WHO EDL, WHO has encouraged countries to develop national essential in vitro diagnostics lists (NEDL) based on the model of the WHO EDL. This guidance was written to facilitate this process.

The first section describes the importance of in vitro diagnostics (IVDs), the benefits of an NEDL, such as in the selection of IVDs for health interventions in UHC priority benefits packages, and the purpose and scope of the document.

The second section presents the WHO EDL, its objectives, scope and contents and the processes for developing and updating it, including the criteria for selecting IVD test categories listed in the WHO EDL. This section also describes the Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD) and provides guidance on managing conflicts of interests.

The third section lists the guiding principles and a proposed process for developing or updating an NEDL on the basis of the evidence-based WHO EDL. Key stakeholders in developing an NEDL and their roles and responsibilities are defined. The section lists the steps in developing and updating an NEDL, with references to the WHO technical report on the selection and use of essential in vitro diagnostics, which summarizes appraisal of the evidence by methodologists and the considerations and deliberations of the SAGE IVD that resulted in inclusion or exclusion of test categories and assay formats in the WHO EDL.

The last section addresses each phase of use of the IVDs listed in an NEDL, with a description of the stakeholders involved in designing implementation and their roles and responsibilities.

The annexes include the templates used for application to the WHO EDL, which can be adapted by countries for their NEDLs. The annexes also provide information on the roles and responsibilities of the committees necessary for the development, updating and implementation of an NEDL. Because of the critical role of IVDs in management of the COVID-19 pandemic, WHO technical guidance on IVDs for COVID-19 is summarized in Annex 5.

This document is intended for ministries of health and policy- and decision-makers, including members of committees appointed for developing or updating an NEDL, and other relevant stakeholders who influence the selection of IVD tests.



# 1. Background

## 1.1 Introduction

In vitro diagnostics (IVDs) are a subset of medical devices, which, when used alone or in combination, are intended by the manufacturer for examination in vitro of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes (1). Laboratory medicine is an essential element of the health-care system and is integral to many clinical decisions (2). Many governments, health agencies and financial donors in low- and middle-income countries, however, have prioritized medicines, with little investment in diagnostics (3).

For too long, diagnostics have been undervalued in global health, although there is now growing recognition of their critical role. It has become clear that medicines are necessary but not enough for good-quality primary care, to prevent outbreaks or to address threats such as antimicrobial resistance and the global epidemic of noncommunicable diseases (NCDs). Diagnosis is the first, critical step in high-quality health care and in containing emergencies (4).

Ensuring the availability, accessibility, affordability and quality of diagnostics is a key element in facilitating universal health coverage (UHC) (5). Diagnostics are also a fundamental component of the detection, containment or control of outbreaks (6). Diagnostic testing has had an enormous impact on the health of the patients around the world; however, in many areas, some of the most treatable diseases and conditions remain health burdens because of a lack of appropriate diagnostics.

Diagnostic techniques used in human health care can be classified as either (i) in vivo techniques, including medical devices for clinical examination, like stethoscopes and blood pressure measurement devices, various types of imaging tests, like ultrasound or computed tomography scanners, and electrophysiology, such as electrocardiograms; or (ii) in vitro tests, which include biochemical, pathology and microbiology tests. The present publication addresses in vitro tests.

IVDs are essential for good health outcomes and are critical in both everyday medical practice and emergencies. Well-developed laboratory capacity is critical for effective health-care delivery; in addition, investment in diagnostic infrastructure helps countries to prepare for outbreaks.

Access to IVD testing has, however, been limited, especially in low- and middle-income countries. Laboratory capacity has often been neglected in public health systems, resulting in weak laboratory systems, especially in resource-limited countries. The services tend to be fragmented, duplicated and lacking in standards and oversight. Moreover, a focus on disease-specific programmes, all of which require laboratories, has meant that laboratories are not considered an element of the overall health system (7). In many countries, laboratory budgets are not adequate because they are not funded within the public health system. Further, in many low- and middle-income countries, clinicians do not have access to even the basic diagnostic tests necessary for accurate diagnosis of common health problems. In a study of 10 countries, only 2% of facilities had all of the eight diagnostic tests included in the survey, which included simple tests such as those for haemoglobin, malaria, pregnancy and HIV (8). Limited availability of tests in primary care contributes significantly to diagnostic errors, leading to unsafe primary health care (9).

WHO published the first edition of the WHO Model List of Essential in Vitro Diagnostics (EDL) in 2018 (10), followed by the second edition in 2019 (11) and the third edition in 2021 (12). “Essential diagnostics” are those that satisfy the priority health care needs of the population and are selected with due regard to disease prevalence, public health relevance, evidence of efficacy and accuracy and comparative cost-effectiveness. IVDs in the WHO EDL are intended to be available in the context of functioning health systems, always performed with assured quality and adequate information. The goal of the WHO EDL is to help countries

advance UHC, address health emergencies and promote healthier populations, which are the three strategic priorities of the WHO Thirteenth General Programme of Work (2019–2023).

## **1.2 Importance of a list of essential in vitro diagnostics**

Some countries may already have some lists that include IVDs, such as a list of minimum diagnostic tests, a national list for procurement and reimbursement, a “positive” list, a national reference list, a national basic list or a national essential list. Such lists could be drawn up by a national or regional committee, an agency or unit in the ministry of health or an insurance agency.

For the purpose of this document, a national list of essential in vitro diagnostics (NEDL) is a policy document that lists categories of tests that are considered by the ministry of health as high priorities for availability at appropriate levels of the national health-care system. Such a list should be based on scientific evidence and defined according to the country’s context and needs. The list helps to focus resources on the most important items and is aspirational, in that it allows countries to aim for a complete set of items considered by an expert panel to be essential. An NEDL supports the selection of IVDs for health interventions in UHC priority benefits packages, and formulation of an NEDL is an opportunity to update the policy and regulatory framework to provide good-quality, affordable IVDs in the country.

When the NEDL is available and used to guide procurement and reimbursement in UHC priority benefits packages, it can serve as the basis for improving the availability and quality of IVDs for patients and also for reducing out-of-pocket expenditure for these tests. In addition, an NEDL can be useful for developing medical guidelines and laboratory accreditation schemes and also as a basis for research and development of new appropriate, effective IVDs.

The goal of an NEDL is to increase access to essential IVDs. The NEDL could therefore be used as a basis for building and strengthening diagnostic testing capacity in the country. This will require broad, sustained investment in laboratory capacity at all levels of the health-care system, in addition to effective specimen referral systems. An example of a NEDL can be found in reference 13.

## **1.3 Purpose and scope of the document**

This document is intended to provide guidance to countries on methods for developing and updating an NEDL. It describes the best practices for selecting categories of IVD tests for an NEDL, consistent with the evidence-based methods used to update the WHO EDL. The document guides identification of the most relevant categories of IVDs listed in the WHO EDL for inclusion in the NEDL according to the country’s context and needs, national health plans, national laboratory strategic plan, priority health interventions, national programmes, insurance packages, UHC packages and other related initiatives. The document also includes an overview of use of an NEDL for enabling and improving access to clinical laboratory services.

Guidance is not provided on regulation or procurement of IVDs or on products that have been prequalified by WHO. Detailed WHO guidance on WHO prequalification and procurement of IVDs is available on WHO’s prequalification portal (14).

## **1.4 Intended readership**

The document is intended for ministries of health, policy- and decision-makers, including members of committees appointed for developing or updating an NEDL, and other stakeholders who influence the selection of IVD tests.

## 2. The WHO Model List of Essential In Vitro Diagnostics

The WHO EDL is an evidence-based resource consisting of a list of categories of essential IVD tests and recommended assay formats for those tests.

### 2.1 Objective

The WHO EDL was developed to provide evidence-based guidance to countries for creating or updating their NEDLs and to guide policy on access to clinical laboratory services (10). It can be used by countries to prioritize the IVDs that should be available at different levels of the health-care system and to support them in allocating often scarce resources to essential IVDs for ensuring a healthier population.

The WHO EDL can also be informative for United Nations agencies and nongovernmental organizations that support the selection, procurement, supply, donation or provision of IVDs as well as for private health technology and manufacturing sectors, so that they focus on the IVDs necessary to address global health issues (11).

The WHO EDL is not intended to be prescriptive with respect to IVDs nor to the level of the health-care system at which they can or should be used. Rather, it is a guide and should be adapted by countries to their needs and resources (11). The WHO EDL is a dynamic list and is regularly updated (12, 15).

### 2.2 Context among other WHO model lists

The WHO EDL is one of a number of evidence-based lists published by WHO for Member States, donor agencies and policy-makers to select health products. The lists are complementary. The listed products cover the entire continuum of care – prevention, diagnosis, treatment, rehabilitation and palliation.

Publications that complement the WHO EDL are described below.

- WHO published its first Model List of Essential Medicines (EML) in 1977 to improve access to medicines. More than 100 countries have used the WHO EML to formulate their national EML and to use them to control medicines prices, prioritize procurement, streamline the supply chain, develop guidelines and ensure access. This list is updated every 2 years (16).
- Since 2015, WHO has prepared lists of Priority Medical Devices for prevention, protection, diagnosis and treatment in areas including reproductive, maternal, new-born and child health, cancer management, Ebola virus disease and COVID-19 (17).
- Since 2017, the WHO Priority Assistive Products List has provided guidance on 50 assistive devices (18).

### 2.3 Scope

The WHO EDL includes general and disease-specific IVDs and the most appropriate assay formats for conducting each of the tests (10–12). The diagnostic tests listed in the WHO EDL are organized as follows (12):

- general IVDs that can be used for routine patient care as well as for detection and diagnosis of various diseases and conditions;

- IVDs for the detection, diagnosis and monitoring of specific diseases. The first edition of the EDL listed tests for HIV infection, tuberculosis, malaria and hepatitis B and C as well as syphilis and human papillomavirus infection. Later editions extended the scope of diseases to include noncommunicable diseases such as cancer, cardiovascular diseases and endocrine disorders;
- tests for screening blood donations for transfusion; and
- “Do Not Do” recommendations: some tests have been listed for discontinuation on the basis of either evidence of harm or lack of benefit. The listings are supported by current WHO policies.

## 2.4 Use in outbreak response

The International Health Regulations (2005), adopted by the World Health Assembly in 2005, are a legally-binding agreement signed by 196 countries. They place specific responsibilities on WHO Member States to build and strengthen national capacity for the surveillance, detection, assessment, early notification and response to disease outbreaks and other emergencies of potential public health concern. The core capacity requirements for surveillance and response include the provision of laboratory services (19).

The WHO EDL includes IVDs for outbreaks and emergencies that countries may adopt. For example, tests for Zika virus were added in the second edition (2019). In response to the ongoing COVID-19 pandemic, two SARS-CoV-2 tests were added in the third edition (2021), which include SARS-CoV-2 nucleic acid tests and antigen rapid diagnostic tests, with corresponding links to the WHO Emergency Use Listing for IVDs to detect SARS-CoV-2 (20) and WHO guidance on SARS-CoV-2 laboratory and diagnosis (21). It is important that IVDs for outbreaks also be considered for inclusion in NEDLs.

## 2.5 Criteria for selection of test categories

The following criteria are used to include or exclude tests in the WHO EDL (11):

- the public health impact of the test category, as determined, for example, by the disease burden;
- the availability of commercial IVDs for the test category under consideration, as confirmed by sound, adequate data on quality, safety, performance and regulatory status;
- the availability of published evidence on clinical utility;
- the availability of published evidence of diagnostic and clinical accuracy;
- the availability of published evidence of their public health impact;
- the availability of evidence on cost-effectiveness;
- the appropriateness of the IVD category for use at specified levels of the health-care system; and
- the infrastructure required and operational characteristics, such as intended user(s), specimen type, storage conditions and associated equipment.

## 2.6 Content and presentation

The WHO EDL is presented by health-care facility level in two tiers (10, 11) and a section on “Do Not Do” recommendations (12) as shown below:

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

## II. Health care facilities with clinical laboratories, in three sections:

II.a General IVDs for use in clinical laboratories

II.b Disease-specific IVDs for use in clinical laboratories

II.c Disease-specific for IVDs for blood-screening laboratories for transfusion purposes

## III. “Do Not Do” recommendations

Community settings and health facilities without laboratories include health posts and centres, doctors’ offices, outreach clinics, ambulatory care and home- and self-testing. Specimens may be collected, transported to and processed at a higher tier of the health system. The tests in tier I of the EDL are also assumed to be available, with the extended list, in tier II at health-care facilities with laboratories, although the assay formats may differ.

Tier II of the EDL includes additional tests for district, regional, provincial or specialized hospitals or laboratories and for national reference laboratories. It is assumed that trained laboratory technologists, specialist expertise and laboratory infrastructure and equipment are available at the appropriate level. All diagnostic tests available in community settings and health facilities, as described for tier I, are assumed to be available at higher levels, as appropriate.

General IVDs are grouped by test discipline, e.g. haematology, clinical chemistry, clinical microbiology, and disease-specific IVDs are grouped by disease type (11, 12).

For each diagnostic test listed in the WHO EDL, the following are described (11, 12):

- test purpose: the intended use of the diagnostic test;
- assay format: the method on which the test is based, e.g. immunoassay, nucleic acid test;
- specimen type: the types of specimens that can be tested. The types listed for each diagnostic test category are possible specimens for that category; however, not all test brands in each category will have been validated for all the specimen types listed. Users should always follow the manufacturer’s instructions for specimen preparation and storage.
- WHO prequalified or recommended products (if available): tests for which name brand products are either prequalified, listed for emergency use or otherwise recommended by WHO; a link is provided.
- WHO supporting documents when available: if there is WHO guidance on use of the test category, a link is provided to the appropriate WHO site.

The “Do Not Do” recommendations refer to test categories that have been listed for discontinuation. The recommendations are based on evidence of either harm or lack of benefit. Listings are supported by current WHO policies.

As the WHO EDL is not intended as a guideline for use of the test categories listed, available clinical guidelines are included as source documents.

The WHO 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. Performance characteristics should, however, be considered when selecting IVDs for inclusion in the EDL.

## 2.7 Relationship to the list of WHO-prequalified in vitro diagnostic products

The WHO EDL and the WHO list of prequalified IVDs are complementary but distinct. The prequalification list includes IVD products that have been assessed by WHO and are identified by brand, regulatory version and place of manufacture, while the EDL lists generic categories of IVDs. The scope of the prequalification list is narrower than that of the WHO EDL, as not all the tests listed in the EDL are candidates for prequalification.

In the context of the WHO EDL, the prequalification list should be viewed as a resource, as it lists specific prequalified products that correspond to certain categories of tests in the WHO EDL. Relevant links to prequalified products are provided in the WHO EDL (10, 14).

## 2.8 WHO Strategic Advisory Group of Experts on in vitro diagnostics

SAGE IVD was conceived in 2018 as an advisory body on matters of global policy and strategy related to IVDs, including advising WHO on the tests to be included in the EDL (10, 22). SAGE IVD members serve in their personal capacities and represent the broad range of disciplines required to advise on the many aspects of in vitro diagnostics and other clinical laboratory related activities. WHO maintains a roster of experts on IVDs from which it selects the SAGE IVD members. Applications to the roster of experts may be submitted periodically and are kept by the EDL Secretariat for review by a selection panel.

Members of the SAGE IVD are selected and appointed by the Director-General or by the Assistant Director-General of the Access to Medicines and Health Products Division of WHO. Detailed information on the selection criteria for members and information on how to apply is available in the terms of reference for the SAGE IVD (22).

## 2.9 Development and updating of the list

The review and updating of the WHO EDL is a dynamic, transparent process. The list is updated regularly, with periodic calls for submission of applications. The EDL secretariat oversees submissions, and the SAGE IVD is responsible for reviewing applications and making recommendations. Applications for inclusion of diagnostic test categories in the WHO EDL can be submitted by, or through, relevant WHO department(s) by WHO regional or country offices and by other stakeholders, such as academia, nongovernmental organizations, Member States, companies in the in vitro diagnostic industry and in vitro diagnostic industry associations (15, 23).

Submission takes place in two phases: pre-submission and full submission (15, 24):

Pre-submission is used to request:

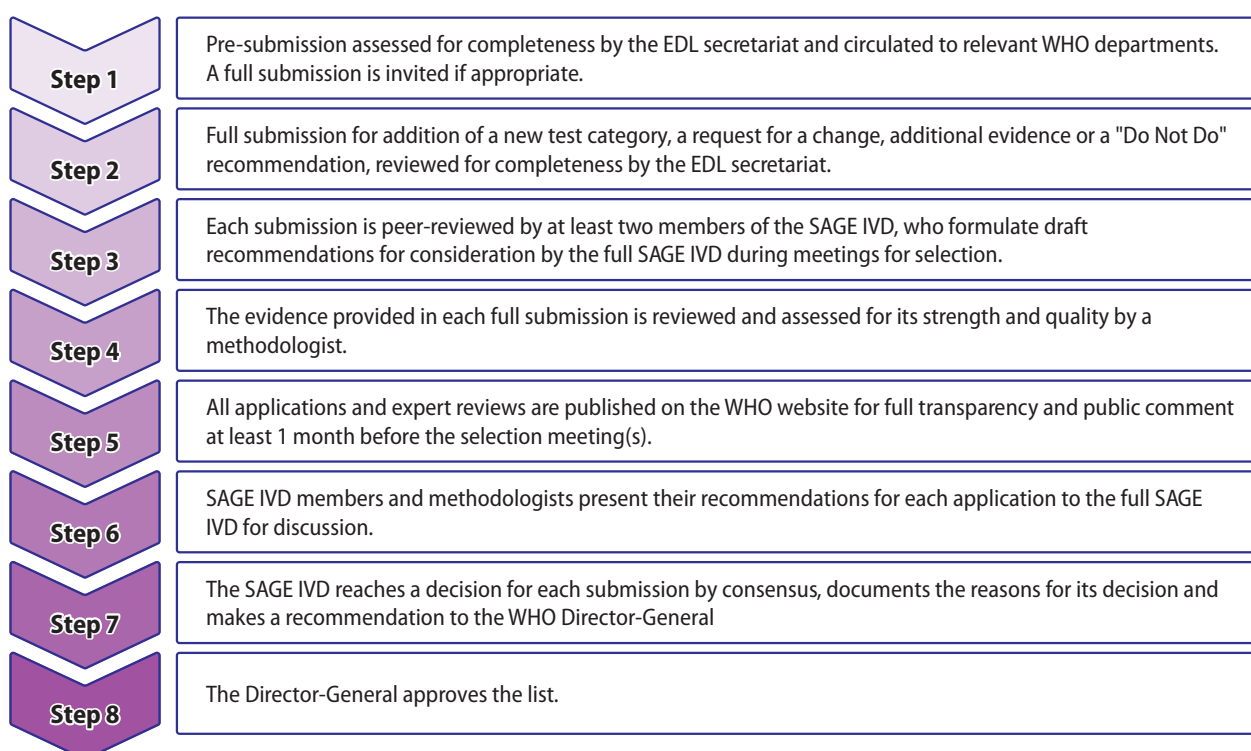
- inclusion of a new test category,
- a change to an existing entry in the EDL,
- removal of a test category from the EDL or
- “Do Not Do” recommendation for a test category.

A pre-submission contains information on the applicant, the disease or condition addressed, a description of the test category and the availability of commercial products for conducting the test and lists of relevant evidence to support the application. This allows the EDL secretariat, in collaboration with WHO programmes, to determine whether there is sufficient supporting information for the test category under review to be considered for the EDL. Thereafter, successful applicants are invited to provide a full submission.

A full submission must provide detailed information on the characteristics of the test category, the commercial availability of products for conducting the test, scientific evidence of its clinical accuracy and utility and relevant features for implementation, such as training and equipment requirements and data on comparative cost and cost-effectiveness.

Submissions for the WHO EDL are now sent electronically through a web-based application, although paper-based applications were sent for the first three editions of the list.

Fig. 1 summarizes the process for establishing the WHO EDL.

**Fig. 1. Summary of the WHO EDL submission process**

## Types of evidence included in the review of submissions for test categories in the EDL

The review by SAGE IVD of submissions to the EDL is extensive and rigorous; countries that are considering inclusion of diagnostic tests categories for their NEDL can be assured that any diagnostic test in the WHO EDL has been thoroughly considered. The review of submissions to the WHO EDL covers the following main types of evidence:

- systematic reviews and primary studies of the clinical accuracy of the test when used in clinical practice;
- systematic reviews and primary studies of the clinical utility and impact of the test on patient management and care;
- recommendations from guidelines issued by WHO or other recognized expert bodies on use of the diagnostic test; and
- available evidence on comparative cost and cost-effectiveness.

Submission form templates for the WHO EDL are provided in Annex 1.

## 2.10 Management of conflicts of interest

In order to ensure the highest levels of integrity and public confidence in any of WHO's outputs, WHO requires that any expert serving in an advisory role disclose activities or work performed that may result in a potential or reasonably perceived conflict of interest related to the subject matter under discussion. Therefore, all members of the SAGE IVD are required, before their appointment, to submit a declaration of interests with respect to work they undertake in their advisory role and in reviewing submissions for in vitro diagnostics on the Model List. Any declared potential conflict is reviewed, and mitigation measures may be undertaken (23).

The term “conflict of interests” refers to any interest declared by an expert that may affect or reasonably be perceived to affect the expert’s objectivity and independence in providing advice to WHO. WHO’s rules on conflicts of interests are designed to avoid compromising situations that could undermine or otherwise affect the work of the expert, the committee or activity in which the expert is involved or WHO as a whole. Consequently, the scope of the inquiry is any interest that could reasonably be perceived to affect the functions that the expert is performing.

The different types of interests that could impair or could be perceived to impair an expert’s independent judgement when making recommendations include (23):

- financial interests: any income or support received by the expert for activities that could benefit from the outcomes of the work discussed or performed for WHO. These include personal financial gain from honoraria, investments in stocks and bonds, funding for research (e.g. from manufacturers of in vitro diagnostics). This type of interest also applies to members of the expert’s immediate family (children or spouse).
- public statements and positions: experts may have strongly supported positions on topics related to the meeting or work to be performed, including membership in an organization that publicly supports certain positions that the expert is required to defend or a position stated by the expert during judiciary proceedings or regulatory processes.
- link to the tobacco industry: given the nature of WHO’s work, any link to the tobacco industry must be declared by experts.

Any declared interest must be the subject of a conflict of interest assessment.

SAGE IVD members contribute to a continuous process that culminates in periodic SAGE IVD meetings and publication of the list. They are therefore required to inform the EDL secretariat if a new potential conflict arises. A new declaration is requested before the periodic SAGE IVD meeting, during which potential conflicts are reviewed and made known to the rest of the committee. Members are also asked to state any new potential conflict at the beginning of the meeting.

Several options are available for mitigating and managing a declared conflict of interests:

- During work before the SAGE IVD meeting, SAGE IVD members with a potential conflict of interests may be requested to abstain from reviewing specific submissions, or their tenure may be terminated if no mitigation measures can be put in place.
- During the SAGE IVD meeting, members may be allowed to be present during the review of submissions but be asked to step out during deliberations about the inclusion or exclusion of a test category; or members may be asked to recuse themselves from any discussion related to the specific subject matter for which the potential conflict may exist.

Potential conflicts of interest are managed according to WHO rules and procedures with the WHO Office of Compliance, Risk Management and Ethics (25).

### 3. Development and updating of a national list of essential in vitro diagnostics

An NEDL can be the first opportunity to embed priority tests as essential in the provision of health care, to build on existing IVD initiatives or to list IVDs that are relevant for new health programmes and public health emergencies. Development of an NEDL requires consideration of the context of each country.

WHO acknowledge that the following proposed approach is one among several alternatives and that the final process at country level may differ from that proposed by WHO, furthermore, the process described in this document will be subject to review and will be updated based on new available evidence and experiences shared by countries.

#### 3.1 Guiding principles

The following guiding principles should be followed to ensure a successful development, updating and future implementation of an NEDL.

- **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**;
- **systematic, rigorous evidence-based evaluation** for developing and updating the NEDL;
- **inclusion and participation** of relevant stakeholders through an open, transparent application process widely disseminated throughout the country;
- **use of aspirational values in NEDL development** to include tests that will enable provision of comprehensive care and support UHC, emergencies, outbreaks and the well-being of the population; and
- **periodic review and updating of the NEDL** according to an institutional process.

#### 3.2 Committees and functions

To develop an NEDL, the ministry of health should appoint a national high-level committee for IVDs or use an existing high-level unit, agency or working group that is usually charged with selecting IVDs and prioritizing health products for the population. This strategic committee is in turn responsible for appointing a technical committee (NEDL committee) for technical leadership and guidance on evaluating and selecting essential IVDs for the country by adapting and applying the WHO EDL process.

##### National ministry of health high-level committee

This committee may be formed by the ministry of health and senior officials of other relevant ministries and departments. Alternatively, existing committees that address IVDs may be used. The role of this committee is to provide strategic leadership for development of the list, including final approval. The roles and responsibilities of this committee are listed in Annex 2. This type of committee usually exists in the ministry of health and is responsible for defining essential and priority programmes, health products and interventions and making decisions. Suggestions for members of this committee are:

- senior officials in the ministry of health, including a laboratory directorate or unit;
- representatives of other ministries involved in health service provision, such as military and social insurance;
- a representative of the national regulatory agency for health products and testing providers; and
- a representative of health service provision, benefits package or national insurance services.

### **NEDL committee, supported by a small secretariat**

This committee should be appointed by the national ministry of health high-level committee. The committee should assume technical leadership for evaluating evidence and selecting IVDs for the NEDL. The roles and responsibilities of the NEDL committee are listed in Annex 3. The membership of this committee may include but need not be limited to:

- personnel from the ministry of health or another national or regional authority involved in the development of national or regional policies and diagnostics guidelines;
- specialists and technical experts in the various areas of IVDs;
- experts in clinical laboratory, anatomical pathology and blood bank operations; and
- experts in evidence synthesis and appraisal, evidence-based medicine and health technology assessment.

This committee can consult additional specialists in various clinical disciplines (infectious diseases and noncommunicable diseases) as necessary. Representatives from both the public and the private health-care sector can be summoned by the NEDL committee.

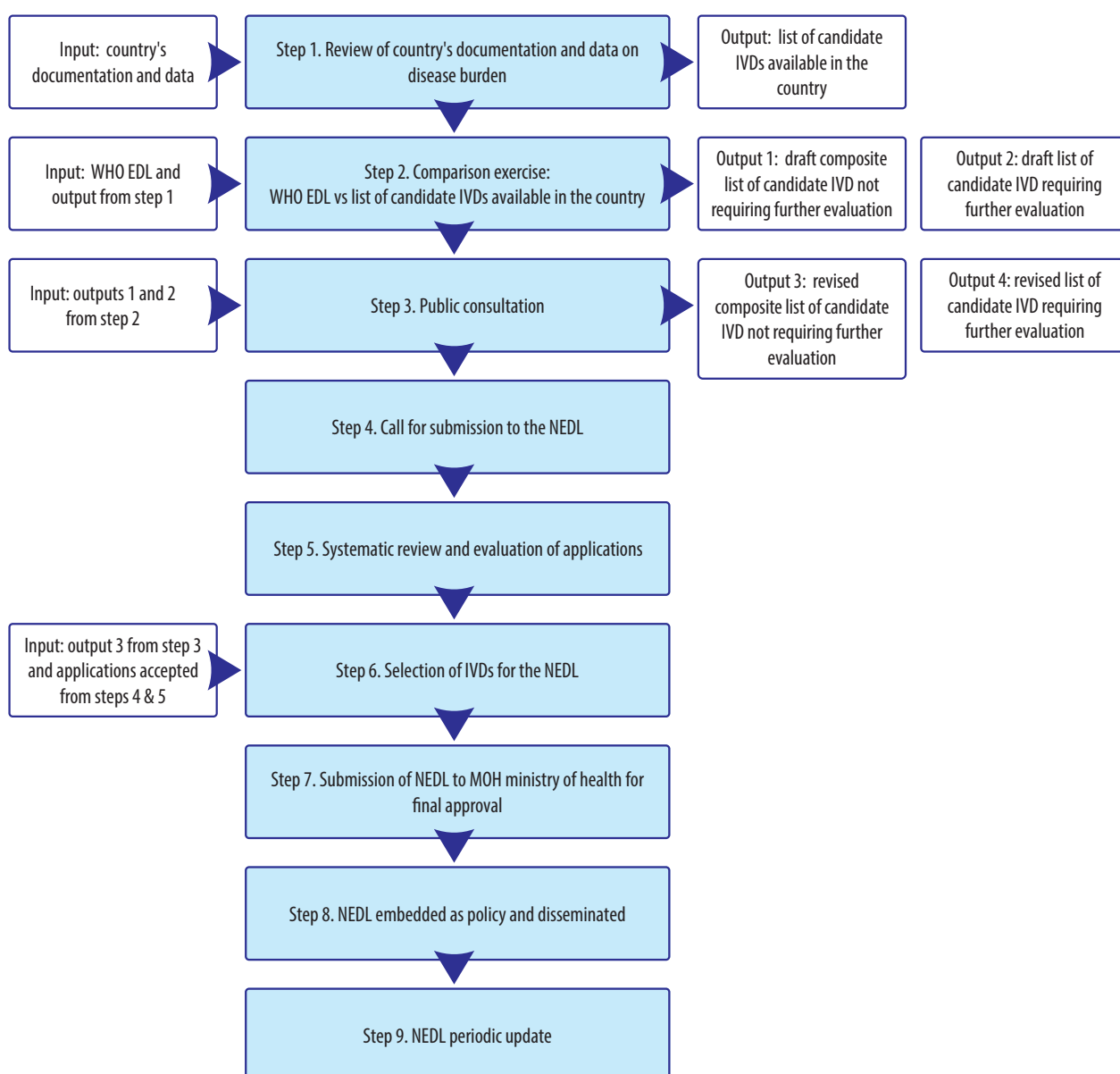
### **Managing conflicts of interest**

Conflicts of interests in the selection and participation of members of committees should be handled with the same level of scrutiny as that used to manage the SAGE IVD at WHO (see section 2.10) (23) and in accordance with local guidelines.

## **3.3 Process**

The purpose of the WHO EDL is to provide a blueprint on which countries can base their national lists. The process used to establish the WHO EDL can be replicated at country level with consideration of local conditions, such as national and subnational disease burden and the availability of treatments. Countries may adjust the list according to their needs and resources and introduce or modify certain elements. Furthermore, countries may choose to follow a different approach from that described in the present document. Fig. 2 shows the steps in developing or updating an NEDL.

**Fig. 2. Stepwise process for developing or updating an NEDL**



## Step 1. Setting up: review of relevant national documentation and data

The first step in developing an NEDL should be a review of all relevant lists and policies on IVDs available in the country, such as:

- IVD procurement list(s) at the ministry of health or central medical stores;
- minimum diagnostic test list;
- national laboratory services catalogue;
- IVD tests available at all tiers of the national laboratory system and testing sites;
- IVDs listed in priority benefits packages or other health insurance packages linked to UHC and reimbursement schemes;
- IVDs listed in national clinical practice guidance, protocols or care pathways;
- policies and guidance of national health programmes (e.g. tuberculosis, HIV, diabetes, maternal and child health) or a list of the IVDs listed in such documents; and

- policies and guidance on IVDs for notifiable diseases and epidemics or a list of the IVDs in these documents.

Likewise, published data on disease burden, prevalence proportions and incidence rates should be reviewed. Countries that have a national EML could also review it to identify those IVDs that are essential for effective use of the medicines listed.

The NEDL committee will be responsible for reviewing all applicable national documentation and preparing a list of candidate IVD tests categories, with the name of the test, assay format(s), assay purpose and specimen type.

## **Step 2. Comparison exercise: WHO EDL vs list of candidate IVD tests categories available in the country**

The NEDL committee should review the WHO EDL and compare the tests listed in the WHO EDL and the list of candidate IVD tests categories produced in step 1. This exercise is intended to identify the IVDs already available in the country which match (test category, test purpose and assay format) the tests listed in the WHO EDL and could be considered for listing in the NEDL without further evaluation of evidence, and those IVDs that should undergo a full evaluation of the scientific evidence.

During the comparison exercise, the committee could encounter multiples scenarios such as the following.

### **Scenario A: The candidate IVD test does not require further evaluation of evidence in order to be listed in the NEDL.**

The candidate IVD is fully matched with the IVD listed in the EDL with regard to diagnostic test category, test purpose and assay format, and national selection is advised in order to be in line with selection for the WHO EDL, without further evaluation of evidence. The NEDL committee should consider whether SAGE IVD's recommendations for the test are applicable to the local context.

### **Scenario B: The candidate test category is listed in the WHO EDL, but the format is different from that listed in the WHO EDL.**

When a candidate IVD test is listed in the WHO EDL but the assay format is different, a full evaluation of scientific evidence (as described in steps 4 and 5) is required. The NEDL committee is advised to consult the EDL secretariat, as the candidate assay format may be being evaluated for the next edition of the WHO EDL.

Assays format(s) listed in the WHO EDL for that test category could be selected for the NEDL without further evaluation of evidence if it meets the country's needs.

### **Scenario C: The candidate test category and assay format are not listed in the WHO EDL and have not been evaluated by the WHO SAGE IVD.**

The NEDL committee is advised to contact the EDL secretariat, as the candidate test might be undergoing evaluation for the next iteration of the WHO EDL. The country could postpone the decision on including the candidate test to avoid duplicating the evidence synthesis being undertaken by SAGE IVD. If the candidate test is not being reviewed by the SAGE IVD, the NEDL committee should conduct a full evaluation of scientific evidence, as described in steps 4 and 5.

### **Scenario D: The candidate test category and assay format are not listed in the WHO EDL and have been rejected or deleted by the WHO SAGE IVD.**

Generally, SAGE IVD recommends exclusion of a test category (12) because of lack of evidence

- of the utility, impact or adequate performance of the test; or

- because evidence is available for the test category but was not included in the submission, in which case SAGE IVD would recommend re-submission for the next edition.

Test categories that have been considered and rejected or deleted by SAGE IVD are described in the WHO Technical Report Series on the selection and use of essential in vitro diagnostics for the edition for which they were discussed. The NEDL committee should review the reasons for which the test category was excluded from the WHO EDL. Tests that were rejected because of lack of evidence may be considered by the NEDL committee if the test is highly significant for the country. In this case, the NEDL committee should conduct a full evaluation of the scientific evidence, as described in steps 4 and 5.

### **Scenario E: Use of the candidate IVD tests is not recommended in the WHO EDL.**

When a candidate IVD test is listed in the WHO EDL as a “Do Not Do” recommendation, the candidate test should not be included in the NEDL or, if appropriate, they should be listed in a “Do Not Do” recommendations section, as in the WHO EDL. The test categories listed in the “Do Not Do” section of the EDL have been listed for discontinuation on the basis of evidence of harm or lack of benefit. The listings are supported by current WHO policies.

The outputs of step 2 will be:

- a draft composite list of candidate IVD tests that do not require further evaluation of evidence in order to be listed in the NEDL and
- a draft list of candidate IVDs tests for which the evidence must be further evaluated to be listed in the NEDL and will be subject to a call for submissions.

#### **Useful resources**

**The WHO Technical Report, The selection and use of essential in vitro diagnostics (12)**, includes the WHO model list of essential in vitro diagnostics and a complete description of every submission considered, a summary of the evidence appraised by specialist methodologists and a summary of the deliberations and recommendations of the SAGE IVD. It is therefore a useful resource, providing Member States with the evidence for considering national selections in line with selections for the WHO EDL without further evaluation of evidence (26).

**eEDL**, a user-friendly web-based application of the WHO EDL, became available in Beta format in January 2021. It provides information on the characteristics of tests and a summary of SAGE IVD recommendations (<https://edl.medevis.test.evidenceprime.com/>).

The NEDL committee must consider the test categories and assay formats listed in the WHO EDL for incorporation in the composite list of IVDs with due regard to their country’s context and public health priorities. Some factors to be considered that are the burden of disease, epidemiological needs or priorities (e.g. tackling antimicrobial resistance, disease elimination priorities), availability of treatments (e.g. medicines listed in the national EML), genetic and environmental factors and local demographics.

### **Step 3. Public consultation on the outputs of step 2 to inform the next step, including a call for submissions to the NEDL**

The two outputs of step 2 (the draft composite list of candidate IVD tests that do not require further evaluation before listing in the NEDL and the draft list of candidate IVDs tests for which further evaluation of evidence is required for listing in the NEDL and will be subject to a call for submissions to the NEDL) should be posted for public consultation on the relevant national web pages and disseminated to stakeholders for approximately 4 weeks. The comments received should be considered by the NEDL committee to refine the outputs of step 2 if necessary and to inform the call for submissions to the NEDL.

#### Step 4. A call for submissions to the NEDL by the NEDL committee

The NEDL committee will prepare and launch a call for submissions to the NEDL for IVDs identified as requiring further evaluation of evidence. The call will also be open to IVD tests that are neither listed in the WHO EDL nor currently listed in the NEDL but are relevant to the country's context and public health priorities.

Applications to the NEDL should be open to all, including health institutions, academia, manufacturers, nongovernmental organizations, professional associations and patient advocates. The NEDL committee should take pertinent measures to ensure that the call is widely disseminated throughout the country in order to reach all relevant stakeholders.

Applications must provide an evidence-based justification for inclusion, amendments (e.g. changes to the test purpose or specimen type) or deletion of a test category or assay format. The information that could be included in an application is listed in the box below.

##### Information required for an NEDL application form

1. Applicant information
2. Name(s) of any organization(s) supporting the application
3. Name of the test category
4. Purpose of the submission (summary statement of the proposal for inclusion, change or deletion)
5. Disease or condition addressed by the test
6. Test purpose
7. Use of the test (e.g. algorithms, diagnostic strategies)
8. Examples of commercially available IVD products
9. Intended users of the test
10. Public health impact of the disease or condition addressed
11. Potential public health impact of the test
12. Clinical utility of the test
13. Evidence of clinical accuracy (primary studies and systematic reviews)
14. Evidence of the impact on patient management (primary studies and systematic reviews)
15. Guidelines recommendations
16. Performance characteristics of commercially available IVD products
17. Personnel training requirements
18. Equipment required
19. Energy and power requirements
20. Data on comparative cost and cost-effectiveness
21. Ethical issues
22. Equity and human rights issues

Submission formats used for the WHO EDL are provided in Annex 1. They may be adapted as necessary to reflect local processes.

#### Step 5. Standardized review and evaluation of applications

The NEDL committee should have a process for standardized review and evaluation of applications. A rigorous process such as that used for the WHO EDL should be considered. The assessment must be based on appraisal of robust evidence on the performance, utility, availability and cost-effectiveness of the tests and assay formats.

The process listed below is based on that used for the WHO EDL. It could be used for standardized review of applications for the NEDL.

1. The NEDL committee reviews the application for completeness.
2. The application is posted on the designated ministry of health website for public review and comments.
3. All reviews and comments received are published on the designated ministry of health website for full transparency.
4. Specialist technical assessment(s) are made of the data presented in the application by a methodologist or expert in evidence appraisal.
5. Each application is reviewed by at least two members of the committee, who formulate draft recommendations for consideration by the full committee during the meeting for selection.

## Step 6. Selection of IVD tests

The NEDL committee should organize meetings for selection, in which all members of the committee should participate in order to ratify the composite list of IVDs produced in step 2 and to make their recommendations for each application received to the full committee for discussion. The NEDL committee is expected to reach a decision on each application by consensus and to document the reasons for their decisions and recommendations, including allocation of tests to each tier of the health-care system.

Candidate tests may be selected if they are found to have significant impact and satisfactory performance, are cost-effective and are compatible with the country's needs.

If inclusion of a test appears to be relevant but additional information or evidence is necessary, an approach similar to that used by the SAGE IVD could be considered, namely "conditional listing". In such cases, a test is added to the NEDL but its listing is contingent on a review of additional information specific to the local context within a specified time, to be defined by the committee. Examples of this type of recommendation can be found in the reports in the WHO Technical Report Series.

Tests for which there is evidence of harm should not be considered by the committee for inclusion in the NEDL or, if appropriate, they should be listed in a "Do Not Do" recommendations section, as in the WHO EDL.

The WHO EDL is divided into two tiers; however, the tiers will depend on the country and are based on the country's needs and resources (11). The two tiers of the WHO EDL are described in section 2. Countries that are adapting the WHO EDL should add granularity to the levels of the health-care system appropriate to the local context. Careful consideration is therefore required in deciding which tests should be allocated to each tier of the health system.

The 2008 Maputo declaration (27) provided much-needed momentum to countries and partners seeking to strengthen laboratory and testing services as a major pillar of the health-care system. It acknowledges that a tiered, integrated laboratory network is the best model for delivering testing services to different levels of the health-care system. The report describes the requirements for standardization and harmonization of laboratory equipment and supplies at each tier of the testing network. Much work in laboratory strengthening has been based on the Maputo declaration (27, 28). It should be noted that, since 2008, new point-of-care technologies and new developments have increased the availability of tests for use in primary health care to ensure early diagnosis of diseases and outbreaks

A "tiered testing network" is an integrated system of laboratories and testing sites aligned with the public health delivery network. Each level of the network has requirements in terms of infrastructure, technology and human resources. The main levels of the network are generally described as follows.

**Level I. Primary care setting:** These sites serve outpatients and are staffed with health-care workers and lay providers, usually with no access to a laboratory. Such sites may conduct certain point-of-care tests and a few basic tests. They may also collect specimens for referral to testing and laboratories at a higher level. Self-testing may be included. Clean water, electricity and refrigeration may not be available.

Level II, Districts: These testing sites are intermediate referral facilities (e.g. district hospitals) staffed with laboratory technicians and sometimes with laboratory technicians. They offer more diagnostic services and support testing services at level I. They may also provide support for quality assurance and training.

Level III, Regions or provinces: Sites in regional or provincial referral hospitals or laboratories that are staffed with laboratory specialists and technicians. They perform more complex tests, offer a complete “menu” of tests and can process large volumes of specimens. Level-III sites test specimens collected by lower-level facilities and support those facilities in quality assurance, training and surveillance.

Level IV, national or regional reference laboratories: National or regional public health reference laboratories are staffed with laboratory specialists and technicians. They can be expected to perform the most complex types of testing (of specimens taken at facilities lower in the system or by receiving patients referred directly from other facilities), support lower-level sites, intervene in policy, evaluate new technologies being considered for use in a country, conduct surveillance of diseases of public health concern and are referral centres for quality assurance and training.

### **Step 7. Finalization of the lists by the NEDL committee and submission to the national high-level committee and the ministry of health for approval**

The NEDL committee finalizes the list and compiles a detailed report of the decision-making process, the data reviewed and evidence appraisal for each of the test categories considered during development or updating of the NEDL. The report should contain the reasons for the committee’s decisions, a summary of their deliberations and any caveats or supplemental information related to the use of the test such as any recommended limitations of the use of the test. The final NEDL should be presented to the relevant highest authority in ministry of health for approval.

### **Step 8. Recognition by the ministry of health of the NEDL as a policy and encouragement of implementation**

Once the final NEDL is approved by the ministry of health, it should be embedded as policy and made widely available in the public domain, for example on the ministry of health website or as a printed version. The NEDL should be launched publicly to ensure that the intended use, legitimacy and authority are clear to all (29),

### **Step 9. Periodic update of the NEDL**

The approved NEDL should be a “living” document. As more resources become available, policy is changed or other health priorities for intervention arise, the NEDL should be modified in a consultative process such as that described in this section. Countries should review the NEDL periodically and during health emergencies and epidemics. The NEDL committee should be responsible for periodic updating. As the capacity necessary for updating the NEDL may be considerable, countries might define sections of the NEDL that should be updated and identify areas for extension of IVDs and areas that are no longer a priority.

The concept of a list of essential IVDs is global and forward-looking and includes regular updating to reflect new IVD options, evolving diagnostic needs and continued development of better IVDs, including for emerging diseases (12, 15). Guidelines for use of the tests in the NEDL should be reviewed if necessary, after the NEDL has been updated.

WHO encourages countries to contact the EDL Secretariat at [EDLsecretariat@who.int](mailto:EDLsecretariat@who.int) to suggest new test categories to be considered in subsequent editions of the WHO EDL.

## 4. Use of a national list of essential in vitro diagnostics

Once a ministry of health has authorized and approved an NEDL, it should be implemented within a defined period. A national implementation committee could be appointed by the ministry of health, which would be responsible for an implementation plan and for providing the diagnostic tests listed in the NEDL. Potential members of the national implementation committee and their roles and responsibilities are listed in Annex 4. The national implementation committee should further appoint regional, state, district and provincial teams to include the IVDs listed in the NEDL in their area.

The steps proposed below are broad suggestions to be considered by countries and should be adapted to the local situation, needs and capacity. The steps listed below will not be suitable for all situations but are elements that might be considered by countries in implementing or improving testing services according to the NEDL.

### 4.1 Steps in organizing testing services after publication of the national list of essential in vitro diagnostic tests

#### Planning

##### Baseline assessment of available resources and testing capacities

The national implementation committee should lead a baseline assessment, which might include:

- the organization of laboratory systems, policies for selecting IVDs, current processes and stakeholders for selecting IVDs;
- a review of existing resources, such as finances, laboratory networks and policies and a regulatory framework for provision of services that require IVDs;
- if possible, an assessment of public health-care facilities, public laboratories and community testing sites for IVDs; and
- the availability of resources for provision of IVD infrastructure, equipment, human resources and supply.

The assessment could be conducted by physical inspection of sites or by distributing a questionnaire to solicit the necessary information.

##### Preparation of an implementation plan

The national implementation committee, with support from regional, state, district or provincial teams, should prepare a plan to define each phase of implementation, including the types of health facilities and community sites to be covered, the diagnostic tests to be introduced (IVD category and assay format according to the NEDL) and the timelines and resources required. Implementation strategies for remote areas should be prepared separately.

The implementation plan should also address building integrated testing capacity for managing outbreaks and emergencies, which would require enhancing diagnostic capacity for surveillance and outbreak detection and response at both national level and in community settings.

## **Gap analysis of resources**

The national implementation committee should conduct an analysis to assess gaps in the resources (i.e. financial and testing capacity such as infrastructure and human resources), policies and regulatory framework necessary for implementation. Policies, strategies and action plans should also be formulated for health technologies, specifically medical devices.

Lists should be prepared of the equipment and human resources required; the infrastructure to be enhanced at each health facility, laboratory and other testing sites; enhancements in the supply chain and storage; and training required. The lists should be prepared for each health facility and carefully validated by the person in charge of the facility to ensure that there are no shortages of equipment, human resources, reagents or consumables when diagnostics tests are provided.

Decisions should be taken on which tests will be covered under reimbursement or insurance packages and which tests will be provided for a fee.

## **Selection of in vitro diagnostic products for procurement**

The national implementation committee, with support from relevant members of NEDL committee, should carefully assess all new IVD products. A comparative analysis of existing and new products might be required. The performance, quality, usability, safety, acceptability, cost-effectiveness, availability and regulatory status of all new products should be evaluated to ensure the requisite diagnostic services at the desired level of the health-care system and the purpose for which these products are intended to be used. Products found to be compatible with the country's needs and resources should be listed for procurement. Detailed technical specifications for procurement should be developed to comply with local regulations.

## **Assessment of budgets**

Budgets should be assessed by the ministry of health, and the approved amount should be within the available resources. The implementation plan should be revised, and the final list of items for procurement, enhancement of infrastructure and supply chain and recruitment of human resources should be prepared in accordance with the final approved budget.

## **Operationalization**

Once the implementation plan is finalized and the necessary budgets are approved, the following activities may be considered to ensure access to IVDs according to population needs, the country or setting and available resources.

- identification of dedicated teams for implementation;
- detailed mapping of health facilities for establishing laboratories, including mapping of lower- to higher-level facilities;
- establishing and upgrading laboratories if necessary;
- regulation, registration or accreditation of laboratories;
- instituting a laboratory information management system, if none is available;
- recruitment, training and retention of laboratory personnel;
- procurement of equipment, reagents and consumables;
- establishment of a robust supply chain for transport of reagents and consumables;
- institution of monitoring mechanisms, data tools and monitoring teams;
- preparation of standard operating procedures for specimen collection, transport, storage, testing, reporting and redressal of grievances;
- preparation of a detailed logistics plan for specimen transport and cold chain;

- validation of new equipment, new kits and reagents;
- establishment of an equipment maintenance programme;
- creation of a support system for community health workers who conduct tests in the community;
- institution of an effective biomedical waste management programme; and
- development of effective information, education and communication materials for beneficiaries of diagnostic services.

Countries could pilot-test implementation and then introduce phased implementation. Tests would be introduced at selected facilities or at selected tiers of the health-care system and be extended to all tiers and facilities later. Routine tests could be provided during the initial phases and complex tests later. Phased roll-out would give time to ensure robust processes for delivering high-quality services from the outset. Furthermore, if the quality and availability of services are satisfactory from the beginning, the services are likely to become popular among physicians at health facilities, which will foster adequate use of the diagnostic services.

Regional, state, district and provincial authorities should ensure:

- inspection of laboratories for functional equipment and reagents and assessment of processes;
- monitoring of service availability (such as sampling and testing services, time to test reports) and use of services (number of patients tested, number of tests of each type conducted, percentage of patients tested, patient:test ratio) at health facilities, stand-alone laboratories and community testing sites;
- monitoring of cold chain, specimen transport, quality assurance at testing and specimen collection sites;
- on-the-job training (such as with online modules) of laboratory staff, health workers who conduct tests, health workers who take samples and staff who transport specimens;
- institution of internal and external quality assurance programmes;
- collection of feedback on testing services from regional, district and provincial health officials, heads of health facilities, clinicians, laboratory staff and patients;
- monitoring use of new equipment to ensure adequate utilization;
- ensuring the availability of stocks of reagents and consumables and their supply to testing sites;
- monitoring and troubleshooting software used for patient registration, data transfer from point-of-care devices used in communities; and
- post-marketing surveillance of tests.

The ministry of health should maintain its commitment to continue implementation and strive to respect the timelines for the next phases of implementation. Additional activities that may be required are as follows.

- Extend testing services to more health facilities, laboratories and testing sites.
- Extend the range of tests (if the test menu was planned to be implemented in phases).
- Establish links between districts and provinces and reference laboratories.
- Expand internal and external quality assurance programmes.
- Initiate planning for complex tests, such as molecular tests, where capacity did not exist previously.
- Extend services of centralized laboratories to health facilities through, for example, a hub-and-spoke model, and initiate sample transport from lower-level sites to higher-level laboratories.
- Initiate planning for community testing programmes.
- Initiate accreditation of well-established laboratories, if not already done.
- Conduct post-marketing surveillance of tests.
- Extend training to laboratory staff in health facilities, stand-alone laboratories and health-care workers at community testing sites.
- Provide support to clinicians at health facilities for use of standard diagnostic guidelines.

- Support equipment maintenance and calibration.
- Monitoring and evaluation:
  - Assess full implementation of testing services listed in the NEDL.
  - Assess the outcomes of provision of in vitro diagnostic services, such as the number of patients tested, types of diseases diagnosed, improvement in health outcomes, reduction in out-of-pocket expenditure and in cost of health care.
  - Calculate financial expenditure and resources consumed for provision of diagnostic services, and match them with benefits received in terms of services provided (such as number of patients tested, numbers of tests of each type conducted, numbers of diseases of each type diagnosed).
  - Assess cost-effectiveness of testing services,
- Plan financial resources required for provision of the requisite testing services in the future.

In the long term, the aim of the national high-level committee should be to provide in vitro diagnostic services, with all relevant diagnostic tests and the most appropriate technologies accessible by the population. This should include the use of integrated testing platforms for effective management of major outbreaks and emergencies. Government authorities should also create an enabling environment for research and development, manufacture and improved market access of new, affordable technologies. The government should also establish testing and calibration laboratories to ensure the quality of medical devices, reagents and kits and plan, install and maintain biomedical equipment and provide training for the diagnostic services. Furthermore, it should ensure that teaching institutes can provide certification courses for laboratory professionals and institutes that can provide accreditation of laboratories.

## 4.2 WHO resources for use of in vitro diagnostics

WHO resources can assist countries in developing laboratory policies and strategies for strengthening laboratory capacity, quality management systems, testing methods for a wide range of diseases, information on the quality of certain diagnostic products and web resources to support market access for validated IVDs.<sup>1</sup>

**WHO also provides guidance documents on outbreak and emergency response, including technical guidance on laboratory diagnostics for COVID-19. These resources are listed in Annex 5.**

<sup>1</sup> [https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab\\_1](https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1) (accessed 29 April 2021)

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## Annex 1. WHO EDL submission forms

### 1.1 WHO EDL pre-submission form (addition of a new test category)

#### Applicant's information

Name of the organization submitting the application (when applicable)

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Contact person, name and information on the organization(s) submitting the application

Last name:	First name:
Email:	Phone number:
Other information:	

#### Name of test category

1. Generic name of the test being addressed in this submission

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#### Disease or condition addressed

2. Please briefly describe the disease or condition being addressed by the proposed test category

--

#### ICD-11 reference

3. Please specify the disease(s) or condition(s) targeted by the IVD category using the International Classification of Diseases (ICD)

<ul style="list-style-type: none"><li><input type="checkbox"/> Certain infectious or parasitic diseases</li><li><input type="checkbox"/> Neoplasms</li><li><input type="checkbox"/> Diseases of the blood or blood-forming organs</li><li><input type="checkbox"/> Diseases of the immune system</li><li><input type="checkbox"/> Endocrine, nutritional or metabolic diseases</li><li><input type="checkbox"/> Mental, behavioural or neurodevelopmental disorders</li><li><input type="checkbox"/> Sleep-wake disorders</li><li><input type="checkbox"/> Diseases of the nervous system</li><li><input type="checkbox"/> Diseases of the visual system</li><li><input type="checkbox"/> Diseases of the ear or mastoid process</li><li><input type="checkbox"/> Diseases of the circulatory system</li><li><input type="checkbox"/> Diseases of the respiratory system</li><li><input type="checkbox"/> Diseases of the digestive system</li><li><input type="checkbox"/> Diseases of the skin</li><li><input type="checkbox"/> Diseases of the musculoskeletal system or connective tissue</li><li><input type="checkbox"/> Diseases of the genitourinary system</li><li><input type="checkbox"/> Conditions related to sexual health</li><li><input type="checkbox"/> Pregnancy, childbirth or the puerperium</li><li><input type="checkbox"/> Certain conditions originating in the perinatal period</li><li><input type="checkbox"/> Developmental anomalies</li><li><input type="checkbox"/> Other</li></ul>
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4. Please provide the ICD-11 code(s) for the disease(s) or condition(s) that apply

### Test purpose

5. Please select all test purposes that apply

☐ Screening  
☐ Diagnosis  
☐ To aid in diagnosis  
☐ Staging  
☐ Prognosis  
☐ Monitoring  
☐ Surveillance  
☐ Other

If there are several test purposes in the list that apply, please provide more background information:

### Proposed wording for the purpose of the test in the EDL

6. Please formulate the test purpose as you would like it to appear in the EDL (limited to 20 words)

### Use of the test

7. Please explain how the test is used

### Commercially available IVD products in the proposed new category

8. Please provide a list of examples of commercially available IVD products in the test category being submitted

### Intended users of the test

9. Considering the tests mentioned above, who are the intended users?

☐ Self-testing  
☐ Lay caregiver  
☐ Lay health worker  
☐ Non-laboratory trained health care professional  
☐ Laboratory technician/technologist  
☐ Laboratory professional with specialized skills e.g. microbiologist, anatomical pathologist, clinical pathologist etc.

### Evidence for clinical accuracy

10. Please provide a list of the most recent published references to peer-reviewed studies and systematic reviews that support your submission.

### Evidence of clinical utility/impact of the test on patient management and care:

11. Please provide a list of the most recent published references to peer-reviewed studies and systematic reviews that support your submission.

**Guidelines for use of the test:**

12. Please provide a list of references to any guidelines that support or describe use of this test. e.g. WHO, national agencies or relevant professional societies or working groups

**Link to medicines in the WHO Essential Medicines List (EML)**

13. Please briefly describe how the test supports treatment with medicines listed in the EML (if applicable).

**Additional information**

14. Please provide additional information that you would like to have considered.

## 1.2 WHO EDL full submission form (addition of a new test category)

### Pre-submission response ID

1. Please indicate your pre-submission response ID.

### Applicant's information

2. Primary contact person

Last name:	First name:
Email:	Phone number:
Other information:	

3. Secondary contact person (If applicable)

Last name:	First name:
Email:	Phone number:
Other information:	

4. Details of organization making the submission

5. Details of organizations supporting the submission (If applicable)

### Name of test category

6. Generic name of the test being addressed in this submission

### Public health impact of the disease/condition

7. Please detail the public health relevance of the condition addressed with the proposed test, and add references.

### Potential public health impact of the test

8. Please explain in detail how the proposed test benefits public health, and add references.

### Clinical utility of the proposed test category

9. Please detail the clinical utility of the proposed test or the potential impact of the test on patient management and care.

### Evidence on clinical accuracy

10. Please provide a brief description of any systematic reviews of the clinical accuracy of the test evaluating how the test performs when used in patients in clinical practice. If no systematic reviews are available, please state so.

Please attach the systematic review(s) to which you referred:

Please upload at most 10 files	<input type="button" value="Upload"/>
--------------------------------	---------------------------------------

11. Please provide a brief description of primary studies of clinical accuracy of the test evaluating how the test performs when used in patients in clinical practice. If no primary studies are available, please state so.

Please attach the primary studies to which you referred:

Please upload at most 10 files

Upload

### Evidence on clinical utility/impact

12. Please provide a brief description of any systematic reviews of the clinical utility/impact of the test on patient management and care. If no systematic reviews are available, please state so.

Please attach the systematic review(s) to which you referred:

Please upload at most 10 files

Upload

13. Please provide a brief description of primary studies of the clinical utility/impact of the test on patient management and care. If no primary studies are available, please state so.

Please attach the primary studies to which you referred:

Please upload at most 10 files

Upload

### Recommendations

14. Please provide details of any guideline recommendations concerning use of the test

Please attach the guideline(s) to which you referred:

Please upload at most 10 files

Upload

### Commercially available IVD products in the proposed new category

15. Please complete the following table to provide a list of examples of commercially available IVD products in the test category being submitted.

Please attach the table with the requested information and relevant instructions for uses

Upload

### Training requirements

16. From the list of IVDs (from 15 above), please select the training requirements

- ☐ None – read instructions
- ☐ Minimal training
- ☐ One-day training (in person or by videoconference)
- ☐ On-site training for clinical and technical staff
- ☐ Significant training required
- ☐ Certification for use

### Equipment requirements

17. From the list of IVDs (from 15 above), please describe in general terms what, if any, equipment is required other than that provided with the test.

### Energy requirements

18. From the list of IVDs (from 15 above), please select any energy source required for performance of the test.

- ☐ No external power supply required
- ☐ Battery powered
- ☐ Continuous electrical power
- ☐ Other

### Landscape reviews

19. Please provide any landscape reviews describing the test technologies and their use and possibly their performance. If no landscape review is available, please state so.

Please attach the document(s) to which you referred:

Please upload at most 10 files

Upload

### Cost and cost-effectiveness:

20. Please provide a summary of data on comparative cost and cost-effectiveness, or state if not available

### Ethical issues

21. Please detail any important ethical considerations related to the proposed test category and any consequences of its use.

### Equity and human rights issues:

22. Please indicate whether the test reduces inequities and increases accessibility or whether the test may be inaccessible to some populations.

## 1.3 WHO EDL edit a test category form

### Applicant's information

Name of the organization submitting the application (when applicable)

Contact person, name and information on the organization(s) submitting the application

Last name:	First name:
Email:	Phone number:
Other information:	

### Test category addressed in this submission

1. Name of the test category

 Select from list

### Qualifying information for edit

Current information:

Discipline

Disease/condition

Test purpose

Assay format

Specimen type

Facility level

Proposed edit:

Discipline

Disease/condition

Test purpose

Assay format

Specimen type

Facility level

### Evidence and justification

2. Please provide the most recent or emerging observational data, primary studies or systematic reviews related to the proposed modification in test purpose, assay formats or specimen types, or of the health-care setting/facility level in which the test may be performed.

3. Please attach the evidence to which you referred:

Please upload at most 10 files

Upload

### Recommendations

4. Please provide details of any guideline recommendations supporting the change to the test category.

5. Please attach the recommendations to which you referred:

Please upload at most 10 files

Upload

## 1.4 WHO EDL removal of a test category form

### Applicant's information

Name of the organization submitting the application (when applicable)

Contact person, name and information on the organization(s) submitting the application

Last name:	First name:
Email:	Phone number:
Other information:	

### Test category addressed in this submission

1. Name of the test category

<input type="text"/>	<input type="button" value="Pick from list"/>
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### Qualifying information for removal

2. Please describe the main reason for removing the IVD from the list.

### Evidence and justification

3. Please provide the most recent or emerging observational data, primary studies or systematic reviews supporting removal of the test.

4. Please attach the evidence to which you referred:

Please upload at most 10 files	<input type="button" value="Upload"/>
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### Recommendations

5. Please provide details of any guideline recommendations supporting removal of the test.

6. Please attach the recommendations to which you referred:

Please upload at most 10 files	<input type="button" value="Upload"/>
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## 1.5 WHO EDL submission of additional evidence form (requested by SAGE IVD for previously submitted test category in the WHO EDL)

### Applicant's information

Name of the organization submitting the application (when applicable)

Contact person, name and information on the organization(s) submitting the application

Last name:	First name:
Email:	Phone number:
Other information:	

### Test category addressed in this submission

1. Name of the test category

2. Information on your previous submission for this test category

Year of submission:
Pre-submission ID:
Full-submissions ID:

### SAGE IVD request

3. Please phrase exactly what SAGE IVD requested of you:

### Additional evidence

4. Please describe the additional **evidence** to fulfil SAGE IVD request:

5. Please attach the additional evidence to which you referred:

Please upload at most 10 files	<input type="button" value="Upload"/>
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### Recommendations

6. Please provide details of any guideline recommendations as additional evidence to meet the SAGE IVD request (if applicable):

7. Please attach the recommendations to which you referred:

Please upload at most 10 files	<input type="button" value="Upload"/>
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### SAGE IVD and EDL secretariat additional requests

8. If applicable, provide any other information requested by the EDL secretariat based on findings from the SAGE IVD

9. Please attach additional files:

Please upload at most 10 files	<input type="button" value="Upload"/>
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## Annex 2. Roles and responsibilities of a national high-level committee

1. The ministry of health, as the leader of the process, should secure political commitment for development of an NEDL, including garnering support from other relevant ministries. It is responsible for overseeing development and implementation of the NEDL.
2. Appoint a national technical committee for development of the NEDL (NEDL committee) and for its implementation (Implementation committee), with adequate representation of all relevant stakeholders. For implementation, regional or state subcommittees could also be appointed.
3. Oversee the work of the NEDL committee.
4. Assess the available resources and existing policies and regulatory frameworks, and assess possible expansion of resources and, if required, modifications to policies and regulatory frameworks to ensure provision of robust clinical laboratory and pathology services.
5. Ensure that the NEDL is aligned with the goals of national health plans and caters to diagnostic needs of priority health interventions.
6. Forge partnerships with national and international agencies for technical support in the development and implementation of the NEDL and to ensure funding to extend the number of IVDs provided.
7. Ensure that the NEDL is approved, is embedded as policy and is disseminated to government officials for implementation.
8. Provide guidance to the implementation committee on the availability of resources for implementation and regulatory structures for procurement of products and services.
9. Make available adequate resources (funds, equipment, infrastructure, human resources) for smooth roll out of clinical laboratory and pathology services and for their future expansion.
10. Oversee the work of the implementation committee for provision of the diagnostic tests listed in the NEDL.
11. Hold extraordinary sessions for outbreaks and health emergencies, with the ministry of health.
12. Provide an enabling environment for research and development, manufacture, market access and validation of IVD products to increase access to high-quality, affordable technologies in the country.
13. Ensure that the NEDL is continually updated with the necessary tests and relevant technologies, as and when the resources, policies and regulatory framework of the country permit.

## **Annex 3. Roles and responsibilities of a national list of essential in vitro diagnostics committee**

1. Define and execute the process for developing and updating the NEDL.
2. Assess which IVDs are available in the country, including test lists, policies and guidelines.
3. Review the WHO EDL and WHO Technical Report Series for selection and use of essential in vitro diagnostics.
4. Consider comments from public consultation of draft lists.
5. Prepare and help to disseminate a call for submissions to the NEDL.
6. Assess the evidence available for the tests and assay formats proposed for the NEDL for clinical utility, performance, appropriateness, cost-effectiveness and compatibility with the country's needs, and prepare a final NEDL that meets the country's needs.
7. Provide regular updates to the national high-level committee on development of the NEDL.
8. Assess the additional resources and modifications to policies and regulatory framework required to ensure provision of the diagnostic tests listed in the NEDL.
9. Submit the NEDL for approval to the high-level committee.
10. Facilitate dissemination of the final NEDL after its notification.
11. Periodically update the NEDL according to requirements for new tests, the availability of additional resources and any necessary changes in policy and the regulatory framework.
12. Hold extraordinary sessions for outbreaks and health emergencies.
13. Provide technical support to the Implementation committee in designing the implementation plan and procurement. Some members of an NEDL committee may also serve on the implementation committee.

## Annex 4. Proposed members of a national committee and their roles and responsibilities

### Government

- official who oversees existing diagnostic services;
- representatives of national directorate (or equivalent) for existing diagnostic services;
- representatives of national commissions (if any) or heads of task forces on major diseases and health programmes (e.g. HIV, tuberculosis, noncommunicable diseases, reproductive and child health, school health);
- representatives of task forces on universal health coverage, primary health care, surveillance programmes;
- representatives of notifiable diseases programme;
- representative of national procurement agency and heads of regional or state procurement agencies with robust procurement practices;
- representative of national supply chain department or heads of regional or state supply chains with robust supply chains;
- representative of national public works department (civil work);
- representative of department of finance in ministry of health;
- representative of department of information technology in ministry of health;
- representative of department of human resources in ministry of health;
- representative of department of training in ministry of health;
- laboratory specialists (pathologists, microbiologists, biochemists, laboratory medicine, blood bank officer) from each tier of the public health-care system;
- senior laboratory technicians in each section of public laboratories and blood banks;
- senior programme managers and public health administrators in the ministry of health with extensive experience of working in urban and rural areas;
- representative of biomedical engineering department

### External experts

- laboratory specialists (pathologists, microbiologists, biochemists, laboratory medicine, blood bank officer) from the private sector;
- senior laboratory technicians of each section of laboratories and blood banks;
- supply chain specialists;
- inventory management specialists;
- cold chain specialists;
- public health specialists with extensive experience in diagnostics in public health;
- representatives of organizations with extensive experience in quality management;
- information technology organizations with extensive experience in laboratory information systems and inventory management system software;
- training organizations with extensive experience in training laboratory staff;
- training organizations with extensive experience in training community health workers;
- representatives of organizations with extensive experience in preparation of standard treatment guideline modules (online and offline);
- representatives of organizations with extensive experience in infection control and biosafety;
- representatives of organizations with extensive experience in monitoring and evaluation.

## Roles and responsibilities of a national implementation committee

The national implementation committee is responsible for the overall design, implementation and monitoring of testing services in the country. Its roles and responsibilities are the following.

With the NEDL committee (leading development of the NEDL), finalize the mode of delivery of tests:

- List the tests to be provided through reimbursement, benefit packages and health insurance schemes.
- List the tests to be conducted at each testing site.
- List the tests to be provided through referral systems, in which specimens will be transported from lower-level health facilities or communities to centralized laboratories for testing (stand alone or located within higher-level health facilities).
- List the tests to be provided in the community, including door to door and mobile vans.
- List the tests to be provided in mass screening programmes (e.g. camps).
- List the tests to be included in existing vertical programmes (for tuberculosis, HIV, malaria).
- Integrate laboratory systems on multi-testing platforms.
- List the tests that will be outsourced to private providers.
- List the tests to be made available through point-of-care devices.
- List newly introduced tests.

With national, regional and state diagnostics teams:

- Prepare timelines for implementation.
- Prepare a broad implementation plan comprising the phases of implementation, timelines and structure of national, regional, state and district implementation teams.
- Assess the numbers of laboratories and testing sites available, to be established or to be upgraded (such as centralized laboratories, referral laboratories, mobile laboratories).
- Map health facilities and community testing sites (from which samples will be transported) to laboratories for testing, and prepare detailed logistics.
- Prepare lists of essential equipment and reagents and specifications and quality standards for procurement.
- Select in vitro diagnostic products after assessing their performance, usability, acceptability, cost-effectiveness and regulatory status.
- Rationalize use of existing equipment.
- Prepare a list for procurement of equipment, reagents and consumables, mobile vans and other machines, including generators and air conditioners. Monitor the purchase and supply of the material.
- Assess the human resources to be recruited, and prepare a plan for rationalizing use of existing human resources.
- Prepare training structures, training modules and standard operating procedures for preanalytical, analytical and postanalytical processes, quality assurance and equipment maintenance.
- Prepare a plan for infrastructure development and for enhancement of laboratories and testing sites.
- Prepare budgets for implementation, including capital expenditure.
- Provide guidance on procurement of equipment and new technologies.
- Supervise and provide training to laboratory staff, community health workers, supply chain staff, information technology staff and other relevant staff.
- Develop monitoring, outcome and output indicators, and establish the necessary infrastructure, tracking systems and detailed processes to be monitored. Institute use of data tools for monitoring use of testing services and consumption of funds.

- Institute quality management systems.
- Establish patient specimen transport systems.
- Monitor use of diagnostic services and the availability and quality of the services.

With the national high-level committee and the health departments of regions and states:

- Ensure timely approval and release of adequate funds for implementation and procurement.
- Provide regular updates to the national high-level committee on implementation.
- Assess the funds used for provision of testing services, with details of expenditure under different budget headings, and provide updates on the funds used to the national high-level committee.
- Assess the cost-effectiveness of testing services.
- Determine any amendments to be made to policies and the regulatory framework and the formulation of new policies for smooth introduction of diagnostic services, and advocate for the changes to the national high-level committee.
- Work with national and state authorities to explore indigenous manufacturing, innovation and affordable diagnostics.

## Annex 5. WHO technical guidance and other relevant documents on laboratory and diagnostics for COVID-19 (as of 1 July 2021)

Document name	Document type	Link	Key points
Recommendations for national SARS-CoV-2 testing strategies and diagnostic capacities. 25 June 2021	Interim guidance	<a href="https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng">https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng</a>	<p>Diagnostic testing for SARS-CoV-2 is a critical component to the overall prevention and control strategy for COVID-19.</p> <p>Countries should have a national testing strategy in place with clear objectives that can be adapted according to changes in the epidemiological situation, available resources and tools, and country specific context.</p> <p>It is critical that all SARS-CoV-2 testing is linked to public health actions to ensure appropriate clinical care and support and to carry out contact tracing to break chains of transmission.</p> <p>All individuals meeting the suspected case definition for COVID-19 should be tested for SARS-CoV-2, regardless of vaccination status or disease history.</p> <p>Individuals meeting the suspected case definition for COVID-19 should be prioritized for testing. If resources are constrained and it is not possible to test all individuals meeting the case definition, the following cases should be prioritized for testing: individuals who are at risk of developing severe disease; health workers; inpatients in health facilities; the first symptomatic individual or subset of symptomatic individuals in a closed setting (e.g. long-term care facilities) in the setting of a suspected outbreak.</p> <p>Nucleic acid amplification tests (NAAT) are the reference standard for diagnosis of acute SARS-CoV-2 infection.</p> <p>Countries can use high quality antigen-detection lateral flow or rapid diagnostic tests (Ag-RDTs), which are simple to use and offer rapid results, to achieve high coverage of testing, ideally testing all symptomatic individuals meeting the COVID-19 case definition as soon as possible from disease onset (within the first week of illness).</p> <p>Testing of asymptomatic individuals with NAAT or Ag-RDTs is currently recommended only for specific groups including contacts of confirmed or probable COVID-19 cases and frequently exposed groups such as health care workers and long-term care facility workers.</p> <p>Widespread screening of asymptomatic individuals is not a currently recommended strategy due to the significant costs associated with it and the lack of data on its operational effectiveness.</p> <p>Considerations for the use of self-testing should include improved access to testing and potential risks that may affect outbreak control.</p> <p>Mutation-detecting NAAT assays may be used as a screening tool for SARS-CoV-2 variants, but the presence of a specific variant should be confirmed through sequencing. Such tests should be appropriately validated for their purpose.</p> <p>The network of SARS-CoV-2 testing facilities should leverage and build on existing capacities and capabilities, be able to integrate new diagnostic technologies and adapt capacity according to the epidemiological situation, available resources and country specific context.</p>

Continued

Document name	Document type	Link	Key points
SARS-CoV-2 Antigen Rapid Diagnostic Test training package v 2.0. 7 June 2021	Training package	<a href="https://extranet.who.int/hslp/content/sars-cov-2-antigen-rapid-diagnostic-test-training-package">https://extranet.who.int/hslp/content/sars-cov-2-antigen-rapid-diagnostic-test-training-package</a>	<p>This training package is a structured comprehensive collection of training resources and tools to enable institutions to organize, run and evaluate training of trainers and/or training of health workers who will be performing SARS-CoV-2 testing using Antigen RDTs.</p> <p>The training package can be used in face to face training or as a blend of remote and face to face training. Materials can be adapted and customized based on national guidelines and target group of participants.</p> <p>The training addresses the theoretical and practical components of SARS-CoV-2 Antigen RDT testing and provide trainees with the skills and resources on how to safely perform SARS-CoV-2 Antigen RDT testing.</p>
Laboratory biosafety guidance related to coronavirus disease (COVID-19). 28 January 2021	Interim guidance	<a href="https://www.who.int/publications/i/item/WHO-WPE-GIH-2021.1">https://www.who.int/publications/i/item/WHO-WPE-GIH-2021.1</a>	<p>All procedures must be performed only after risk assessment and only by personnel with demonstrated capability, in strict observance of any relevant protocols at all times.</p> <p>Specimens should initially be processed (before inactivation) in a validated biological safety cabinet or primary containment device.</p> <p>Non-propagative diagnostic laboratory work (for example, sequencing, nucleic acid amplification test [NAAT]) should be conducted at a facility with heightened control measures, similar to biosafety level 2.</p> <p>Point-of-care, near-point-of-care assays and antigen-detecting rapid diagnostic tests (Ag-RDTs) can be performed on a bench without a biological safety cabinet if local risk assessment allows and proper precautions are in place.</p> <p>Propagative work (for example, virus culture or neutralization assays) should be conducted in a containment laboratory with inward directional airflow (heightened control measures or biosafety level 3).</p> <p>Appropriate disinfectants with proven activity against enveloped viruses should be used (for example, hypochlorite [bleach], alcohol, povidone-iodine, chloroxylenol, chlorhexidine, benzalkonium chloride).</p> <p>Patient specimens from suspected or confirmed cases should be transported as UN3373, "Biological substance category B". Viral cultures or isolates should be transported as UN2814 category A, "infectious substance, affecting humans".</p>

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Document name	Document type	Link	Key points
Genomic sequencing of SARS-CoV-2: a guide to implementation for maximum impact on public health. 8 January 2021	Implementation guide	<a href="https://www.who.int/publications/i/item/9789240018440">https://www.who.int/publications/i/item/9789240018440</a>	Metagenomic sequencing was fundamental to the detection and characterization of the novel pathogen. Early sharing of SARS-CoV-2 genome sequences allowed rapid development of molecular diagnostic assays, which improved global preparedness and contributed to the design of countermeasures and investigation of disease epidemiology.
			Sequencing should be conducted with due consideration of available resources and capacities and should not draw capacity away from equally vital areas.
			Despite recent advances in the generation of virus sequences, challenges remain. In many settings, the requirement for rapid importation of temperature-sensitive reagents was a significant barrier to adoption of within-country portable sequencing approaches early during COVID-19.
			Public health laboratories generally have more expertise in molecular genetics than in computational phylogenetics and bioinformatics. Strengthened, long-term investment in phylogenetics and bioinformatics
			training is necessary to obtain the maximum benefit from the increasing possibilities for laboratory sequencing in this and subsequent epidemics.
			Several devices are available for sequencing SARS-CoV-2 genomes; each may be more or less appropriate in certain circumstances.
			Laboratories planning to adopt sequencing could benefit from programmes that provide support for formal validation of their sequencing pipelines.
			For most goals, both virus sequence data and sample metadata are required. Many analyses rely on ability to compare locally acquired virus sequences with the global virus genomic diversity. It is therefore crucial that virus genomic sequences are appropriately shared. This is occurring at an impressive rate via repositories such as GISAID and GenBank.
			A strong, resilient global sequencing network could maximize the public health impact of sequencing, not only for SARS-CoV-2 but also for future emerging pathogens.

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Document name	Document type	Link	Key points
SARS-CoV-2 antigen-detecting rapid diagnostic tests: An implementation guide. 21 December 2020	Implementation guide	<a href="https://www.who.int/publications/i/item/9789240017740">https://www.who.int/publications/i/item/9789240017740</a>	Only Ag-RDTs that meet recommended performance criteria should be considered for use and only in areas where NAAT is unavailable or where the health system may be overburdened, resulting in prolonged NAAT turnaround times (> 48–72 h).
			Testing with Ag-RDTs should be conducted by trained operators in strict accordance with the manufacturers' instructions. For best results, tests should be performed within the first 5–7 days after the onset of symptoms.
			Use cases currently recommended for SARS-CoV-2 Ag-RDTs:
			<p>(i) Outbreak investigation, contact tracing</p> <ul style="list-style-type: none"> <li>– to respond to suspected outbreaks of COVID-19 in remote settings, institutions and semi-closed communities where NAAT is not immediately available;</li> <li>– to support outbreak investigations (e.g. in closed or semi-closed settings such as schools, care homes, workplaces). Where COVID-19 outbreaks have been confirmed, Ag-RDTs could be used to screen at-risk individuals and rapidly isolate positive cases.</li> </ul> <p>(ii) Monitoring trends in disease incidence</p> <ul style="list-style-type: none"> <li>– to monitor trends in COVID-19 rates in communities, particularly among essential workers and health workers during outbreaks or in regions of widespread community transmission where the positive and negative predictive value of an Ag-RDT result is sufficient to enable effective infection control.</li> </ul> <p>(iii) Widespread community transmission</p> <ul style="list-style-type: none"> <li>– for early detection and isolation of positive cases in health facilities, COVID-19 testing centres or sites, care homes, prisons, schools, front-line and health care workers and for contact tracing.</li> </ul> <p>(iv) Testing of asymptomatic contacts of cases</p> <p>Despite the second general recommendation, testing of asymptomatic contacts of cases may be considered even if the Ag-RDT is not specifically authorized for this use, as asymptomatic cases have viral loads similar to those of symptomatic cases. In this situation, a negative Ag-RDT result should be considered presumptive and is not sufficient to remove a contact from quarantine requirements. Positive Ag-RDT results, however, can be useful for targeting isolation procedures and broadening contact-tracing.</p>
			Specific examples of settings in which Ag-RDTs should not be used are:
			<ul style="list-style-type: none"> <li>• in individuals without symptoms, unless the person is a contact of a confirmed case;</li> <li>• where there are zero or only sporadic cases;</li> <li>• where appropriate biosafety and infection prevention and control measures are limited or lacking;</li> <li>• where management of a patient and/or use of COVID-19 countermeasures do not change according to the result of the test;</li> <li>• for screening at points of entry or before travel (unless all Ag-RDT-positive results can be confirmed by NAAT); and</li> <li>• in screening before elective surgery or blood donation.</li> </ul>

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Document name	Document type	Link	Key points
Diagnostics, therapeutics, vaccine readiness, and other health products for COVID-19: a module from the suite of health service capacity assessments in the context of the COVID-19 pandemic. A module from the suite of health service capacity assessments in the context of the COVID-19 pandemic. 20 November 2020	Interim guidance	<a href="https://apps.who.int/iris/handle/10665/336747">https://apps.who.int/iris/handle/10665/336747</a>	The tool allows COVID-19 health facilities to assess the availability and status of stockout of critical COVID-19 medicines, equipment and supplies on site and to identify areas for further attention to enable the facility to respond effectively to the pandemic
			The tool is designed for use from the early stages of the emergency to early recovery.
Assessment tool for laboratories implementing SARS-CoV-2 testing: Interim guidance. 23 October 2020	Interim guidance	<a href="https://www.who.int/publications/i/item/assessment-tool-for-laboratories-implementing-covid-19-virus-testing">https://www.who.int/publications/i/item/assessment-tool-for-laboratories-implementing-covid-19-virus-testing</a>	The new Excel tool incorporates core sections of the WHO 2012 laboratory assessment tool, while adding a section specifically on testing for SARS-CoV-2. Overall, the new tool enables rapid identification of strengths and weaknesses of a laboratory to determine the capacity for SARS-CoV-2 testing.
			Identification of laboratory (laboratory type, level, participation in international programmes, disciplines addressed, average number of specimens tested per day, average number of polymerase chain reaction (PCR) or reverse-transcription (RT)-PCR test run per week)
Laboratory assessment tool for laboratories implementing SARS-CoV-2 testing. 23 October 2020.	Excel tool	<a href="https://www.who.int/publications/i/item/laboratory-assessment-tool-for-laboratories-implementing-covid-19-virus-testing">https://www.who.int/publications/i/item/laboratory-assessment-tool-for-laboratories-implementing-covid-19-virus-testing</a>	Assessment of core capacities of the laboratory: <ul style="list-style-type: none"> <li>• Organization and management</li> <li>• Documents</li> <li>• Specimen collection, handling and transport</li> <li>• Data and information management</li> <li>• Consumables and reagents management</li> <li>• Equipment management</li> <li>• Facilities</li> <li>• Human resource</li> <li>• Biorisk management</li> </ul>
			Assessment of specificities in SARS-CoV-2 testing <ul style="list-style-type: none"> <li>• Laboratory capacity</li> <li>• Testing capability</li> </ul>

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Document name	Document type	Link	Key points
Target product profiles for priority diagnostics to support response to the COVID-19 v.1.0. 28 September 2020	Research and development blueprint	<a href="https://www.who.int/publications/m/item/covid-19-target-product-profiles-for-priority-diagnostics-to-support-response-to-the-covid-19-pandemic-v.0.1">https://www.who.int/publications/m/item/covid-19-target-product-profiles-for-priority-diagnostics-to-support-response-to-the-covid-19-pandemic-v.0.1</a>	<p>WHO currently recommends a single approach to clinical diagnostic testing for disease confirmation: detection of unique sequences of SARS-CoV-2 RNA by NAAT, such as real-time (r) RT-PCR.</p> <p>WHO encourages use serological surveys of antibody responses to better understand the extent of and risk factors for COVID-19 infection through enhanced surveillance to calculate the attack rate in different populations.</p> <p>In settings where RT-PCR is unavailable or the turnaround time for results is long (e.g, several days to weeks), rapid antigen detecting tests may facilitate earlier diagnosis and the necessary action.</p> <p>In clinical situations in which NAAT assays are negative in symptomatic individuals with a strong epidemiological link to a confirmed case of COVID-19 infection, paired serum samples (in the acute and convalescent phase) can support a retrospective diagnosis of COVID-19.</p> <p>Target product profile 1. Point-of-care testing for suspected COVID-19 cases and their close contacts to diagnose acute SARS-CoV-2 infection in areas where reference assay testing is unavailable, or the turnaround time obviates its clinical utility. Particularly useful during suspected SARS-CoV-2 outbreaks; in areas with confirmed SARS-CoV-2 community-wide transmission; confirmed outbreaks in closed or semi-closed communities; in high-risk groups; among contacts of confirmed cases; and as a tool to monitor disease incidence</p> <p>i. Target molecule (analyte to be detected): Acceptable: SARS-CoV biomarker (e.g. RNA, protein or antigen(s) specific for acute, e.g. first week after onset of symptoms/ current infection (assumption that SARS-CoV-1 is not circulating). Desirable: SARS-CoV-2 only biomarker (e.g. RNA, protein/antigen) specific for acute and subacute, e.g. first 2 weeks after onset of symptoms or current infection</p> <p>ii. Analytical sensitivity, limit of detection: Acceptable: equivalent to 106 genomic copies/mL or cycle threshold <math>\approx</math> 25–30. Desirable: equivalent to 104 genomic copies/mL or cycle threshold <math>\approx</math> &gt; 30.</p> <p>iii. Analytical specificity: Acceptable: Assay detects all SARS-CoV-2 viral strains and does not cross-react with common interfering substances or other human coronaviruses (except SARS-CoV-1) or any other common human diseases, especially those with similar presenting signs and symptoms of COVID19 (e.g. influenza A, B, respiratory syncytial virus, malaria, dengue). Desirable: same as for the acceptable criteria and does not cross-react with SARS-CoV-1</p> <p>iv. Sensitivity: Acceptable: <math>\geq</math> 80%. Desirable: <math>\geq</math> 90%. Specificity: Acceptable: <math>\geq</math> 97%. Desirable: &gt; 99%.</p> <p>v. Type of analysis: qualitative, semi-quantitative or quantitative</p> <p>vi. Sample type: Acceptable: nasopharyngeal, oropharyngeal swab (or wash), nasal swab (anterior nares or mid-turbinate), nasal wash, sputum. Desirable: anterior nares, saliva or oral fluid, sputum</p>

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Document name	Document type	Link	Key points
			<p>Target product profile 2. Test for diagnosis or confirmation of acute or subacute SARS-CoV-2 infection, suitable for low- or high-volume facilities. This test could be used for repeat assessment throughout the period of viral shedding.</p> <p>i. Target molecule (analyte to be detected): must have at least one target specific for SAR-CoV-2 RNA or protein or antigen.</p> <p>ii. Analytical sensitivity or limit of detection: Acceptable: equivalent to 103 genomic copies/mL in any respiratory tract specimen. Desirable: equivalent to 102 genomic copies/mL in upper and lower respiratory tract specimens and stool.</p> <p>iii. Analytical specificity: assay detects only circulating SARS-CoV-2 viral strains; no interference by other substances</p> <p>iv. Sensitivity: Acceptable: <math>\geq 95\%</math>. Desirable: <math>\geq 98\%</math>. Specificity: Acceptable: <math>\geq 99\%</math>. Desirable: <math>\geq 99\%</math>.</p> <p>v. Type of analysis: Acceptable: Qualitative (information sufficient for clinical decision-making). Desirable: Qualitative and quantitative according to analyte detected</p> <p>vi. Sample type: Acceptable: any of the following: swabs -nasopharyngeal, oropharyngeal, nasal; washes -oropharyngeal, nasal, bronchoalveolar; sputum. Desirable: sample types amenable to self-collection and/or easy to collect: saliva/oral fluid, stool; inactivated samples</p>
			<p>Target product profile 3. Point-of-care test for prior infection with SARS-CoV-2. Ideal for settings with no good options for sample transport and/or access to laboratory infrastructure. The primary use is to support epidemiological surveys and surveillance activities to guide public health measures. These tests are not intended to detect or exclude active infection.</p> <p>i. Target molecule (analyte to be detected): at least one isotype or other biomarker(s) specific to prior SARS-CoV-2 infection.</p> <p>ii. Analytical sensitivity/ limit of detection: Currently, there is no international standard or units to express limits of detection; in the interim, limit of detection can be expressed as the minimum detectable concentration of analyte in well-characterized samples from patients with a history of NAAT-confirmed SARS-CoV-2 infection.</p> <p>iii. Analytical specificity: Detects only SARS-CoV-2 specific isotype or biomarker and does not cross-react with common interfering substances or infectious diseases as per WHO submission requirements: In-vitro diagnostics detecting antibodies to SARS-CoV-2 virus (EUL, Tables 1 and 2) (plus biotin)</p> <p>iv. Sensitivity: Acceptable: <math>\geq 90\%</math>. Desirable: <math>\geq 95\%</math>. Specificity: Acceptable: <math>\geq 97\%</math>. Desirable: <math>\geq 99\%</math>.</p> <p>v. Type of analysis: qualitative</p> <p>vi. Sample type: Plasma, serum but must show equivalence in capillary blood from finger or heel stick and/or saliva or oral fluid.</p>

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Document name	Document type	Link	Key points
			<p>Target product profile 4. Test for previous SARS-CoV-2 infection for moderate- to high-volume needs. This test is designed to support seroprevalence surveys. Also helpful in blood donor screening for plasma therapy/therapeutic antibodies, in planning and evaluating the results of vaccine trials (if they can differentiate between vaccine and natural immune responses). In cases where NAAT assays are negative and there is a strong epidemiological link to COVID-19 infection, paired serum samples (in the acute and convalescent phase) or biomarkers specific for recent infection can support a diagnosis of COVID-19. The quantitative version of this test could potentially further serve to detect the presence, nature and abundance of antibodies necessary to provide protective immunity.</p> <p>i. Target molecule (analyte to be detected): Acceptable: at least one antibody isotype or other biomarker(s) specific to prior SARS-CoV2 infection. Desirable: More than one antibody isotype or other biomarker(s) specific to prior SARS-CoV- 2 infection; discriminates between natural immune response and vaccine-induced response.</p> <p>ii. Analytical sensitivity/limit of detection: currently, there is no international standard or units to express limits of detection; in the interim, limit of detection can be expressed as the minimum detectable concentration of analyte in well-characterized samples from patients with a history of NAAT-confirmed SARS-CoV-2 infection.</p> <p>iii. Analytical specificity: detects only SARS-CoV-2-specific isotype or biomarker and does not cross-react with common interfering substances or infectious diseases as per WHO submission requirements: In-vitro diagnostics detecting antibodies to SARS-CoV-2 virus (EUL Tables 1 and 2) (plus biotin)</p> <p>iv. Sensitivity: Acceptable: <math>\geq 95\%</math>. Desirable: <math>\geq 98\%</math>. Specificity: Acceptable: <math>\geq 97\%</math>. Desirable: <math>\geq 99\%</math></p> <p>v. Type of analysis: semiquantitative or quantitative</p> <p>vi. Sample type: Acceptable: plasma, serum. Desirable: same plus one or more others: whole blood (fresh or frozen or dried blood smear), dried plasma spots; oral fluid (fresh or frozen)</p>
Diagnostic testing for SARS-CoV-2 Interim guidance. 11 September 2020	Interim guidance	<a href="https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2">https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2</a>	<p>Standard confirmation of acute SARS-CoV-2 infections is based on detection of unique viral sequences by NAATs, such as rRT-PCR.</p> <p>Optimal diagnostics consist of a NAAT assay with at least two independent targets on the SARS-CoV-2 genome; however, in areas with widespread transmission of SARS-CoV-2, a simple algorithm might be adopted with one single discriminatory target. When using a one-target assay, it is recommended that a strategy be in place to monitor for mutations that might affect performance.</p> <p>Considerations for selecting the right NAAT for the laboratory (Annex 3): manufacturing quality, targets, controls, instrumentation, workflow, ease of use, storage and shipment requirements, training needs and access, need for ancillary reagents, continuity of supply.</p>

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Document name	Document type	Link	Key points
			For manual PCR systems, each NAAT sample should include internal controls and ideally a specimen collection control (human gene target). Additionally, external controls are recommended for each test run.
			Other amplification and detection methods, such as CRISPR (targeting clustered regularly interspaced short palindromic repeats), isothermal nucleic acid amplification technologies (e.g. reverse transcription loop-mediated isothermal amplification and molecular microarray assays are being developed or commercialized.
			RDT based on antigen detection: clinical data on performance still limited. When their performance is acceptable, these tests could be used in a diagnostic algorithm (depending on the sensitivity and specificity of the antigen test and on the prevalence of SARS-CoV-2 infection in the population to be tested). Most of these are lateral flow immunoassays.
			Serology testing: useful for serosurveillance in investigation of an outbreak. Antibody detection tests should be used with caution and not to determine acute infections or for contact-tracing. A reliable diagnosis of COVID-19 based on patients' antibody response will often be possible only in the recovery phase, when opportunities for clinical intervention or interruption of disease transmission have passed. Therefore, serology is not a suitable replacement for virological assays to inform contact-tracing or clinical management.
			Serology testing: commercial and non-commercial tests to measure binding antibodies (total immunoglobulins (Igs), IgG, IgM, and/or IgA in different combinations) by various techniques, including lateral flow immunoassays, enzyme-linked immunosorbent assays and chemiluminescence immunoassays. Their performance varies widely in different testing groups, and understanding of these variations in performance will require further study.
			Serology testing: non-quantitative assays (e.g. lateral flow assays) are currently not recommended for acute diagnosis and clinical management, and their role in epidemiological surveys is being studied.
			Specimen types: respiratory samples are the preferred type for diagnosis: upper respiratory tract (nasopharyngeal and oropharyngeal swabs), lower respiratory tract (sputum, bronchoalveolar lavage); limited evidence for oral fluid specimens, saliva, gargling or mouth wash, faecal specimens. Saliva is not recommended as the sole specimen type for routine clinical diagnosis; faecal specimens can be considered when respiratory specimens are negative and clinical suspicion of infection remains; serum specimens: paired samples taken in acute and convalescent phase can be used retrospectively to determine whether the individual has had COVID-19 when the infection could not be detected with NAAT; other body fluids: limited evidence for urine, semen, cerebrospinal fluid and ocular fluid; post-mortem specimens: post-mortem swabs, needle biopsy or tissue specimens from autopsy, including lung tissue.

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Document name	Document type	Link	Key points
Antigen detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. 11 September 2020	Interim guidance	<a href="https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays">https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays</a>	Most Ag-RDTs for COVID-19 involve a sandwich immunodetection method in a simple-to-use lateral flow test format.
			In the case of RDTs for SARS-CoV-2, the target analyte is often the virus' nucleocapsid protein, because of its relative abundance.
			After the respiratory specimen has been collected and applied to the test strip, results are read by the operator within 10–30 min with or without a reader instrument.
			Most of the currently manufactured tests require nasal or nasopharyngeal swab samples. Studies are being conducted on the performance of the tests with alternative sample types, such as saliva and oral fluid, and sample collection systems.
			Ag-RDTs are less sensitive than NAAT.
			Data on the sensitivity and specificity of currently available Ag-RDTs for SARS-CoV-2 are derived from studies that varied in design and in the test brands evaluated. Their sensitivity as compared with that of NAAT in samples from the upper respiratory tract (nasal or nasopharyngeal swabs) appears to be highly variable, ranging from 0 to 94%, but their specificity is consistently reported to be high (> 97%).
			Ag-RDTs are most likely to perform well in patients with high viral loads (cycle threshold values $\leq 25$ or $> 106$ genomic virus copies/mL), which usually appear in the pre-symptomatic (1–3 days before symptom onset) and early symptomatic phases of the illness (within the first 5–7 days of illness).
			Minimum performance requirements: $\geq 80\%$ sensitivity and $\geq 97\%$ specificity as compared with a NAAT reference assay
			SARS-CoV-2 Ag-RDTs that meet the minimum performance requirements can be used to diagnose SARS-CoV-2 infection within the first 5–7 days after the onset of symptoms in settings where NAAT is unavailable or where a long turnaround time obviates their clinical utility.

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Document name	Document type	Link	Key points
			<p>Appropriate scenarios for use of COVID-19 Ag-RDTs:</p> <ul style="list-style-type: none"> <li>(i) to respond to suspected outbreaks of COVID-19 in remote settings, institutions and semi-closed communities where NAAT is not immediately available</li> <li>(ii) to support outbreak investigations (e.g. in closed or semi-closed groups including schools, care-homes, cruise ships, prisons, workplaces and dormitories)</li> <li>(iii) To monitor trends in disease incidence in communities, particularly among essential workers and health workers during outbreaks or in regions of widespread community transmission where the positive and negative predictive value of an Ag-RDT result are sufficient for effective infection control.</li> <li>(iv) Where there is widespread community transmission, RDTs may be used for early detection and isolation of positive cases in health facilities, COVID-19 testing centres or sites, care homes, prisons, schools, front-line and health-care workers and for contact tracing.</li> <li>(v) Testing of asymptomatic contacts of cases may be considered even if the Ag-RDT is not specifically authorized for this use, as asymptomatic cases have been shown to have viral loads similar to those of symptomatic cases, although, in that situation, a negative Ag-RDT should not remove quarantine requirements for a contact.</li> </ul> <p>Use of Ag-RDTs is not recommended in settings or populations with a low expected prevalence of disease (e.g. screening at points of entry, blood donation, elective surgery), especially where confirmatory testing by NAAT is not readily available. Such use will not be possible until there are more data from high-quality studies confirming the high specificity (&gt; 99%) of one or more of the commercialized Ag-RDT test kits</p> <p>Given the relatively low prevalence of active SARS-CoV-2 infections, even in settings with community transmission, high specificity (minimum &gt; 97% and ideally &gt; 99%) is necessary to avoid many false-positive results. Sensitivity will depend on the status of patients studied (e.g. severity of illness, days since onset of symptoms) as well as the product quality, but should reach a minimum of ≥ 80%.</p>
Home care for patients with suspected or confirmed COVID-19 and management of their contacts. 13 August 2020	Interim guidance	<a href="https://www.who.int/publications/i/item/home-care-for-patients-with-suspected-novel-coronavirus-(ncov)-infection-presenting-with-mild-symptoms-and-management-of-contacts">https://www.who.int/publications/i/item/home-care-for-patients-with-suspected-novel-coronavirus-(ncov)-infection-presenting-with-mild-symptoms-and-management-of-contacts</a>	<p>Personal protective equipment: medical masks and gloves</p> <p>Home pulse oximetry can be used to identify low oxygen levels in patients with initially mild or moderate COVID-19 or silent hypoxia, when a patient does not appear to be short of breath but his or her oxygen levels are lower than expected. Home pulse oximetry can be used to identify individuals who require medical evaluation, oxygen therapy or hospitalization, even before they show clinical danger signs or worsening symptoms.</p>

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Document name	Document type	Link	Key points
Global COVID-19 clinical platform: rapid core case report form. 13 July 2020	Case report form	<a href="https://www.who.int/publications/i/item/WHO-2019-nCoV-Clinical_CRF-2020.4">https://www.who.int/publications/i/item/WHO-2019-nCoV-Clinical_CRF-2020.4</a>	Laboratory tests requested to be reported by States Parties to the International Health Regulations (2005): <ul style="list-style-type: none"> <li>• Haemoglobin</li> <li>• Haematocrit</li> </ul>
Global COVID-19 clinical platform: pregnancy case report form. 13 July 2020	Case report form	<a href="https://www.who.int/publications/i/item/WHO-2019-nCoV-Pregnancy_CRF-2020.5">https://www.who.int/publications/i/item/WHO-2019-nCoV-Pregnancy_CRF-2020.5</a>	<ul style="list-style-type: none"> <li>• White blood cell count</li> <li>• Platelets</li> <li>• Activated partial thromboplastin time</li> <li>• International normalized ratio</li> <li>• D-Dimer</li> <li>• Prothrombin time (seconds)</li> <li>• Creatinine</li> <li>• Urea (blood urea nitrogen)</li> <li>• Lactate</li> <li>• Sodium</li> <li>• Potassium</li> <li>• Procalcitonin</li> <li>• C-Reactive protein</li> <li>• Erythrocyte sedimentation rate</li> <li>• Alanine aminotransferase, serum glutamic pyruvic transaminase</li> <li>• Aspartate aminotransferase, serum glutamic-oxaloacetic transaminase</li> <li>• Total bilirubin</li> <li>• Lactate dehydrogenase</li> <li>• Creatine kinase</li> <li>• Troponin</li> <li>• Ferritin</li> <li>• Interleukin-6</li> </ul> <p>Testing during an illness episode for the following pathogens:</p> <ul style="list-style-type: none"> <li>• Influenza virus</li> <li>• Coronavirus: Middle East respiratory syndrome coronavirus, SARS-CoV-2</li> <li>• Other respiratory pathogens (to be specified)</li> <li>• Viral haemorrhagic fever (r to be specified)</li> <li>• Other pathogens of public health interest (to be specified)</li> <li>• Falciparum malaria</li> <li>• Non-falciparum malaria</li> <li>• HIV</li> </ul>
Guidance on maintaining a safe and adequate blood supply during the coronavirus disease 2019 (COVID-19) pandemic and on the collection of COVID-19 convalescent plasma, 10 July, 2020	Interim guidance	<a href="https://apps.who.int/iris/handle/10665/333182">https://apps.who.int/iris/handle/10665/333182</a>	<p>The COVID-19 pandemic has reduced the supply of blood and blood components and adversely affected blood system activities in many countries.</p> <p>SARS-CoV-2 has not been reported to be transmitted through blood or blood components.</p> <p>Potential blood donors should be informed that they should self-defer if they have risk factors for COVID-19 or feel unwell.</p>

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Document name	Document type	Link	Key points
			In areas with widespread community transmission of SARS-CoV-2, people who donate blood should be advised to inform the blood centre immediately if they develop a respiratory illness within 14 days of donation.
			People with possible direct exposure to SARS-CoV-2 from close contact with a confirmed case or care of an infected patient and those who have travelled from areas with community transmission should not donate blood for a minimum of 14 days (one incubation period).
			People who had a positive test for SARS-CoV-2 but never had symptoms should not donate blood for 14 days after the last positive test.
			People who have recovered from diagnosed COVID-19 should not routinely donate blood for 14 days after full resolution of symptoms and cessation of therapy for their illness.
			Blood and components collected within 14 days before disease onset in the donor or within 14 days of exposure to a contact may be recalled as a precautionary measure.
			Testing of the blood supply is premature in the absence of cases of transfusion transmission or demonstrated infectivity of SARS-CoV-2 in blood collected from asymptomatic people, including those who are pre-symptomatic.
			Haemovigilance is invaluable in understanding the risk from blood and components and the overall effectiveness of the measures taken by the blood service.
			The blood service must ensure the continuity of supplies of laboratory equipment and critical material.
			Governmental authorities should identify blood collection as an essential service and provide mechanisms to assure that blood donors are not penalized.
			WHO strongly recommends that COVID-19 convalescent plasma be used in randomized controlled trials as the most effective and efficient strategy for determining the efficacy and safety of this experimental therapy.
			Ideally, donations of convalescent plasma should be obtained by plasmapheresis to avoid unnecessary red blood cell loss in the donor and to optimize the volume of plasma that can be collected. Infection control precautions should follow WHO interim guidance on rational use of personal protective equipment, taking into consideration that the donor has fully recovered from COVID-19. Red blood cell concentrates that are prepared as a by-product of preparation of COVID-19 convalescent plasma can be released for transfusion if the donor was asymptomatic for at least 14 days after full recovery from symptoms.

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Document name	Document type	Link	Key points
Case report form for suspected cases of multisystem inflammatory syndrome in children and adolescents temporally related to COVID-19. 1 June 2020	Case report form	<a href="https://www.who.int/publications/item/WHO-2019-nCoV-MIS_Children_CRF-2020.2">https://www.who.int/publications/item/WHO-2019-nCoV-MIS_Children_CRF-2020.2</a>	Features of myocardial dysfunction, pericarditis, valvulitis or coronary abnormalities (echograph findings or elevated troponin or N-terminal pro b-type natriuretic peptide)
			Evidence of coagulopathy (abnormal prothrombin time, partial prothrombin time, elevated D-dimers)
			Elevated markers of inflammation such as erythrocyte sedimentation rate, C-reactive protein or procalcitonin
			Evidence of COVID-19 (RT-PCR, antigen test or serology positive)
			Markers of inflammation or coagulopathy: haemoglobin, total white blood cell count, neutrophils, lymphocytes, haematocrit, platelets, activated partial thromboplastin time, prothrombin time (seconds), international normalized ratio, fibrinogen, procalcitonin, C-reactive protein, erythrocyte sedimentation rate, D-dimer, interleukin-6, interleukin-10
			Markers of organ dysfunction: creatinine, sodium, potassium, urea (blood urea nitrogen), glucose, pro-brain natriuretic protein, troponin, creatine kinase, lactate dehydrogenase, triglycerides, alanine aminotransferase, serum glutamic pyruvic transaminase, total bilirubin, aspartate aminotransferase, serum glutamic-oxaloacetic transaminase, albumin, lactate, ferritin
			Bacterial pathogen testing
			SARS-CoV-2 testing: RT-PCR, rapid antigen test, rapid antibody test, enzyme-linked immunosorbent assay, neutralization test
			Imaging testing: chest X ray, chest computed tomography, echocardiography
Clinical management of COVID-19 Interim guidance. 27 May 2020	Interim guidance	<a href="https://apps.who.int/iris/bitstream/handle/10665/332196/WHO-2019-nCoV-clinical-2020.5-eng.pdf?sequence=1&amp;isAllowed=y">https://apps.who.int/iris/bitstream/handle/10665/332196/WHO-2019-nCoV-clinical-2020.5-eng.pdf?sequence=1&amp;isAllowed=y</a>	Supportive care: Oxygen supplementary therapy, nasal prongs, high-flow nasal cannula, mask, mask with reservoir, continuous positive airway pressure, non-invasive ventilation mask: non-invasive ventilation. Bilevel or continuous positive airway pressure: invasive ventilation
			Use of intermittent pneumatic compression devices (mechanical prophylaxis to prevent venous thromboembolism)
			D-Dimer measurement
			Oxygen and respiratory support (systems)
			Chest imaging (radiograph, computed tomography scan, ultrasound) to determine the severity of COVID-19 and identify or exclude pulmonary complications
			Clinical laboratory tests: blood gases (including lactate), coagulation tests, bilirubin, complete blood count
			Personal protective equipment (including medical masks)
			Use of stethoscopes, blood pressure cuffs, pulse oximeters and thermometers (in health facilities and for hospitalized patients)
			SARS-CoV-2 laboratory diagnosis: testing by RT-PCR

Continued

Document name	Document type	Link	Key points
			SARS-CoV-2 antibody tests are not recommended for diagnosis of current COVID-19.
			When collecting upper respiratory tract samples, use viral swabs (sterile Dacron or rayon, not cotton) and viral transport media.
			Pulse oximeters, functioning oxygen systems and disposable, single-use, oxygen-delivering interfaces (nasal cannula, Venturi mask and face mask with reservoir bag) should be used in any part of health facilities that may receive patients with severe COVID-19 (including emergency units, critical care units, primary care, outpatient clinics) and in pre-hospital settings and ad-hoc community facilities.
			Haematology and biochemistry laboratory testing and electrocardiogram and chest imaging for severe COVID-19 (pneumonia)
			Laboratory tests and/or imaging for patients with COVID-19 with signs or symptoms suggestive of venous or arterial thromboembolism
			Non-invasive ventilation or high-flow nasal oxygen systems
			Central venous and arterial catheters
			Closed suctioning systems
			Ventilator circuits or mechanical ventilation
Clinical care of severe acute respiratory infections – Tool kit. 11 April 2020	Interim guidance	<a href="https://www.who.int/publications/i/item/clinical-care-of-severe-acute-respiratory-infections-tool-kit">https://www.who.int/publications/i/item/clinical-care-of-severe-acute-respiratory-infections-tool-kit</a>	Essential In-vitro diagnostics tests to be obtained: complete blood cell count, chemistry panel, glucose, upper respiratory tract specimens for viral testing (during influenza season), blood sample for culture (when possible, before first dose of antimicrobials)
			Chest radiograph
			Blood gas analysis and monitoring: to measure the partial oxygen pressure and carbon dioxide in arterial (or venous or capillary) blood; also indicates the blood pH.
			Blood gas analysis provides information on oxygenation, ventilation and circulation, and on electrolyte concentrations (particularly sodium and potassium) which are measured in the same blood sample and analyser.
			Venous and capillary blood are easier to monitor than arterial blood but are of no use for determining oxygenation.
			The carbon dioxide level in arterial, capillary or venous blood indicates alveolar ventilation and is used to monitor trends in the efficiency of ventilation.
			pH is a direct indicator of overall acid–base status in arterial, capillary and venous blood.
			The probable cause of pH disturbance can be inferred only from the partial pressure of carbon dioxide and the blood bicarbonate concentration.

Continued

Document name	Document type	Link	Key points
			<p>In patients with severe acute respiratory infection, the differential diagnosis should include community-acquired infection, including influenza, or novel virus infection, such as COVID-19. The differential diagnosis should also be informed by local epidemiology, including viral infections such as malaria, dengue or tuberculosis.</p> <p>In endemic settings, arbovirus infection (dengue/ or chikungunya) should also be considered in the differential diagnosis of undifferentiated febrile illness.</p> <p>Collect blood and sputum and culture for bacteria that cause pneumonia and sepsis, ideally before antimicrobial therapy.</p> <p>Differential diagnosis of common viral infections include: respiratory syncytial virus, parainfluenza virus, rhinoviruses, adenovirus, enterovirus (EVD68), human metapneumovirus, bocavirus, influenza virus.</p>
Advice on the use of point-of-care immunodiagnostic test for COVID-19 Scientific brief. 8 April 2020	Scientific brief	<a href="https://www.who.int/publications/i/item/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19-scientific-brief">https://www.who.int/publications/i/item/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19-scientific-brief</a>	<p>Rapid diagnostic tests based on antigen detection: The information on Ag-RDTs in this document was updated with the guidance included in the document "Antigen detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays", 11 September 2020.</p> <p>Rapid diagnostic tests based on host antibody detection: tests to detect antibody responses to COVID-19 in the population will be critical in the development of vaccines and to understanding the extent of infection among people who are not identified during active case finding and surveillance, the attack rate in the population and the infection fatality rate. For clinical diagnosis, however, such tests have limited utility, because they cannot quickly diagnose acute infection to inform the course of treatment.</p>
Laboratory testing for coronavirus disease (COVID-19) in suspected human cases. Interim guidance. 19 March 2020	Interim guidance	<a href="https://www.who.int/publications/i/item/10665-331501">https://www.who.int/publications/i/item/10665-331501</a>	Updated, new version: "Diagnostic testing for SARS-CoV-2 Interim guidance", 11 September 2020

Note: The above listing was accurate as of 1 July 2021; however, many of the documents are regularly updated. Readers are thus encouraged to look for recent versions on the WHO website, at: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications?publicationtypes=f85a3610-b102-4287-a6df-f3bc0b2e9f7c>





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[https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab\\_1](https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1)

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