TECHNICAL SPECIFICATIONS FOR SELECTION OF ESSENTIAL IN VITRO DIAGNOSTICS FOR **SARS-COV-2**

14 June 2021

World Health Organization

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WHO continues to monitor the situation closely for any changes that may affect these technical specifications. Should any factors change, WHO will issue a further update. Otherwise, these technical specifications will expire 2 years after the date of publication.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned.

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Introduction

Technical specifications enable procurement officers / agencies to adopt a systematic, unbiased approach in the selection process of medical products. This approach results in procurement, leasing or donation of appropriate commodities in line with the needs of each level of the health-care system and local setting requirements. It also informs biomedical engineering professionals, the private health sector, the medical device industry, and intergovernmental and international agencies about the characteristics of the products required. Technical specifications for in vitro diagnostics (IVDs) constitute a set of predefined criteria and baseline requirements to ensure good quality, safety, performance and efficacy. The specifications are decisive companions to the *WHO Model List of Essential In Vitro Diagnostics* (EDL) that will allow Member States, donor agencies and nongovernmental organizations (NGOs) to select specific products within each test category of the EDL and will guide procurement decisions. The present publication defines the basic generic technical characteristics of IVDs for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) listed in WHO EDL 3. WHO will review and update this document periodically.

Objective

To provide information regarding technical specifications for SARS-CoV-2 antigen and nucleic acid testing (NAT) IVDs.

Target Audience

This resource is intended for programme managers, laboratory managers, procurement officers, planning officers in ministries of health, biomedical engineering professionals, the private health sector, the medical device industry, and intergovernmental and international agencies.

Methodology

WHO EDL 3 includes two IVD tests for coronavirus (COVID-19): the SARS-CoV-2 antigen rapid test and the SARS-CoV-2 nucleic acid test. Basic generic technical characteristics were developed for both tests. The process for developing these technical specifications included mapping and review of all WHO technical guidance documents and publications on COVID-19/SARS-CoV-2 IVDs, as well as review of the *WHO Emergency Use Listing* (EUL) *for IVDs Detecting SARS-CoV-2* and analysis of the products listed on it by December 2020. The guidance documents analysed were the following: *Antigen Detection in the Diagnosis of SARS-CoV-2 Infection using Rapid Immunoassays*; *Diagnostic Testing for SARS-CoV-2: Interim Guidance*; *Target Product Profiles for Priority Diagnostics to Support Response to the COVID-19 Pandemic v.1.0*; WHO EDL 3; the WHO SARS-CoV-2 Antigen Rapid Diagnostic Test (RDT) training package; *WHO Guidance for Procurement of In Vitro Diagnostics and Related Laboratory Items and Equipment*; *Procurement Considerations for COVID-19 Diagnostics* and *How to Plan and Budget for Your Healthcare Technology*. The draft document was then reviewed by WHO staff and SAGE IVD members with expertise on COVID-19 IVDs before being posted on the WHO website for two weeks for public consultation. All SAGE IVD members are required to provide declaration of interest that are reviewed by the WHO EDL secretariat. The draft was also sent to relevant networks before being finalized.

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SARS-CoV-2 antigen

SARS-CoV-2 antigen

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	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Name, Category and Coding	
1	WHO category / MedTech Europe (MTE) code	Under development
2	Generic name	SARS-CoV-2 antigen
3	Specific type or variation (optional)	RDT with visual interpretation of results
4	Alternative name/s (optional)	COVID-19 antigen rapid test
5	Keywords (optional)	Coronavirus disease, COVID-19 RDT, SARS-CoV-2 antigen detection test.
	Intended Use	
6	Detection target	SARS-CoV-2 biomarker (e.g. protein/antigen) specific for acute/current infection (e.g. first week after onset of symptoms). In the case of SARS-CoV-2 RDTs, the target analyte is often the virus's nucleocapsid protein, preferred because of its relative abundance.
7	Test purpose	To diagnose COVID-19 in settings where NAT is unavailable or where prolonged turnaround times of NAT preclude clinical utility. To aid in the diagnosis of COVID-19 in the early symptomatic phase of illness, or in asymptomatic individuals having known contact with a confirmed case.
8	Specific disorder/condition	COVID-19
9	Test format	RDT qualitative