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.

WHO reference number: WHO/2019-nCoV/Essential_IVDs/2021.1

Contents

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.

Acknowledgement

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SARS-CoV-2 antigen

SARS-CoV-2 antigen

Version No.: One (1)
Date of initial version: 01 December 2020
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Prepared by: WHO

	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
10	Specimen type	Upper respiratory specimens (e.g. nasopharyngeal or nasal swab)
11	Testing population	Patients in the early symptomatic phase of the illness (within the first 5–7 days of illness) and asymptomatic individuals having known contact with a confirmed case.
12	Intended users	Health-care workers and laboratory technicians who have been trained in biosafety, specimen collection, and performing and interpreting SARS-CoV-2 testing using antigen RDTs.
13	Level of the health-care system	For use in community settings and health facilities without laboratories and in health facilities with laboratories.

SARS-CoV-2 antigen *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Performance Characteristics	
14	Clinical sensitivity	Should reach a minimum of 80%
15	Clinical specificity	Should reach a minimum of 97%
16	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 presenting with similar signs and symptoms of COVID-19 (e.g. influenza A, B; respiratory syncytial virus [RSV]; malaria; dengue). Desirable: Same description as for the acceptable criteria, and it does not cross-react with SARS-CoV-1.
17	Limit of detection	Acceptable: $10^2 - 10^3$ TCID50/mL Ideal: $<1 \times 10^2$ TCID50/mL
18	Invalid / error / unreturnable rate	< 5% invalid results with correct use by operator
19	Precision (repeatability/reproducibility)	Not applicable
20	Trueness of measurement: bias	Not applicable
	Technical and Operational Characteristics	
21	Principle of the assay	Lateral flow immunochromatography
22	Specimen(s) stability	Ideally, specimens should be tested immediately after collection. If immediate testing is not possible, specimens may be stored at room temperature or refrigerated according to the manufacturer's instructions. In some cases, specimens can be stored at room temperature (15–25°C) for up to 1 hour prior to testing. If the ambient temperature is over 30°C, specimens should be stored in a refrigerator or cool box (at 2–8°C) for up to 4 hours (e.g. during transportation and prior to testing). In some cases, specimens may be collected and stored for longer periods of time if swabs are placed in viral transport media (VTM). VTM should be used only if validated by the manufacturer. Always follow the manufacturer's instructions for use.
23	Specimen(s) volume	Single swab
24	Type of result	Qualitative
25	Time to result	Acceptable: 10 to < 30 minutes Ideal: < 15 minutes
26	End-point stability	Fixed reading time. Always follow the manufacturer's instructions for use.

SARS-CoV-2 antigen *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Technical and Operational Characteristics	
27	Ease of use for point-of-care tests only: number of steps that require precision	≤ 5
28	Specimen throughput per operator, per hour, per 8-hour working day or per batched run	≥ 5/hour per operator
29	Test limitations	Neither the quantitative value nor the concentration of SARS-CoV-2 antigen can be determined by this qualitative test. The test result must always be evaluated along with other data available to the physician. A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained. Positive test results do not rule out co-infections with other pathogens. Test procedure, precautions and interpretation of test results must be followed strictly. Failure to accurately follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results. The test is not designed to detect non-SARS-CoV-2 coronaviruses.
30	Internal quality control	Internal control (for sample flow/migration) within the individual testing device.
31	Compatibility with external quality control material	Manufacturer should state any external quality controls that the IVD is not compatible with.
32	Transport stability of kit/reagents (temperature and humidity)	2–40°C; humidity 75–80%. Do not freeze
33	Storage stability of kit/reagents (temperature and humidity)	2–40°C; humidity 75–80%. Do not freeze
34	On-board stability of kit/reagents (temperature and humidity)	Not applicable
35	In-use stability of kit/reagents (temperature and humidity)	30 minutes for single-use test after opening the pouch
36	Transport stability for specimen collection media (temperature and humidity)	2–30°C
37	Storage stability for specimen collection media (temperature and humidity)	2–30°C
38	In-use stability for specimen collection media (temperature and humidity)	At 2–8°C for up to 12 hours, or at 25°C for up to 8 hours
39	Transport stability for controls/calibrators (temperature and humidity)	Not applicable
40	Storage stability for controls/calibrators (temperature and humidity)	Not applicable
41	On-board stability for controls/calibrators (temperature and humidity)	Not applicable

SARS-CoV-2 antigen *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Technical and Operational Characteristics	
42	In-use stability for controls/calibrators (temperature and humidity)	Not applicable
43	Shelf life of kit/reagents upon manufacture (months)	At least 12 months
44	Remaining shelf life of kit/reagents upon delivery (months)	Minimum 6 months
	Instrument Physical and Technical Characteristics	
45	Size of device (height x width x depth)	Not applicable
46	Weight of the device (kg)	Not applicable
47	Power requirements	Not applicable
48	Time to battery charge	Not applicable
49	Battery duration	Not applicable
50	Alternative charging options	Not applicable
51	Operating conditions (temperature and humidity)	Not applicable
52	User interface	Not applicable
53	Displayed parameters	Not applicable
54	Display languages	Not applicable
55	Built-in memory storage capacity	Not applicable
56	Diagnostic connectivity	Not applicable
57	Open or closed system	Not applicable
58	Multidisease testing capabilities / test menu availability	Not applicable
	Infrastructure Requirements	
59	Water requirements	Not applicable
60	Refrigeration or cold chain for storage of kit/reagents	No
61	Refrigeration or cold chain for reconstituted reagents and controls	Not applicable
	Accessories, Consumables, Spare Parts and Other Components	
62	Kit component – test/reagents/consumables (if relevant)	Test devices, reagent solutions, tubes, tube caps, sterile swabs for specimen collection, VTM (if required/applicable), instructions for use.

SARS-CoV-2 antigen *continued*

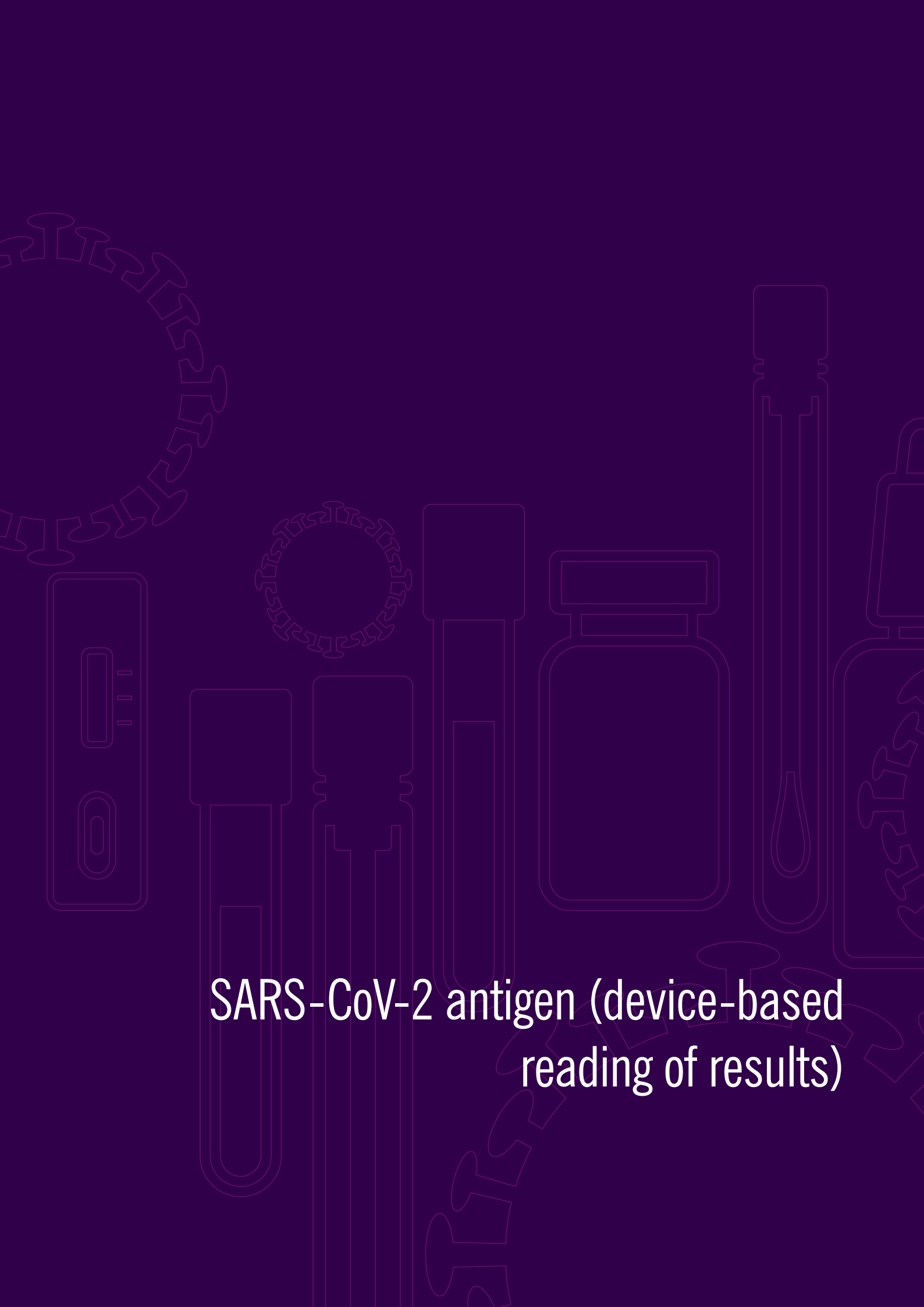
	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Accessories, Consumables, Spare Parts and Other Components	
63	Reagent kit size (number of tests)	25–50 individual test devices/cassettes
64	Consumables required but not provided in the test kit	Disposable gloves, biohazard bags, micropipette tips
65	Other auxiliary laboratory equipment required but not provided	Timer, biohazard container, tube rack, micropipettes (for specimens collected in VTM).
66	Spare parts (if relevant)	Not applicable
	Documentation	
67	Instrument operator manual	Not applicable
68	Instructions for use	Instructions for use submitted in the local language. Must relate to regulatory version registered for sale and use in country of supply.
69	Certificate of analysis	A certificate of analysis is a document issued by the quality assurance department of a legal manufacturer confirming that a regulated product meets its product specification. The certificate of analysis should contain the actual results obtained from the final quality control for lot release performed for each lot of a product.
70	Material safety data sheet	The material safety data sheet is a technical document that should provide detailed and comprehensive information about a product related to (i) the health effects of exposure to the product; (ii) evaluation of hazards related to handling, storage or use of the product; (iii) measures to protect workers at risk of exposure and (iv) emergency procedures.
	Environmental and Safety Requirements	
71	Hazardous classification	Potential source of harm. Classification according to the Global Harmonized System, e.g. health hazard, physical hazard or environmental hazard. This information is usually contained in the material safety data sheet.
72	Disposal requirements	Standard biohazardous waste disposal or incineration of consumables. No high-temperature incineration required.
	Training, Installation and Utilization	
73	Pre-installation requirements (if relevant)	Not applicable
74	Requirements for installation and calibration	Not applicable
75	Training of user/s (if relevant)	At least 0.5 days with instructions for use and quick reference guide(s), including specimen collection, test procedure, results interpretation, quality control and biosafety. See SARS-CoV-2 Antigen Rapid Diagnostic Test training package.

SARS-CoV-2 antigen *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Warranty and Maintenance	
76	Warranty	Not applicable
77	Preventive maintenance	Not applicable
78	Corrective maintenance	Not applicable
79	Type of service contract (including leasing or reagent rental)	Not applicable
80	Spare parts availability post-warranty	Not applicable
81	In-country technical support availability	Availability of local authorized service provider or distributor is recommended.
	Decommissioning	
82	Estimated lifespan	Not applicable
	Quality and Registration	
83	Global regulatory approvals	State regulatory approvals of the product. Careful consideration should be taken to ensure that the selected products have been assessed to an appropriate stringency level based on the risk classification for the concerned IVD. To be provided by manufacturer/supplier (typically verified by regional or national regulatory agencies).There is increasing international harmonisation, facilitated by the International Medical Device Regulators Forum (IMDRF) (see http://www.imdrf.org/) with at least four systems in use: Classes A–D (IMDRF/GHTF [Global Harmonization Task Force]); Classes I, IIa, IIb, III (European Union, Australia); Classes I, II, III (United States of America); Classes I–IV (Japan, Canada), with low-risk devices in Class A or I and high-risk devices in Class D or III (or IV for Japan and Canada). Product shall be cleared by at least one of the five founding members of the GHTF (Australia, Canada, Japan, EU, USA) and comply with the corresponding pre-market requirements as described in the WHO *Guidance for Procurement of In Vitro Diagnostics and Related Laboratory Items and Equipment. WHO Emergency Use Listing (EUL)*.
84	Regulatory version to be procured	Valid certification for the regulatory version that will be subject to the contract required. The certificate shall indicate the name of the regulatory authority and market approval/clearance with number.
85	Free sale certificate	Valid certification for export from country of origin
86	WHO prequalification status	Yes, but only WHO EUL at this time
87	International standards / certifications	ISO 13485: 2016 compliant
88	National registration	Yes, valid certification required

SARS-CoV-2 antigen *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Quality and Registration	
89	Post-market surveillance	Customer complaints require response in a timely manner. Notification to national regulatory authority (NRA) for serious and moderate adverse events according to clients' timelines also required.
90	Field safety corrective actions	Affected customers of any field safety corrective actions (FSCAs) (such as recall or change in labelling) should be informed in a timely manner. NRA should be notified for all FSCAs.
91	Replacement of defective product	Replacement could apply depending on root cause of issue. Refer to service agreement.



SARS-CoV-2 antigen (device-based reading of results)

SARS-CoV-2 antigen (device-based reading of results)

Version No.: One (1)
Date of initial version: 01 December 2020
Date of last modification: 15 March 2021
Date of publication: 14 June 2021
Prepared by: WHO

	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 device-based reading 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
10	Specimen type	Upper respiratory specimens (e.g. nasopharyngeal or nasal swab)
11	Testing population	Patients in the early symptomatic phase of the illness (within the first 5–7 days of illness) and asymptomatic individuals having known contact with a confirmed case.
12	Intended users	Health-care workers and laboratory technicians who have been trained in biosafety, specimen collection, and performing and interpreting SARS-CoV-2 testing using antigen RDTs.
13	Level of the health-care system	For use in community settings and health facilities without laboratories and in health facilities with laboratories.

SARS-CoV-2 antigen (device-based reading of results) *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Performance Characteristics	
14	Clinical sensitivity	Should reach a minimum of 80%
15	Clinical specificity	Should reach a minimum of 97%
16	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 presenting with similar signs and symptoms of COVID-19 (e.g. influenza A, B; RSV; malaria; dengue). Desirable: Same description as for the acceptable criteria, and it does not cross-react with SARS-CoV-1.
17	Limit of detection	Acceptable: $10^2 - 10^3$ TCID50/mL Ideal: $< 1 \times 10^2$ TCID50/mL
18	Invalid / error / unreturnable rate	$<$ 5% invalid results with correct use by operator
19	Precision (repeatability/reproducibility)	Not applicable
20	Trueness of measurement: bias	Not applicable
	Technical and Operational Characteristics	
21	Principle of the assay	Lateral flow immunochromatography
22	Specimen(s) stability	Ideally, specimens should be tested immediately after collection. If this is not possible, specimens may be stored at room temperature or refrigerated according to the manufacturer's instructions. In some cases, specimens can be stored at room temperature (15–25°C) for up to 1 hour prior to testing. If the ambient temperature is over 30°C, specimens should be stored in a refrigerator or cool box (at 2–8°C) for up to 4 hours (e.g. during transportation and prior to testing). In some cases, specimens may be collected and stored for longer periods of time if swabs are placed in VTM. VTM should be used only if validated by the manufacturer. Always follow the manufacturer's instructions for use.
23	Specimen(s) volume	Single swab
24	Type of result	Qualitative
25	Time to result	Acceptable: 10 to $<$ 30 minutes Ideal: $<$ 15 minutes
26	End-point stability	Fixed reading time. Always follow the manufacturer's instructions for use.

SARS-CoV-2 antigen (device-based reading of results) *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Technical and Operational Characteristics	
27	Ease of use for point-of-care tests only: number of steps that require precision	≤ 5
28	Specimen throughput per operator, per hour, per 8-hour working day or per batched run	≥ 5/hour per operator
29	Test limitations	Neither the quantitative value nor the concentration of SARS-CoV-2 antigen can be determined by this qualitative test. Test result must always be evaluated along with other data available to the physician. A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained. Positive test results do not rule out co-infections with other pathogens. Test procedure, precautions and interpretation of test results must be followed strictly. Failure to accurately follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results. The test is not designed to detect non-SARS-CoV-2 coronaviruses.
30	Internal quality control	Internal control (for sample flow/migration) within the individual testing device.
31	Compatibility with external quality control material	External quality assessment material compatible. Manufacturer should state any external quality controls that the IVD is not compatible with. Calibration control for reader, if applicable.
32	Transport stability of kit/reagents (temperature and humidity)	2–40°C; humidity 75–80%. Do not freeze.
33	Storage stability of kit/reagents (temperature and humidity)	2–40°C; humidity 75–80%. Do not freeze.
34	On-board stability of kit/reagents (temperature and humidity)	Not applicable
35	In-use stability of kit/reagents (temperature and humidity)	30 minutes for single-use test after opening the pouch
36	Transport stability for specimen collection media (temperature and humidity)	2–30°C
37	Storage stability for specimen collection media (temperature and humidity)	2–30°C
38	In-use stability for specimen collection media (temperature and humidity)	At 2–8°C for up to 12 hours, or at 25°C for up to 8 hours
39	Transport stability for controls/calibrators (temperature and humidity)	Not applicable
40	Storage stability for controls/calibrators (temperature and humidity)	Not applicable
41	On-board stability for controls/calibrators (temperature and humidity)	Not applicable

SARS-CoV-2 antigen (device-based reading of results) *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Technical and Operational Characteristics	
42	In-use stability for controls/calibrators (temperature and humidity)	Not applicable
43	Shelf life of kit/reagents upon manufacture (months)	At least 12 months
44	Remaining shelf life of kit/reagents upon delivery (months)	Minimum 6 months
	Instrument Physical and Technical Characteristics	
45	Size of device (height x width x depth)	Handheld or small benchtop device (results reading device)
46	Weight of the device (kg)	< 1 kg
47	Power requirements	Rechargeable battery with power connection. Input: 100–240 V (± 10%) / 50–60 Hz.
48	Time to battery charge	2–6 hours
49	Battery duration	6–8 hours full operation
50	Alternative charging options	USB connection or solar power operated
51	Operating conditions (temperature and humidity)	15–35°C and 25–80% relative humidity
52	User interface	Touchscreen, simple test menu, barcode scanner
53	Displayed parameters	Test results per patient ID with date and time, electronic and printed readout, operational status of instrument indicating ongoing analysis, system errors or malfunctions, including insufficient specimen volume and battery status.
54	Display languages	At least the local language and English
55	Built-in memory storage capacity	At least 3000 test results
56	Diagnostic connectivity	Remote export of data is possible; data connectivity via infrared, USB, laboratory information system and programme database to enable information sharing.
57	Open or closed system	Open system
58	Multidisease testing capabilities / test menu availability	The instrument allows for testing other targets using specific test strips or cassettes.
	Infrastructure Requirements	
59	Water requirements	Not applicable
60	Refrigeration or cold chain for storage of kit/reagents	No
61	Refrigeration or cold chain for reconstituted reagents and controls	Not applicable

SARS-CoV-2 antigen (device-based reading of results) *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Accessories, Consumables, Spare Parts and Other Components	
62	Kit component – test/reagents/consumables (if relevant)	Test devices, reagent solutions, tubes, tube caps, sterile swabs for specimen collection, VTM (if required/applicable), instructions for use.
63	Reagent kit size (number of tests)	25–50 individual test devices/cassettes
64	Consumables required but not provided in the test kit	Disposable gloves, biohazard bags, micropipette tips
65	Other auxiliary laboratory equipment required but not provided	Timer, biohazard container, tube rack, micropipettes (for specimens collected in VTM)
66	Spare parts (if relevant)	Two sets of spare/replaceable parts
	Documentation	
67	Instrument operator manual	Operating and service manuals in the local language, including lists of important spares and accessories with their part numbers and list of equipment and procedures required for calibration and routine maintenance. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community.
68	Instructions for use	Instructions for use submitted in the local language. Must relate to regulatory version registered for sale and use in country of supply.
69	Certificate of analysis	A certificate of analysis is a document issued by the quality assurance department of a legal manufacturer that confirms that a regulated product meets its product specification. The certificate of analysis should contain the actual results obtained from the final quality control for lot release performed for each lot of a product.
70	Material safety data sheet	The material safety data sheet is a technical document that should provide detailed and comprehensive information on a product related to (i) the health effects of exposure to the product; (ii) hazard evaluation related to handling, storage or use of the product; (iii) measures to protect workers at risk of exposure and (iv) emergency procedures.
	Environmental and Safety Requirements	
71	Hazardous classification	Potential source of harm. Classification according to the Global Harmonized System, e.g. health hazard, physical hazard or environmental hazard. This information is usually contained in the material safety data sheet.
72	Disposal requirements	Standard biohazardous waste disposal or incineration of consumables. No high-temperature incineration required.

SARS-CoV-2 antigen (device-based reading of results) *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Training, Installation and Utilization	
73	Pre-installation requirements (if relevant)	Not applicable
74	Requirements for installation and calibration	Only minimal calibration to be conducted by testing provider. It is preferable that the instrument automatically read calibration data. Any substantive calibration to be conducted by the supplier should not be separately charged.
75	Training of user/s (if relevant)	At least 0.5 days with instructions for use and quick reference guide(s), including specimen collection, test procedure, results interpretation, quality control and biosafety. See SARS-CoV-2 Antigen Rapid Diagnostic Test training package.
	Warranty and Maintenance	
76	Warranty	At least a 2-year warranty should be provided. The warranty document should state the date of commencement, duration of warranty period and exclusions/inclusions. Other conditions such as maintenance support (if applicable) during warranty must also be specified.
77	Preventive maintenance	Expected minimal maintenance to be conducted by testing provider should be stated. Frequency of servicing based on fixed time periods or on the number of tests the instrument processes.
78	Corrective maintenance	Advanced maintenance tasks required shall be documented, with details of maintenance support from the manufacturer/supplier.
79	Type of service contract (including leasing or reagent rental)	Contract must cover labour, repair, spare parts, loaner instrument, shipping and logistics costs, and training.
80	Spare parts availability post-warranty	To be covered in the service-level agreement. Declaration of number of years that the supply of spares shall be ensured post-warranty.
81	In-country technical support availability	Availability of local authorized service provider or distributor is recommended.
	Decommissioning	
82	Estimated lifespan	3 years. For assumed average frequency of utilization, maintenance and failure, it is better to assess lifespan based on anticipated replacement.

SARS-CoV-2 antigen (device-based reading of results) *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Quality and Registration	
83	Global regulatory approvals	State regulatory approvals of the product. Careful consideration should be taken to ensure that the selected products have been assessed to an appropriate stringency level based on the risk classification for the concerned IVD. To be provided by the manufacturer/supplier (typically verified by regional or national regulatory agencies).There is increasing international harmonization, facilitated by the International Medical Device Regulators Forum (see http://www.imdrf.org/) with at least four systems in use: Classes A–D (IMDRF/GHTF); Classes I, IIa, IIb, III (EU, Australia); Classes I, II, III (USA); Classes I–IV (Japan, Canada), with low-risk devices in Class A or I and high-risk devices in Class D or III (or IV for Japan and Canada). The product shall be cleared by at least one of the five founding members of the GHTF (Australia, Canada, Japan, EU, USA) and comply with the corresponding pre-market requirements as described in the WHO *Guidance for Procurement of In Vitro Diagnostics and Related Laboratory Items and Equipment. WHO Emergency Use Listing (EUL)*.
84	Regulatory version to be procured	Valid certification for the regulatory version that will be subject to the contract required. The certificate shall indicate the name of the regulatory authority and market approval/clearance with number.
85	Free sale certificate	Valid certification for export from country of origin
86	WHO prequalification status	Yes, but only WHO EUL at this time
87	International standards / certifications	ISO 13485: 2016 compliant
88	National registration	Yes, valid certification required
89	Post-market surveillance	Customer complaints require response in a timely manner. Notification to NRA for serious and moderate adverse events according to clients' timelines also required.
90	Field safety corrective actions	Affected customers of any FSCAs (such as recall or change in labelling) should be informed in a timely manner. NRA should be notified for all FSCAs.
91	Replacement of defective product	Replacement could apply depending on root cause of issue. Refer to service agreement.

SARS-CoV-2 nucleic acid test

SARS-CoV-2 nucleic acid test

Version No.: One (1)
Date of initial version: 10 December 2020
Date of last modification: 15 March 2021
Date of publication: 14 June 2021
Prepared by: WHO

	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 nucleic acid test
3	Specific type or variation (optional)	Not applicable
4	Alternative name/s (optional)	SARS-CoV-2 reverse transcription polymerase chain reaction (RT-PCR), SARS-CoV-2 PCR, SARS-CoV-2 nucleic acid amplification test (NAAT), SARS-CoV-2 NAT, COVID-19 PCR, COVID-19 NAT.
5	Keywords (optional)	Coronavirus disease, COVID-19 PCR, COVID-19 diagnosis
	Intended Use	
6	Detection target	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.
7	Test purpose	To diagnose infection by SARS-CoV-2 in symptomatic and asymptomatic individuals suspected of having been exposed. For surveillance and confirmation of outbreaks.
8	Specific disorder/condition	COVID-19
9	Test format	Qualitative NAT, manual and/or automated RT-PCR
10	Specimen type	Upper respiratory specimens (e.g. nasopharyngeal and oropharyngeal) and lower respiratory specimens (e.g. bronchoalveolar lavage).
11	Testing population	Patients with acute or subacute respiratory symptoms, or fever, or other suspicious symptoms of COVID-19 (e.g. anosmia, diarrhoea) and either having had known contact with a probable or confirmed COVID-19 patient, or living in an area of a cluster, or community transmission and symptomatic, pre-symptomatic or asymptomatic close contacts. Suspected COVID-19 cases requiring confirmation or exclusion.
12	Intended users	Laboratory professionals with appropriate training in specimen collection and biosafety and proficient in performing RT-PCR assays.

SARS-CoV-2 nucleic acid test *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Intended Use	
13	Level of the health-care system	For use in clinical laboratories
	Performance Characteristics	
14	Clinical sensitivity	> 95%
15	Clinical specificity	> 99%
16	Analytical specificity	Assay detects only circulating SARS-CoV-2 viral strains; no interference due to other substances.
17	Limit of detection	Acceptable: Equivalent to 10^3 genomic copies per mL in any respiratory tract specimen type. Desirable: Equivalent to 10^2 genomic copies/mL in upper and lower respiratory tract specimens and stool.
18	Invalid / error / unreturnable rate	< 5%
19	Precision (repeatability/reproducibility)	Intra-assay precision (repeatability): CV < 3%; inter-assay precision (reproducibility): CV < 5%.
20	Trueness of measurement: bias	Not applicable
	Technical and Operational Characteristics	
21	Principle of the assay	Detection of unique sequences of SARS-CoV-2 RNA by NAAT, such as real-time RT-PCR (rRT-PCR). The PCR product should be detected via fluorescent oligonucleotide probes that bind specifically to SARS-CoV-2 virus nucleic acid. An rPCR machine should be used to detect the fluorescence.
22	Specimen(s) stability	Ideally, specimens should be tested immediately after collection. If this is not possible, specimens kept in preservative/VTM may be stored at room temperature (15–25°C) for up to 8 hours, up to 12 days refrigerated at 2–8°C or for > 12 days at –70°C. Avoid repeated freeze–thaw cycles. Always follow the manufacturer's instructions for use.
23	Specimen(s) volume	Single swab and specimen transport material (e.g. preservative/VTM).
24	Type of result	Qualitative
25	Time to result	Acceptable: 4–5 hours per test Ideal: < 3.5 hours per test
26	End-point stability	Not applicable
27	Ease of use for point-of-care tests only: number of steps that require precision	Not applicable

SARS-CoV-2 nucleic acid test *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Technical and Operational Characteristics	
28	Specimen throughput per operator, per hour, per 8-hour working day or per batched run	Acceptable: ~188 specimens in 8 hours Ideal: > 188 specimens in 8 hours
29	Test limitations	This assay is limited to laboratory professionals who are properly trained in performing RT-PCR assays. Improper collection, transport or storage of specimens may hinder the ability of the assay to detect the target sequences. Test procedure must be followed strictly according to the manufacturer's instructions. Failure to do so may adversely affect test performance and results. A false negative result may occur due to improper specimen collection, degradation of viral RNA during shipping or storage, presence of RT-PCR inhibitors, SARS-CoV-2 mutation, inadequate number of organisms in the specimen or failure to follow instructions for use. A false positive result may occur due to cross-contamination during specimen handling or preparation, cross-contamination between patient samples or RNA contamination during product handling. This assay cannot rule out diseases caused by other pathogens. Test results must always be evaluated along with other data available to the physician.
30	Internal quality control	Positive control and negative control provided in the kit or are sold separately. If applicable, RNA extraction control (e.g. process control is necessary to ensure successful RNA manual extraction and therefore to minimize false negatives).
31	Compatibility with external quality control material	Compatible with external quality assessment material
32	Transport stability of kit/reagents (temperature and humidity)	–25°C to 25°C, 70% humidity
33	Storage stability of kit/reagents (temperature and humidity)	–25°C to 25°C, 70% humidity
34	On-board stability of kit/reagents (temperature and humidity)	Not applicable
35	In-use stability of kit/reagents (temperature and humidity)	Between 10°C and 35°C; ability to tolerate extremely low relative humidity to condensing humidity. Stability of the kit once opened is 30–60 days.
36	Transport stability for specimen collection media (temperature and humidity)	2–25°C
37	Storage stability for specimen collection media (temperature and humidity)	2–25°C
38	In-use stability for specimen collection media (temperature and humidity)	For up to 48 hours at 2–25°C. If processing is delayed (over 48 hours), specimens must be frozen at –70°C.
39	Transport stability for controls/calibrators (temperature and humidity)	–25°C to 25°C
40	Storage stability for controls/calibrators (temperature and humidity)	–25°C to 25°C

SARS-CoV-2 nucleic acid test *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Technical and Operational Characteristics	
41	On-board stability for controls/calibrators (temperature and humidity)	Not applicable
42	In-use stability for controls/calibrators (temperature and humidity)	Between 10°C and 35°C; ability to tolerate extremely low relative humidity to condensing humidity. Stability of the kit once opened is 30–60 days.
43	Shelf life of kit/reagents upon manufacture (months)	Prolonged shelf life for 12 months or longer is preferred for storage of kits.
44	Remaining shelf life of kit/reagents upon delivery (months)	Minimum 6 months of shelf life remaining when product arrives at point of use.
	Instrument Physical and Technical Characteristics	
45	Size of device (height x width x depth)	Not applicable
46	Weight of the device (kg)	Not applicable
47	Power requirements	Not applicable
48	Time to battery charge	Not applicable
49	Battery duration	Not applicable
50	Alternative charging options	Not applicable
51	Operating conditions (temperature and humidity)	Not applicable
52	User interface	Not applicable
53	Displayed parameters	Not applicable
54	Display languages	Not applicable
55	Built-in memory storage capacity	Not applicable
56	Diagnostic connectivity	Not applicable
57	Open or closed system	Not applicable
58	Multidisease testing capabilities / test menu availability	Not applicable
	Infrastructure Requirements	
59	Water requirements	Molecular-grade water
60	Refrigeration or cold chain for storage of kit/reagents	Yes
61	Refrigeration or cold chain for reconstituted reagents and controls	Yes

SARS-CoV-2 nucleic acid test *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Accessories, Consumables, Spare Parts and Other Components	
62	Kit component – test/reagents/consumables (if relevant)	A kit that is compatible with a range of standard extraction methods (if applicable), and includes all essential assay reagents, controls and consumables needed to perform the assay, including the extraction kit. The inclusion of all necessary PCR reagents essential to perform the assay is a minimum requirement (i.e. primers and enzymes). It is best if a sample collection kit is also included.
63	Reagent kit size (number of tests)	The kit should contain enough reagents/cartridges to perform 10–96 reactions.
64	Consumables required but not provided in the test kit	Sample collection kit, sample transport preservative, ancillary reagents and disposable plasticware.
65	Other auxiliary laboratory equipment required but not provided	Vortex mixer, microcentrifuge, plate centrifuge, plate shaker / rocker, vacuum manifold, magnet for bundled extraction kits, heating block / water bath, –20°C cold block, pipettes (10 μl to 1000 μl), biological safety cabinet, manual or automated nucleic extraction system, rPCR machine (for assay compatible with the most commonly available thermocyclers in low- to middle-income countries [LMICs]). Common thermocyclers in LMICs include: ABI 7500/7500, FAST/7500 FAST Dx, ABI 7300; Qiagen Rotor-Gene Q; Bio-Rad CFX96; Roche LightCycler and QuantStudio 5).
66	Spare parts (if relevant)	Not applicable
	Documentation	
67	Instrument operator manual	Yes (if applicable, i.e. for integrated molecular diagnostic testing platforms).
68	Instructions for use	Instructions for use submitted in the local language. Must relate to regulatory version registered for sale and use in country of supply.
69	Certificate of analysis	A certificate of analysis is a document issued by the quality assurance department of a legal manufacturer that confirms that a regulated product meets its product specification. The certificate of analysis should contain the actual results obtained from final quality control for lot release performed for each lot of a product.
70	Material safety data sheet	The material safety data sheet is a technical document that should provide detailed and comprehensive information of a product related to (i) the health effects of exposure to the product; (ii) hazard evaluation related to handling, storage or use of the product; (iii) measures to protect workers at risk of exposure and (iv) emergency procedures.

SARS-CoV-2 nucleic acid test *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Environmental and Safety Requirements	
71	Hazardous classification	Potential source of harm. Classification according to the Global Harmonized System, e.g. health hazard, physical hazard or environmental hazard. This information is usually contained in the material safety data sheet.
72	Disposal requirements	Standard biohazardous waste disposal or incineration of consumables. No high-temperature incineration required.
	Training, Installation and Utilization	
73	Pre-installation requirements (if relevant)	Not applicable
74	Requirements for installation and calibration	Not applicable
75	Training of user/s (if relevant)	1–3 days (includes test procedure, interpretation of results, quality control, troubleshooting).
	Warranty and Maintenance	
76	Warranty	At least a 2-year warranty should be provided. The warranty document should state the date of commencement, duration of warranty period and exclusions/inclusions. Other conditions such as maintenance support (if applicable) during warranty must also be specified.
77	Preventive maintenance	Expected minimal maintenance to be conducted by testing provider should be stated. Frequency of servicing based on fixed time periods or based on the number of tests the instrument processes.
78	Corrective maintenance	Advanced maintenance tasks required shall be documented, with details of maintenance support from manufacturer/supplier.
79	Type of service contract (including leasing or reagent rental)	Contract must cover labour, repair, spare parts, loaner instrument, shipping and logistics costs, and training.
80	Spare parts availability post-warranty	To be covered in the service-level agreement. Declaration of number of years the supply of spares shall be ensured post-warranty.
81	In-country technical support availability	Availability of local authorized service provider or distributor is recommended.
	Decommissioning	
82	Estimated lifespan	Not applicable

SARS-CoV-2 nucleic acid test *continued*

	IVD TECHNICAL SPECIFICATIONS	DESCRIPTION AND EXAMPLES
	Quality and Registration	
83	Global regulatory approvals	State regulatory approvals of the product. Careful consideration should be taken to ensure that the selected products have been assessed to an appropriate stringency level based on the risk classification for the concerned IVD. To be provided by the manufacturer/supplier (typically verified by regional or national regulatory agencies).There is increasing international harmonization, facilitated by the International Medical Device Regulators Forum (see http://www.imdrf.org/) with at least four systems in use: Classes A–D (IMDRF/GHTF); Classes I, IIa, IIb, III (EU, Australia); Classes I, II, III (USA); Classes I–IV (Japan, Canada), with low-risk devices in Class A or I and high-risk devices in Class D or III (or IV for Japan and Canada). The product shall be cleared by at least one of the five founding members of the GHTF (Australia, Canada, Japan, EU, USA) and comply with the corresponding pre-market requirements as described in the WHO *Guidance for Procurement of In Vitro Diagnostics and Related Laboratory Items and Equipment. WHO Emergency Use Listing (EUL)*.
84	Regulatory version to be procured	Valid certification for the regulatory version that will be subject to the contract required. The certificate shall indicate the name of the regulatory authority and market approval/clearance with number.
85	Free sale certificate	Valid certification for export from country of origin
86	WHO prequalification status	Yes, but only WHO EUL at this time
87	International standards / certifications	ISO 13485: 2016 compliant
88	National registration	Essential. Provide valid certification.
89	Post-market surveillance	Customer complaints require response in a timely manner. Notification to NRA for serious and moderate adverse events according to clients' timelines also required.
90	Field safety corrective actions	Affected customers of any FSCAs (such as recall or change in labelling) should be informed in a timely manner. NRA should be notified for all FSCAs.
91	Replacement of defective product	Replacement could apply depending on root cause of issue. Refer to service agreement.

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3. Guidance for procurement of in vitro diagnostics and related laboratory items and equipment. Geneva: World Health Organization; 2017 (https://www.who.int/diagnostics_laboratory/publications/procurement/en/, accessed 14 May 2021).
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6. SARS-CoV-2 antigen rapid diagnostic test – training package v1.0. Geneva: World Health Organization; 2021 (https://extranet.who.int/goarn/sars-cov-2-antigen-rapid-diagnostic-test-training-package, accessed 14 May 2021).
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World Health Organization

WORLD HEALTH ORGANIZATION
Avenue Appia 20
CH-1211 Geneva 27
Switzerland
www.who.int