World Health Organization

Target product profiles for priority diagnostics to support response to the COVID-19 pandemic v.1.0

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Purpose of the document

Selected disease areas are identified as WHO priorities for research and product development. In the case of COVID-19, target product profile development followed the *COVID-19 Global research and innovation forum: towards a research roadmap*.

The target audience are all those working to evaluate assays for COVID-19 or to develop new assays for COVID-19. The document is also aimed at those developing COVID-19 assays that have not yet reached the clinical testing phase. This document is relevant to those groups who wish to obtain WHO policy recommendations for use and WHO prequalification for their products.

All the requirements contained in WHO guidelines for WHO policy recommendation and prequalification will also apply. The criteria below lay out some of the considerations that will be relevant in WHO's case-by-case assessments of COVID-19 assays in the future. Therefore, should an assay's profile be sufficiently superior to the acceptable characteristics under one or more categories, this may outweigh failure to meet another specific critical characteristic. Assays which fail to meet multiple critical characteristics are unlikely to achieve favourable outcomes from WHO's processes. Likewise, desirable characteristics should not be considered as the maximum desirable characteristics; assays that exceed these characteristics may be round favourable during WHO's review processes.

Acknowledgement

WHO gratefully acknowledges the independent experts that provided input throughout the TPP development process as well as those individuals and stakeholder groups who contributed during the public consultation period (4 -19 August, 2020).

Abbreviations

BSL	biosafety level
CLIA	chemiluminescence immunoassay
COVID-19	coronavirus 2019
Ct	cycle threshold
DBS	dried blood spot
ELISA	enzyme-linked immunoassay
GHS	Global Harmonized System
GI	gastrointestinal
hCoV	human coronavirus
LAN	local area network
LOD	limit of detection
NAAT	nucleic acid amplification
NPV	negative predictive value
PCR	polymerase chain reaction
PPE	personal protective equipment
PPV	positive predictive value
RH	relative humidity
RNA	ribonucleic acid
rRT-PCR	real time reverse transcription polymerase chain reaction
RSV	respiratory syncytial virus
RT	room temperature
SARS-CoV-2	severe acute respiratory syndrome coronavirus - 2
TPP	target product profile
UBS	universal serial bus
WiFi	wireless fidelity
WHO	World Health Organization

I. Background

Reliable diagnostics are critical to the detection of COVID-19 cases to interrupt transmission and identify close contacts, to the understanding of disease epidemiology, and for monitoring drug efficacy and the impact of public health and social measures. Because the symptoms and signs of COVID-19 infection are similar to those of many other common febrile and respiratory illnesses, surveillance and patient management depend on accurate diagnostic testing.

Within days of the full SARS-CoV-2 genome being made available[1], PCR assay protocols were posted on the World Health Organization (WHO) website from partner laboratories[2]. Diagnostic test manufacturers have responded rapidly to the needs of countries, and over 700 products have been released onto the market to detect SARS-CoV-2 specific nucleic acids, antigens (proteins) and human antibodies[3].WHO currently recommends a single approach to clinical diagnostic testing for disease confirmation: the detection of unique sequences of SARS-CoV-2 RNA by nucleic acid amplification testing (NAAT), such as real-time reverse-transcription polymerase chain reaction (rRT-PCR). However, WHO calls for research to develop and evaluate the utility of simpler, more portable detection platforms. WHO guidance also encourages the use serological surveys of antibody responses to better understand the extent of and risk factors for COVID-19 infection through enhanced surveillance investigations to calculate the attack rate in different populations.

Additional use cases for diagnostic testing deserves exploration. In clinical situations where 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. In settings where RT-PCR is unavailable or turnaround times for results are slow (e.g., several days to weeks), rapid antigen detecting tests may facilitate earlier diagnosis and required actions[4].

[1] *Holmes E. Initial genome release of novel coronavirus 2020 [14 January 2020]. Available from:* http://virological.org/t/initial-genome-release-of-novel-coronavirus/319

[2] https://www.who.int/publications/m/item/molecular-assays-to-diagnose-covid-19-summary-table-of-available-protocols (accessed17 July)

[3] FIND COVID-19 Diagnostics Pipeline https://www.finddx.org/covid-19/pipeline/?section=show-all#diag_tab (accessed 15 July 2020)

[4] https://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117

Figure 1: Intended uses for SARS-CoV-2 testing and technologies potentially employed

Intended use	Surveillance (detect acute or past exposure or infection)	Case management of suspects (detect active infection)	Contact tracing (detect asymptomatic or symptomatic acute infection)	Monitoring response or recovery	Prognosis	Vaccine Response	Environmental monitoring
Technology	Molecular detection eg . RT-PCR	Molecular detection eg . RT-PCR	Molecular detection eg . RT-PCR	Molecular detection eg . RT-PCR	Cytokine response	Quantitative, protein specific antibody response	Molecular detection eg . RT-PCR
	Antigen detection	Antigen detection	Antigen detection	Antigen detection	Other biomarkers		Viral culture
	Antibody detection			Antibody detection			

It is anticipated that emerging diagnostic products will not necessarily meet all criteria outlined in the TPP, but that the TPP will nonetheless provide a useful framework to weigh the importance of one feature against another for a specific use case and context. Ultimately, a test that fails to meet multiple 'acceptable' characteristics is unlikely to achieve a favourable outcome. However, meeting several desirable criteria may outweigh failure to meet multiple acceptable characteristics.

In an effort to guide research and development efforts and assist donors, technical agencies and ministries of health to select products that best respond to public health needs, WHO (with input from clinicians, public health experts and laboratory scientists[5] has developed prioritized target product profiles (TTPs) outlining 'acceptable' and 'desirable' characteristics. These profiles are accompanied by a universal cautionary note that positive test results do not rule out co-infection with other bacteria, viruses and/or parasites, and similarly that negative results do not preclude a SARS-CoV-2 infection. Test results should always be considered in combination with other elements of the patient history, physical examination and the epidemiological context.

Due to the urgency of the current situation, the proposed target product profiles are focused on priority use case scenarios to address the greatest needs and are tailored to emerging or existing technologies. This should not discourage SARS-CoV-2 biomarker research or the drive towards superior performance targets or more innovative or more simplified testing formats. Furthermore, as the need for COVID-19 tests crosscuts all cultures, climates and economies, test characteristics that often lead to reduced access to testing such as elevated price, high complexity and requirements for cool or cold chain have been carefully considered. The proposed 'desirable' requirements reflect the specifications that would allow for the broadest uptake and in turn public health impact and should be the target for developers who are starting out or developing new tests and for the next generation of emerging assays.

WHO is closely monitoring scientific advances that will inform future revisions and exploring the interplay of key characteristics such as time-to-results, complexity (number of steps, training requirements) and sensitivity/specificity. As new scientific evidence is generated, these TPPs may require further review and

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revision. Additional TPPs may also be added to the portfolio, such as tools to predict development of severe COVID-19 disease or for use in environmental monitoring.

Four priority TPPs[6] have been drafted through a consultation process for the following intended uses:

i) Point of care test 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 turnaround times obviate clinical utility;
ii) Test for diagnosis or confirmation of acute or subacute SARS-CoV-2 infection, suitable for low or high-volume needs;
iii) Point of care test for prior infection with SARS-CoV-2;
iv) Test for prior infection with SARS-CoV-2 for moderate to high volume needs.

[6] TPPs are living documents and use cases and test requirements may evolve over time

The background rationale and key considerations for each test are presented below:

1. Point of care test 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 turnaround times obviate its clinical utility
For many reasons, including shortages of reagents, lack of technical expertise and inadequate laboratory capacity, rRT-PCR/reference assay testing has either not been broadly available or its availability has not translated into timely diagnostic results because the human and lab capacities have been insufficient to meet demand in many countries. Delayed transport of samples and return of results is a critical problem given the crippling social and economic impact of quarantine and lack of facilities to properly isolate patients awaiting test results. Many countries, especially low- and middle-income countries, rely on centralized testing facilities that rarely meet the needs of patients, caregivers, health workers and society as a whole. Therefore, a highly specific, rapid and easy-to-use test that could identify the majority of patients with early, acute SARS-CoV-2 infection, allowing for immediate implementation of isolation and other efforts to arrest transmission of the virus, would reduce the number of people with suspected infection requiring secondary testing. Such a test would be 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. It is considered acceptable to target patients with high viral loads often present in the first week following infection[7,8,9,10] because they are most likely to transmit the infection to others. Depending on the known or estimated prevalence of COVID-19 among suspected cases or contacts, a test that meets the profile's acceptable or desirable performance characteristics should be sufficient to diagnose SARS-CoV-2 infection and/or exclude a diagnosis without additional confirmatory testing. Regarding programmatic suitability, tests that do not require any additional equipment are desirable, and any equipment required must be portable and battery powered. The profile's acceptable test kit stability and shelf-life characteristics will not meet the needs of many tropical countries where distribution is challenging and cool storage (< 30°C) is not consistently feasible. Test developers are strongly encouraged to achieve desirable characteristics to maximize access in remote settings with hot climates.

[7] Wölfel, R., Corman, V.M., Guggemos, W. *et al.* Virological assessment of hospitalized patients with COVID-2019. *Nature* **581,** 465–469 (2020). https://doi.org/10.1038/s41586-020-2196-x
[8] Bullard J, Dust K, Funk D, et al. Predicting infectious SARS-CoV-2 from diagnostic samples [published online ahead of print, 2020 May 22]. *Clin Infect Dis*. 2020; ciaa638. doi:10.1093/cid/ciaa638
[9] Wang-Da Liu, Sui-Yuan Chang, Ming0Jui Tsai et al. Prolonged virus shedding even after seroconversion in a patient with COVID-19. Journal of Infection. In press. https://doi.org/10.1016/j.jinf.2020.03.063 0163-4453
10 Van Kampen J, van de Vijver D, Fraaij P et al. Shedding of infectious virus in hospitalized patients with coronavirus disease-2019 (COVID-19): duration and key determinants. doi: https://doi.org/10.1101/2020.06.08.20125310 medRxiv preprint

2. Diagnostic or confirmatory test for acute or subacute SARS-CoV-2 infection (e.g. during the first 2 weeks after symptom onset).
A highly accurate diagnostic test for SARS-CoV-2 infection is needed to guide rapid action for isolation and clinical care. Results of such a test would also guide decisions about the need for contact tracing, antiviral therapy for COVID-19 or alternative management for test-negative patients; for monitoring the impact of public health interventions; and targeting and monitoring outcomes of experimental/research interventions, such as on drug efficacy. This test would need to be sensitive and specific enough to be used alone for diagnosis and may also serve as second-line test to confirm results of a point of care test (TPP # 1). Furthermore, tests could be used for repeat assessment throughout the period of viral shedding. To achieve the performance requirements, it is expected that this assay will require instrumentation and may or may not be usable outside laboratory settings. High-throughput laboratory-based instruments and low-throughput near-patient solutions are both needed and are covered in this TPP. Regarding programmatic suitability, the profile's acceptable test kit stability and shelf-life characteristics will not meet the needs of many tropical countries where distribution is challenging and cool storage (< 30°C) is not consistently feasible. Test developers are strongly encouraged to achieve desirable characteristics to maximize access, particularly in remote settings with hot climates. Capacity for multiplexing and sample pooling are important clinical and practical features to link with this test profile but are not included in this first version. Nonetheless, assays adapted and validated for these purposes would be attractive.

3. Point of care test for prior SARS-CoV-2 infection
Easy-to-use tests to detect antibody responses to COVID-19 at the point of care can have a fundamental role in determining the epidemiologic features of the outbreak, including determining the attack rate in different cohorts and calculating the case fatality rate. This test would not have a role in clinical case management since COVID-19 IgM and IgG responses overlap temporally and therefore, determining recency of infection with a single test result is problematic. Furthermore, the specificity of an antibody response for recency of infection falls as the number of previously infected individuals in the population grows. If an initially negative test is repeated after two weeks and is positive this could indicate seroconversion and may support a retrospective diagnosis of recent infection. A point of care test is ideal for settings without good options for sample transport and/or access to laboratory infrastructure. The acceptable performance requirements would need to be demonstrated in one or more target populations, depending on the manufacturer's claims. For example, a test that claims to detect recent infection will need to demonstrate that it meets sensitivity and specificity requirements in cohorts of seroconverting patients/ samples taken after different days of onset since illness. Regarding programmatic suitability, tests that do not require any additional equipment are desirable, and any equipment required must be portable and battery powered. In addition, the profile's acceptable test kit stability and shelf life characteristics will not meet the needs of many tropical countries where distribution is challenging and cool storage (< 30°C) is not consistently feasible. Test developers are strongly encouraged to achieve desirable characteristics to maximize access particularly in remote settings with hot climates.

4. Test for prior SARS-CoV-2 infection for moderate, high volume settings tests
Tests to detect antibody responses to COVID-19 can have a fundamental role in determining the epidemiologic features of the outbreak, including determining the attack rate in different cohorts and calculating the case fatality rate. Such tests could also be helpful in blood donor screening to support 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 the diagnosis of COVID-19. The quantitative version of this test could potentially further serve to detect the presence, nature and abundance of antibodies determined to provide protective immunity. This test is envisioned as supporting seroprevalence surveys and should meet moderate to high volume demands. Therefore, the need for additional equipment and laboratory infrastructure are acceptable characteristics. Furthermore, performance requirements are more stringent than they are for TPP # 3 and need to be achieved for each applicable intended use and in the appropriate target population (e.g. in vaccinated populations or for detection of recent infection in people who have seroconverted).

1. Point of care test (POCT)[1] 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 turnaround times obviate its clinical utility		**Notes**
Intended Use	**In areas with confirmed SARS-CoV-2 community wide transmission or confirmed outbreaks in closed or semi-closed communities and in high risk groups:** Early detection of SARS-CoV-2 cases where molecular/reference assays are not available or services are overloaded, leading to turnaround times that are not useful for guiding clinical case management and infection control measures. **In suspected SARS-CoV-2 outbreak situations:** multiple positive cases highly suggestive of SARS-CoV-2 **Monitor trends in disease incidence**	The primary objectives of the COVID-19 global response are to slow and stop transmission; find, isolate and test every suspect case; and provide timely appropriate care of patients with COVID-19. This test would allow for rapid and early detection of the most infectious SAR-CoV-2 cases (highest viral loads). Where SARS-CoV-2 is known to be circulating (prevalence high), positive results would trigger immediate infection control measures and contact tracing. Mild or no symptoms would be referred for self-isolation and self-care, and those with moderate/severe and or risk factors would be hospitalized and isolated. Confirmatory testing for people who test positive is only recommended where enough tests are available, where disease prevalence is low (<5%) and to confirm suspect outbreaks (positive predictive value unknown). Patients with negative test results should be tested and treated or treated empirically for other diseases as per national guidelines, and those with respiratory symptoms should take precautions to reduce onward transmission and should have repeat SARS-CoV-2 POCT during the first 10 days post onset of symptoms if symptoms persist or worsen.

Target Population/patient	Patients with acute or subacute respiratory symptoms or fever or other suspicious symptoms (diarrhoea, anosmia) and either a known contact with a confirmed or probable COVID-19 patient **or** living in an area of cluster **or** community transmission, and close contacts (with or without symptoms) of index patients (confirmed COVID-19 patients).	Presenting signs and symptoms of COVID-19 vary. Most persons experience fever (83–99%), cough (59–82%), fatigue (44–70%), anorexia (40–84%), shortness of breath (31–40%), myalgias (11–35%). Other non-specific symptoms, such as sore throat, nasal congestion, headache, diarrhoea, nausea and vomiting, have also been reported. Loss of smell (anosmia) or loss of taste (ageusia) preceding the onset of respiratory symptoms has also been reported. Older people and immunosuppressed patients in particular may present with atypical symptoms such as fatigue, reduced alertness, reduced mobility, diarrhoea, loss of appetite, delirium, and absence of fever. Symptoms such as dyspnoea, fever, gastrointestinal (GI) symptoms or fatigue due to physiologic adaptations in pregnant women, adverse pregnancy events, or other diseases such as malaria, may overlap with symptoms of COVID-19. Children might not have reported fever or cough as frequently as adults[2]. Asymptomatic cases have been demonstrated to have viral loads similar to symptomatic cases; however, based on minimum performance characteristics of this TPP, screening of asymptomatic non-contacts with low pre-test probability would likely result in more false positives than true positives and are therefore not currently considered part of the target population.[3]

Key Feature	Acceptable	Desirable	Notes
Target use setting	The tests can be performed outside laboratories including at routine and ad-hoc triage/screening points of health care facilities such as emergency units, mobile units and in the community (contact tracing) by health care workers or laboratory technicians with appropriate training in sample collection, biosafety and in the use of the test.	Same as acceptable but can be self-administered and/or performed by trained lay workers (volunteer/community health workers).	
Target molecule (analyte to be detected)	SARS-CoV biomarker (e.g. RNA, protein/antigen(s) specific for acute e.g. first week after onset of symptoms /current infection (assumption that SARS-CoV-1 is not circulating)	SARS-CoV-2 only biomarker (e.g. RNA, protein/antigen) specific for acute and subacute e.g. first two weeks after onset of symptoms/current infection	Analytes associated with current infection are highest priority (days 1 through 8) as they detect the most infectious cases. On this basis, immunoglobulin-based tests would not be an acceptable analyte.

Key Feature	Acceptable	Desirable	Notes
Analytical sensitivity/Limit of detection	equivalent to 10^6 genomic copies/mL or Ct ≈ 25-30	equivalent to 10^4 genomic copies/mL or Ct≈>30	Variable population characteristics are expected, which will result in variable clinical sensitivity and specificity. Therefore, a limit of detection (LOD) that is based on anticipated viral loads in patient specimens and associated infectivity is critical to anticipate clinical utility. Reports in literature are variable: copies/reaction, copies/mL but most often cycle threshold (Ct) values. Correlation between viral load and transmissibility is not entirely clear - some reports cite inability to culture virus < 10^6 [4,5]. Therefore, we propose a POC test that can consistently detect the most infectious patients (e.g. LOD 10^6) in order to interrupt transmission. Test developers should use well characterized reference material and international standards, when available, to determine limits of detection.
Analytical specificity	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)[6]	Assay detects all SARS-CoV-2 viral strains and does not cross react with common interfering substances or other human coronaviruses 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)[6]	

Key Feature	Acceptable	Desirable	Notes
Sensitivity	≥ 80%	≥90%	The targets are for the estimated true sensitivity and specificity; therefore, the lower bound of confidence intervals should ideally equal or exceed the target. Determination of sensitivity and specificity should be against an approved/authorised by a stringent regulatory aiuthority (SRA), molecular-based COVID-19 assay[7].Product assessment of clinical specificity must include patients/samples with other human coronaviruses and pathogens in differential diagnosis for presenting signs/symptoms. For both sets of criteria, at low prevalence, PPV is <50%, and would require a second test for confirmation; however, negative predictive value (NPV) is high. When prevalence increases to 10-20%, acceptable criteria for PPV increases to >78-89% and NPV remains high (95-98%).
Specificity	≥ 97%	>99%	
Type of analysis	Qualitative (yes/no), semi-quantitative or quantitative	Not applicable	
Interpretation	Visual manual and/or hardware reader (proprietary or smart phone application)	Visual manual read or digital readout via smartphone application reader with connectivity	
Sample type	Nasopharyngeal, oropharyngeal swab (or wash) nasal swab (anterior nares or mid-turbinate), nasal wash, sputum	Anterior nares, saliva/oral fluid, sputum	Specimens that are easier to collect and associated with lower risk of aerosols are preferred i.e., saliva/oral fluid. Ideally the test can meet LOD requirements in an upper and a lower respiratory tract specimen.

Key Feature	Acceptable	Desirable	Notes
Sample collection device	Compatible with an existing swab material e.g. flocked	Compatible with multiple swab materials; self-collection or no swab required e.g. saliva	
End user profile	Trained staff in health care facilities	Trained staff in health care facilities or community level (lay person) or self-administered.	
Training needs (including sample collection, test procedure, results interpretation, QC and biosafety)	0.5 days with instructions for use and quick reference guide (s)	2 hours with instructions for use and quick reference guide (s) including through smart phone application(s) to ensure ongoing compliance and up-to-date training.	
Test procedure			
Sample preparation steps **Need to process the sample before performing the test**	1	0	
Reagents reconstitution **Need to prepare the reagents before utilization**	Reconstitution acceptable if very simple to do.	All reagents ready to use.	
Sample minimum volume	single swab and minimal extraction buffer/diluent.		
Need to transfer a precise volume of sample	Acceptable if autofill or graduated volume markings on sample transfer device is provided	No, or limited to a number of drops.	Addition of drops is not considered 'precise' volume requirement.
Number of timed steps **(use of different reagents/incubation steps)**	$\leq$ 3	1, with the potential for digitally guided workflows and built-in timers to reduce user errors on timed steps.	

Key Feature	Acceptable	Desirable	Notes
Time to result	≤ 40 minutes	≤20 minutes	Expect patients would wait for results.
Sample stability pre-testing	30 minutes (dry, not refrigerated, 10-35°C); 2-4 hrs (dry, refrigerated (4-8°C); 8 hrs (refrigerated (4-8°C) in generic preservative); several days frozen in generic preservative (min -20°C).	i) Test compatible with both dry and preserved samples; ii) 3 hours (dry, not refrigerated (10-40°C); 8 hrs (dry, refrigerated (4-8°C); 24 hrs refrigerated in generic preservative and months frozen in preservative.	Accept tests that have to be done immediately as the point is to do this at the point of care but the ideal would be options for immediate stability, with refrigeration and freezing and that are compatible with both dry and preserved sample types.
Result validity stability	Fixed reading time.	Stored image or 6 weeks.	
Invalid rate	<2% invalid results with correct use by operator.	≤0.5% invalid results with correct use by operator.	
Additional characteristics			
Operating conditions	15-35°C; 25-80% relative humidity up to 1500m.	10-40°C; 25-90% relative humidity up to 3000m.	Ideally tests could support conditions in tropical countries.
Test kit stability and storage conditions	12 months[4] at 4-30°C; tolerates brief periods > 40°C; humidity 75%+ 5% any associated equipment must meet or exceed these requirements.	18-24 months at 4-40°C; tolerates freezing and brief periods > 45°C; humidity 75%+ 5%.; any associated equipment must meet or exceed these requirements.	Expect real time stability data to support shelf life requirements will not be available at the time of product release, but manufacturers should be challenged to meet targets that match what is realistic for supply chains in low- and middle-income countries.
Stability of the kit once opened	30 mins for single use test after opening the pouch.	1 hour for single use test after opening the pouch.	

Key Feature	Acceptable	Desirable	Notes
Specimen capacity & throughput	≥5/hr per operator.	≥10/hr per operator.	Assume that individual tests can be run in parallel - probably not more than 5 per hour at a time feasible per operator.
Safety precautions	Standard respiratory sample collection safety precautions recommended, and all materials are free of components with a GHS classification H (particularly H350, H340, H360)[8]	Tests that minimize the need for biosafety requirement are strongly preferred e.g. with a self-sample collection device with virus inactivation.	
Quality Control	Internal control (for sample flow/migration) is an area or region within the individual testing device; positive control and negative control sold separately; external quality assessment material compatible; calibration control for reader, if applicable.	Internal control is an area or region within the individual testing device; lyophilized positive control and negative (full process) control provided in the kit; external quality assessment material compatible; calibration control for reader, if applicable	
Remote connectivity capacity	Not required for reader independent tests; If device-based: Remote export of data possible.	Test is compatible with readers and other data capture devices; internal memory to store results even if power cut and with the ability to report to country health information management systems using an onboard unique identifier or other personal data protection safeguard, linking the test to the user (e.g., QR codes, 2-D barcoding, etc.)	

Key Feature	Acceptable	Desirable	Notes
Need for additional equipment	Handheld or on desktop: < 1 kg; battery or solar power operated; > 8 hours rechargeable battery life.	No additional equipment required, but if required, it should have potential for digital connectivity through smartphone application(s).	Acknowledge that to achieve higher sensitivity requirements a reader may be necessary.
Need for maintenance/spare parts	None, swap out or replace ancillary device when needed.	None required as device-free.	
Waste/disposal requirements	Routine biohazard waste.	Not applicable.	
Manufacturing	ISO 13485: 2016 compliant	WHO or stringent regulatory authority (SRA) emergency use listing/authorization or WHO Prequalification or other stringent regulatory authority approval	
Accessibility	To maximize accessibility, all product manufacturers should have the capability to rapidly scale-up production and offer the product at a cost that allows broad use, including in low- and middle-income countries.		

1 - POCT refers to decentralized testing that is performed by a minimally trained healthcare professional near a patient and outside of central laboratory testing and test results are generally made available within a single clinical encounter.

2- WHO Clinical management of COVID-19, Interim Guidance, May 2020; https://www.who.int/publications/i/item/clinical-management-of-covid-19 (accessed 29 July, 2020)

3- Lee S, Kim T, Lee E, Lee C, Kim H, Rhee H, et al. Clinical Course and Molecular Viral Shedding Among Asymptomatic and Symptomatic Patients With SARS-CoV2 Infection in a Community Treatment Center in the Republic of Korea. JAMA Intern Med. doi:10.1001/jamainternmed.2020.3862, 2020.

4- Van Kampen J, van de Vijver D, Fraaij P et al. Shedding of infectious virus in hospitalized patients with coronavirus disease-2019 (COVID-19): duration and key determinants. doi: https://doi.org/10.1101/2020.06.08.20125310 medRxiv preprint

5 - Wölfel, R., Corman, V.M., Guggemos, W. *et al.* Virological assessment of hospitalized patients with COVID-2019. *Nature* **581,** 465–469 (2020). https://doi.org/10.1038/s41586-020-2196-x

6 - minimum 6 months shelf-life remaining when product arrives at point of use.

7 - Instructions and requirements for Emergency Use Listing (EUL) submission: In vitro diagnostics detecting SARS-CoV-2 nucleic acid and rapid diagnostics tests detecting SARS-CoV-2 antigens. https://www.who.int/diagnostics_laboratory/200609_final_pqt_ivd_347_instruction_ncov_nat_and_ag_rdts_eul.pdf?ua=1

8 - Global Harmonized System of Classification and Labelling of Chemicals: H350 may cause cancer, H340 may cause genetic defects; H360 may damage fertility of the unborn child

2. Test for diagnosis or confirmation of acute or subacute SARS-CoV-2 infection, suitable for low or high-volume needs			Notes
Intended Use	To detect the presence of virus component(s) to diagnose or confirm acute and subacute SARS-CoV-2 infection e.g. first two weeks since onset of symptoms in suspected cases or contacts (of probable or confirmed COVID-19 patients) with or without symptoms.		Terms acute and subacute to emphasize that this is a test that should work through the period of viral shedding but not to detect patients in the recovery phase of illness.
Target Population/patient	Patients with acute or subacute respiratory symptoms or fever or other suspicious symptoms (anosmia, diarrhoea) and either having had a 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 (positive triage test but low PPV) or exclusion (negative triage test but low NPV) of COVID-19 infection.		
Target use setting - low -and high- volume settings	High-volume needs: reference laboratories or ideally in district hospitals or mobile laboratories by laboratory technicians with appropriate training in sample collection, biosafety and in the use of the test. These labs can of course also serve low-moderate needs.	Low-volume needs/non-laboratory settings: outpatient clinics, emergency units at the point of care or near patient by health care workers or laboratory technicians with appropriate training in sample collection, biosafety and in the use of the test.	Anticipate that laboratory capacity will be required for higher throughput diagnostic testing demands. For low throughput diagnostic test needs, the setting can be outside of laboratories and near patient or point of care.
Target molecule (analyte to be detected)	Must have at least one target specific for SAR-CoV-2 RNA or protein/antigen.	Not applicable.	

Key Feature	Acceptable	Desirable	Notes
Analytical sensitivity/Limit of detection	Equivalent to 10^3 genomic copies per mL in any respiratory tract specimen type.	Equivalent to 10^2 genomic copies/mL in upper and lower respiratory tract specimens and stool.	Test developers should use well characterized reference material and international standards, when available, to determine limits of detection
Analytical specificity	Assay detects only circulating SARS-CoV-2 viral strains; no interference due to interfering substances		Cross reactivity with SARS-CoV-1 could be acceptable as this virus not currently circulating
Sensitivity	≥95%	≥98%	To be determined on target population against reference standard. The targets are for the estimated true sensitivity and specificity; therefore, the lower bound of confidence intervals should ideally equal or exceed the target.
Specificity	≥99%	≥99%	
Type of analysis	Qualitative (info sufficient to inform clinical decision making)	Qualitative and quantitative based on analyte detected	
Interpretation	Qualitative (positive/negative) with patient identification capacity	Qualitative and quantitative, e.g. CT values and amplification curves, with patient identification capacity	
Sample type	Any of the following: swabs – nasopharyngeal, oropharyngeal nasal; washes - oropharyngeal, nasal, bronchoalveolar; sputum	Sample types amenable to self-collection and/or easy to collect: saliva/oral fluid, stool; inactivated samples	
Sample collection device	Compatible with an existing swab material e.g. flocked	Compatible with multiple swab materials including self-collection devices or no swab required e.g. saliva	

Key Feature	Acceptable	Desirable	Notes
Test kit format	A kit that is compatible with range of standard extraction methods (if applicable), and includes all required reagents, controls and needed consumables to perform the assay (excluding sample collection and sample transport preservative)	Low volume (non-laboratory-based testing): closed system with all necessary materials for sample collection, reagents for RNA extraction (if applicable), sample preparation and detection on-board High volume (laboratory based): self-contained kit that includes sample collection, RNA extraction (if applicable), reagents, controls and needed consumables to perform the assay	
End user profile	Laboratory technician	Laboratory technician or trained health worker not requiring very specialized knowledge	
Training needs (includes test procedure, interpretation of results, quality control, troubleshooting)	3 days	1 day with online modules	
Test procedure			
Sample preparation steps (Need to process the sample prior to performing the test)	High volume (lab): Benchtop preparation & transfer of sample. Low volume (non-lab): inactivation step and transfer step	Automated on-board sample preparation within cartridge	
Reagents reconstitution Need to prepare the reagents prior utilization	High throughput (lab): Yes	No	
Need to transfer a precise volume of sample	Yes	No	

Key Feature	Acceptable	Desirable	Notes
Specimen volume	The minimal sample volume required to reach clinically relevant sensitivities and ideally would allow for repeat testing	Not applicable	
Time to result	< 4 hours (half day)	< 45 mins	
Additional characteristics			
Operating conditions	Operation between 10 °C and 35 °C at an altitude up to 2500 meters; ability to tolerate extremely low relative humidity to condensing humidity. Able to function in direct sunlight and low light; able to withstand dusty conditions	Same, plus operation between 10 °C and 40 °C at an altitude up to 3000 meters preferred.	
Sample transport	Compatible with one or more preservative/viral transport medium; stable for at least 12 days at 2-8°C in triple packaging; > 12 days at -70°C	Preparation that stabilizes specimens removing need for cold chain and triple packaging	
Test kit stability and storage conditions	12 months[1], stable between 4-10°C, 70% humidity; 3000 meters altitude; Indicator of instability or expiration	18-24 months, stable between 4-40°C (no cold chain), 90% humidity; 3000 meters altitude; Indicator of instability or expiration	Expect real time stability data to support shelf life requirements will not be available at the time of product release, but manufacturers should be challenged to meet targets that match what is realistic for supply chains in low- and middle-income countries.

Key Feature	Acceptable	Desirable	Notes
Stability of the kit once opened	30 days	60 days	
Specimen capacity & throughput	High volume: can test between 50-150 patient samples in 4 hours. Low volume (non-lab): 1-4 patients per 45 mins	High volume - Can test between 200-500 patient samples in 4 hours; random access option. Low volume (non-lab): 6 patients in 45 mins	
Safety precautions (includes sample collection)	In all cases, PPE for sampler (gloves, gown, mask). High volume/lab-based test: laboratory BSL-2 or equivalent. Low volume/non-lab-based test: good ventilation; easy decontamination of instrument surfaces	Patient provides sample and includes inactivation step (not heat based) or sample enters closed system, which removes biosafety concerns and can follow universal precautions; easy decontamination of instrument surfaces	
Quality Control	Positive control and negative control provided in the kit or are sold separately. If applicable, RNA extraction control	Sample adequacy control and internal extraction control integrated into testing system	
Remote connectivity capacity	Export of data to USB possible with proprietary or 3rd party instrument	Yes, direct electronic data exportation via LAN or WiFi and Bluetooth, possible	
Need for additional equipment	Assay compatible with off-the-shelf equipment only, e.g. PC and at least the two most commonly available thermocyclers with thermocycler-specific CT cut-off values for assay determined	Instrument that runs integrated self-contained assay; highly desirable is open diagnostic platform instrument that runs integrated assays from a range of developers worldwide.	

Key Feature	Acceptable	Desirable	Notes
Need for maintenance	Daily preventive maintenance can be performed by laboratory staff in <30 minutes; self-check alerts operator to instrument errors or warnings; annual maintenance conducted by industry professional under maintenance contract and replacement option	Routine preventive maintenance no more than 30 minutes 1x per week; 2-year maintenance and replacement option or maintenance conducted by onsite trained personnel in less than 1 hour; or ability to calibrate remotely or no calibration needed.	
Waste/disposal requirements	Standard biohazardous waste disposal or incineration of consumables, no high temperature incineration required	Small environmental footprint; recyclable or compostable plastics for test cartridges and other materials after decontamination, no incineration required	
Manufacturing	ISO 13485: 2016 compliant	WHO or stringent regulatory authority (SRA) emergency use listing/authorization or WHO Prequalification or other stringent regulatory authority approval	
Accessibility	To maximize accessibility, all product manufacturers should have the capability to rapidly scale-up production and offer the product at a cost that allows broad use, including in low- and middle-income countries		
1 - minimum 6 months shelf-life remaining when product arrives at point of use.			

3. Point of care test for prior SARS-CoV-2 infection			Notes
Intended Use	Easy to use test that can be used at the point of care to detect prior SARS-CoV-2 infection		The primary use is to support epidemiological surveys and surveillance activities[1] to guide public health measures. These tests are not intended to detect or exclude active infection.
Target Population/patient	*General population involved in surveys/ surveillance activities *Groups at high risk of exposure to SARS-CoV-2		
Target use setting	The tests can be performed outside laboratories e.g. in health facilities or community surveillance settings, by health care workers or laboratory technicians with appropriate training in sample collection, biosafety and in the use of the test. Includes both low- and high-volume settings without access to laboratories.	Same as acceptable but can be performed by trained lay workers (volunteer/community health workers)	In settings without good transport and/or access to laboratory infrastructure, a point of care test may be the only feasible option.
Key Feature	**Acceptable**	**Desirable**	**Notes**
Target molecule (analyte to be detected)	At least one isotype or other biomarker(s) specific to prior SARS-CoV- 2 infection	Not applicable	

Key Feature	Acceptable	Desirable	Notes
Analytical sensitivity/Limit of detection	Currently there is no international standard/units to express limits of detection; in the interim LOD can be expressed as the minimum detectable concentration of analyte in well characterized samples from patients with past history of NAAT-confirmed SARS-CoV-2 infection.	Not applicable	
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 Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting Antibodies to SARS-CoV-2 virus - Emergency Use Listing - Tables 1 and 2 (plus biotin)*[2]	Not applicable	

Key Feature	Acceptable	Desirable	Notes
Sensitivity	≥ 90%	≥95%	The targets are for the estimated true sensitivity; therefore, the lower bound of confidence intervals should ideally equal or exceed the target. These are minimum requirements for a test to fulfil primary intended use i.e., community-based seroprevalence survey for evidence of prior infection with cohorts to include patients > 21 days post onset of symptoms. Determination of sensitivity should be against well characterized samples with evidence of NAAT - confirmed past infection.

Key Feature	Acceptable	Desirable	Notes
Specificity	≥97%	≥99%	The targets are for the estimated true sensitivity and specificity; therefore, the lower bound of confidence intervals should ideally equal or exceed the target
Type of analysis	Qualitative	Not applicable	Cannot be used to demonstrate change in titres in acute and convalescent samples
Interpretation	Visual or portable automated reader	Visual - device free	
Sample type	Plasma, serum but must show equivalence in capillary blood from finger/heel stick and/or saliva/oral fluid	Not applicable	
Test kit format	Kit contains materials for sample collection and all that is required to perform the test i.e., sample collection, transfer devices, test devices and reagents	Same plus controls	
End user profile	Health care facility worker	Lay person/non-professional staff	
Training needs	≤0.5 days	≤2 hours with instructions for use and quick reference guide(s)	
Test procedure			

Key Feature	Acceptable	Desirable	Notes
Sample preparation steps (Need to process the sample prior to performing the test)	1	0	
Reagents reconstitution Need to prepare the reagents prior utilization	Reconstitution acceptable if very simple to do.	No, all reagents ready to use	
Need to transfer a precise volume of sample	Acceptable if autofill or graduated volume markings on sample transfer device is provided	No, or limited to a number of drops	
Number of timed steps (use of different reagents/incubation steps)	≤2	1	
Time to result	≤40 minutes	≤ 20minutes	
Sample stability pre-testing	30 minutes RT (10-35°C); 8 hrs refrigerated (2-8°C)	3 hrs RT (10-35°C); and 24hrs refrigerated (2-8°C)	
Result validity stability	Fixed reading time	Stored image or 6 weeks	
Invalid rate	<5% invalid results with correct use.	≤1% invalid results with correct use.	Assumes invalid rate during correct use. Rate of invalidity for all controls, exogenous and/or endogenous, due to test failure.
Additional characteristics			
Operating conditions	15-35°C; 25-80% RH; altitude up to 1500 m	10-40°C; 25-90% RH; altitude up to 3000m	
Test kit stability and storage conditions	12 months, stable between 2-30°C, 70% humidity; tolerates brief periods > 40°C; any associated equipment must meet or exceed these requirements.	18-24 months, stable between 2-40°C, 90% humidity; tolerates brief periods > 45°C; any associated equipment must meet or exceed these requirements.	

Key Feature	Acceptable	Desirable	Notes
Stability of the kit once opened	1 hour	4 hours	
Specimen capacity & throughput	≥5/hr per operator	≥10/hr per operator	
Safety precautions	Standard blood collection safety precautions needed, and all materials are free of components with a GHS classification H (particularly H350, H340, H360[3]); PPE for sampler if ongoing community transmission of SARS-CoV-2	Not applicable	
Quality Control	Internal control (for sample flow/migration) is an area or region within the individual testing device; positive control and negative control sold separately; external quality assessment material compatible	Internal control is an area or region within the individual testing device; lyophilized positive control and negative (full process) control provided in the kit; external quality assessment material compatible	
Remote connectivity capacity	If device-based: remote export of data possible. If no device: i) export could be available through separate 3rd party reader and ii) results can be entered in application platform	Test is compatible with readers and other data capture devices	
Need for additional equipment	Handheld: < 1 kg; battery or solar power operated; > 6 hours rechargeable battery life	No additional equipment required	
Need for maintenance/spare parts	None, swap out or replace ancillary device when needed	None required as device-free	

Key Feature	Acceptable	Desirable	Notes
Waste/disposal requirements	Standard biohazardous waste disposal or incineration of consumables, no high temperature incineration required	Small environmental footprint; recyclable or compostable plastics for test cartridges and other materials after decontamination; no incineration required	
Accessibility	To maximize accessibility, all product manufacturers should have the capability to rapidly scale-up production and offer the product at a cost that allows broad use, including in low- and middle-income countries		

1 Epidemiological surveys to determine the presence and extent of disease, in particular, the rate of asymptomatic infections, and to better estimate morbidity and mortality. In smaller groups (households, communities and health care workers). These could potentially help guide control measures, but additional testing is required to determine the amount, quality and durability of the antibodies to guide decisions such as returning to work, re-opening of schools, etc.
2 https://www.who.int/diagnostics_laboratory/200703_pqt_ivd_352_v2_eul_immunoassay_requirements_ncov.pdf?ua=1 (accessed 29 July 2020)
3 Global Harmonized System of Classification and Labelling of Chemicals: H350 may cause cancer, H340 may cause genetic defects; H360 may damage fertility of the unborn child

4. Test for prior SARS-CoV-2 infection for moderate, high volume needs			Notes
Intended Use	Test used to detect prior SARS-CoV-2 infection; potentially to aid in discrimination between natural infection and vaccination; confirmation of POCT prior infection test (TPP No. 3)		The primary intended use is to support epidemiological surveys and surveillance activities[1] to guide public health measures and to plan and evaluate the results of vaccine trials and development of therapeutic antibodies. These tests are not intended to detect or exclude active infection.
Target Population/patient	*General population involved in surveys/ surveillance activities including post vaccination to distinguish natural versus vaccine-induced response; *Groups at high risk of exposure to SARS-CoV-2 ;* Blood donor screening (e.g. for therapeutic antibodies); *Patients with delayed presentation and high index of suspicion for COVID-19 infection and who are negative for tests that detect virus specific analytes (e.g. RNA, antigens) and can have acute and convalescent (2-4 weeks post illness) blood draws		Acknowledging potential role for this test to aid in retrospective diagnosis of SARS-CoV-2 patients based on a rise in antibody titres or seroconversion.
Target use setting	District and reference-level laboratories by laboratory technicians with appropriate training in sample collection, biosafety and in the use of the test		This test is expected to require some laboratory capacity and support high volume demands.
Target molecule (analyte to be detected)	At least one antibody isotype or other biomarker(s) specific to prior SARS-CoV-2 infection	More than one antibody isotype or other biomarker(s) specific to prior SARS-CoV- 2 infection; discriminates between natural immune response and vaccination-induced response	

Key Feature	Acceptable	Desirable	Notes
Analytical sensitivity/Limit of detection	Currently there is no international standard/units to express limits of detection; in the interim, LOD can be expressed as the minimum detectable concentration of analyte in well characterized samples from patients with past history of NAAT-confirmed SARS-CoV-2 infection.	Not applicable	
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 Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting Antibodies to SARS-CoV-2 virus - Emergency Use Listing - Tables 1 and 2 (plus biotin)*[2]	Not applicable	

Key Feature	Acceptable	Desirable	Notes
Sensitivity	≥ 95%	≥98%	The targets are for the estimated true sensitivity and specificity; therefore, the lower bound of confidence intervals should ideally equal or exceed the target. These are minimum requirements for test to fulfil primary intended use i.e., community based seroprevalence survey for evidence of prior infection with cohorts to include patients > 21 days post onset of symptoms and eventually vaccinated and non-vaccinated individuals. For detection of recent infection, samples after different days of onset since illness will be required to determine sensitivity/specificity for this testing indication. Determination of sensitivity should be against well characterized samples with evidence of NAAT -confirmed past infection.
Specificity	≥97%	≥99%	
Type of analysis	Semi-quantitative/quantitative	Not applicable	Ideally quantitative so that change in titres can be measured
Interpretation	Thresholds/cut-offs for each analyte, include borderline or equivocal; patient identification capacity	Same, plus neutralizing antibody; vaccine versus natural response	
Sample type	Plasma, serum	Same plus one or more others: whole blood (fresh or frozen or DBS), dried plasma spots; oral fluid (fresh or frozen)	Sample types that are the easiest to collect are preferred, Traditional samples - serum, plasma acceptable

Key Feature	Acceptable	Desirable	Notes
Test kit format	Kit contains all that is applicable i.e., test devices or plates or beads and reagents (conjugate, substrate)	Kit contains all that is required for performing the test i.e., test devices or plates or beads and reagents e.g. conjugate, substrate and controls	
End user profile	Sample collection: trained health worker or lay person (volunteer/community health worker); assay: trained laboratory technicians	Not applicable	
Training needs	1-3 days	0.5-2 days	Duration of training will be dependent on assay and instrument complexity and if laboratory technicians have previous experience with similar assays
Test procedure			
Sample preparation steps (Need to process the sample prior to performing the test)	< 3	1	
Reagents reconstitution Need to prepare the reagents prior utilization	Yes	No	
Sample stability pre-testing	Will vary by sample type but stability of primary collection sample for 1 week at 4-8°C will be sufficient for most settings.	Primary collection sample stable for 72 hours at ambient temperature 10-35°C; ideally stabilizing reagent that allows for minimum one-week testing delay at ambient temperature	

Key Feature	Acceptable	Desirable	Notes
Time to result	4-6 hrs	<2hrs	
Additional characteristics			
Operating conditions	15-30°C; 25-80% RH	10-35°C; 25-90% RH	
Test kit stability and storage conditions	12 months, stable between 4-8°C, 70% humidity; can tolerate several days > 40°C	18-24 months, stable between 4-40°C, 90% humidity	
Specimen capacity & throughput	≈ 40 samples , 2-5 hours per set up	Batch testing (≈50 - 150 patients per hour/operator) with option for single assessment /random access on same platform	Acceptable: roughly equivalent to 96 well plate ELISA - samples run in duplicate
Safety precautions	BSL-2 or equivalent with adequate normal testing precautions for infectious agents	Not applicable	
Quality Control	Endogenous control included; positive, negative controls sold separately	All controls included in the kit	
Remote connectivity capacity	Export of data to USB possible with proprietary or 3rd party instrument	Direct electronic data exportation via LAN or WiFi and Bluetooth, possible	
Need for additional equipment	Assay compatible with non-automated, open systems or proprietary automated systems	Automated, non-proprietary/open systems	

Key Feature	Acceptable	Desirable	Notes
Need for maintenance/spare parts	Daily preventive maintenance can be performed by laboratory staff in <30 minutes; self-check alerts operator to instrument errors or warnings; annual maintenance conducted by industry professional under maintenance contract and replacement option	Routine preventive maintenance no more than 30 minutes 1x per week; 2-year maintenance and replacement option or maintenance conducted by onsite trained personnel in less than 1 hour; or ability to calibrate remotely or no calibration needed	
Waste/disposal requirements	Standard biohazardous waste disposal or incineration of consumables, no high temperature incineration required	Small environmental footprint; recyclable or compostable plastics for test cartridges and other materials after decontamination, no incineration required	
Accessibility	To maximize accessibility, all product manufacturers should have the capability to rapidly scale-up production and offer the product at a cost that allows broad use, including in low- and middle-income countries		

1 Epidemiological surveys to determine the presence and extent of disease, in particular, the rate of asymptomatic infections, and to better estimate morbidity and mortality. In smaller groups (households, communities and health care workers). These could potentially help guide control measures, but additional testing may be required to determine the specific amount, quality and durability of the antibodies to guide decisions such as returning to work, re-opening of schools, etc.
2 https://www.who.int/diagnostics_laboratory/200703_pqt_ivd_352_v2_eul_immunoassay_requirements_ncov.pdf?ua=1 (accessed 29 July 2020)

The above prioritization decisions are preliminary and may change as further information is provided to WHO

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