Procurement Considerations for COVID-19 Diagnostics

Since the beginning of February, over 55 million diagnostic products have been procured and 35 million shipped or delivered to over 160 countries by procurement members of the Diagnostics Consortium for COVID-19, including the Global Fund to Fight AIDS, Tuberculosis and Malaria, Stop TB Partnership's Global Drug Facility (GDF), PAHO, UNDP, Unicef, Unitaid/CHAI, and WHO. However, the COVID-19 pandemic has led to continued constraints and challenges for diagnostic products. Testing rates across countries and regions have varied and there remains a significant need to further expand testing capacity in order to support clinical care and reduce transmission.

Low- and middle-income countries as well as some high-income small island developing states have continued to experience restrictions in test access due to competition for limited volumes with high-income countries. Manufacturers have also faced challenges scaling up manufacturing to meet all testing needs. Prices for diagnostic products remain high and some national governments continue to face restricted access to tests. At the request of the UN Secretary-General and in support of the UN Crisis Management Team, the COVID-19 Supply Chain System (CSCS) and Diagnostics Consortium for COVID-19 was created to establish an inter-agency collaboration in an effort to support all Member States and in particular 144 low- and middle-income countries, as well as some high-income small island developing states, doing so through consolidating demand, developing equitable allocations mechanisms, coordinating procurement, and providing visibility and transparency with shipments and distribution.

This document aims to bring clarity on the process of requesting and receiving globally sourced COVID-19 critical diagnostics supplies. A number of key topics are addressed, including:

- Testing overview and constrained volumes allocation and availability
- Procurement and product selection considerations
- Ordering diagnostics products

Testing overview and constrained volumes allocation and availability
Both molecular and antigen-based rapid diagnostic tests are recommended for clinical management and use; however, core differences should be considered when determining the appropriate national testing strategy. A number of key guidance documents exist to support these efforts:

- Diagnostic testing for SARS-CoV-2
- Laboratory testing strategy recommendations for COVID-19: interim guidance
- Guidance on the use of antigen-detection in the diagnosis of SARS-CoV-2 has been developed

Manual molecular tests
Currently, manual molecular tests and sample collection kits have unrestricted volumes available and thus are considered 'unconstrained'. These tests can be requested and procured by any Member States, non-governmental organizations, private institutions, or other subnational, national, regional, or international institution or organization.

Automated molecular tests
Automated molecular tests, particularly Abbott, Cepheid, and Roche tests continue to provide reduced volumes for low- and middle-income countries through the Diagnostics Consortium for COVID-19, such that these volumes remain constrained or scarce. The volume constraints are continually being reviewed by members of the Diagnostics Consortium. Low- and middle-income countries and seven high-income small island developing states (total = 144) are eligible to procure constrained volumes. These volumes are primarily available only to national governments. A humanitarian stockpile is under consideration for

constrained volumes. An allocation model is developed to determine an equitable allocation and distribution of constrained volumes.

Allocation principles

The following principles guide the allocation model for constrained volumes.

Allocation Criteria

- *Vulnerability criteria*: several vulnerability criteria were considered as a proxy of health system capacity. The Universal Health Coverage index was determined to be the best proxy and is a robust metric. The UHC index for each country can be found in Annex A1.1 of the *Primary Health Care on the Road to Universal Health Coverage: 2019 Global Monitoring Report.*
- *Epidemiological consideration*: it will also be important to consider the epidemiological need of countries. The number of cases per population forecasted using the WHO's Essential Supplies Forecasting Tool with data from the Imperial College's SEIR model was used to understand the epidemiological context of each country. Based on the cases per population, countries were put into quartiles. Countries in the top quartile (most cases per population) would receive 25% more volumes, while those in the second quartile would receive 10% more volumes.

Operational Adjustments

- *Maximum volumes*: given significant populations of some countries and relatively small available volumes, countries should receive **no more than 10%** of the total available volume. Device capacity was also taken into consideration for the automated platforms. In a 24-hour day, 470 (Abbott), 168 (Cepheid – 4-module device) and 1,344/3,072 Roche 6800/8800 specimens can be run. The number of devices per country were considered and a 30-day month – countries were not allocated beyond that potential capacity limit.
- *Minimum volumes*: for operational and logistic purposes, it was determined that a minimum of six (6) kits would be allocated for Abbott and Roche. For Cepheid, the minimum test volumes are 1,000 tests – this can be revisited in future periods as larger volumes are available.
- *Test distribution*: given operational and logistical considerations, those countries with Roche cobas 6800 or 8800 devices and eligible will receive Roche tests per the above principles, while Abbott volumes will be distributed amongst those countries with the Abbott m2000 technology, but not to countries that have both Abbott and Roche devices. All countries with known Cepheid device footprint will be allocated with Cepheid tests.
- *Country eligibility*: Abbott and Roche have restricted country eligibility to tests, primarily to the AFRO region.

Due to varying supply availability, maximum global volumes for eligible countries are adjusted based on supply commitments across a rolling 6-month timeframe.

September to February test volumes are provided below:

	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Total
Abbott – AFRO + EMRO	400,000	400,000	400,000	400,000	400,000	400,000	2.4 M
Abbott – Asia	77,000	77,000	77,000	77,000	77,000	77,000	462,000
Abbott – AMRO	30,000	30,000	30,000	30,000	30,000	30,000	180,000
Cepheid	210,000	290,000	235,000	300,000	310,000	655,000	2 M
Roche – AFRO	87,492	87,492	87,492	104,000	164,000	180,000	710,476
Manual tests	Unconstrained						
Abbott Panbio Ag RDT	~10 M	~10 M	~10 M	~10 M	~10 M	~10 M	~60 M
SD Biosensor Ag RDT	~10 M	~10 M	~10 M	~10 M	~10 M	~10 M	~60 M
Sample collection kits	Unconstrained						

Antigen-based rapid diagnostic tests

Antigen-based rapid diagnostic tests have recently entered the market and two (as of October 31st, 2019) have been listed on WHO's Emergency Use Listing. A recent agreement between the Bill and Melinda Gates Foundation and both companies makes at least 20 million tests per month available for low- and middle-income countries. To access these tests, purchasers may place orders directly with the companies or utilize one of the available multilateral procurement channels, described later in this section. The funded demand and requests are being followed closely to determine whether these tests may be constrained in volume availability. If they become constrained, an allocation model using the same principles as above will be implemented to ensure equitable distribution.

Procurement and product selection considerations

In order to better support country consideration and product selection of tests, a number of key characteristics can be considered for procurement. Further, product selection tools have been developed to serve as an overview, information share, and guide for countries conducting such exercises. Please reach out to: COVID19Enquiry-Diagnostics@who.int to request the product selection tools.

These product selection tools and considerations should not be considered prescriptive nor replace traditional open, competitive tendering processes. Further, they should not be considered as WHO or other agency preference, but rather serve as an informative base for product selection for countries interested. Further, countries and other end-users should adapt this tool, the criteria, and scoring mechanism as best suits their context.

Key product selection characteristics for manual molecular tests

Given the large number of suppliers with manual assays on the market, a prioritization methodology is helpful to countries to identify specific suppliers and assays that best meet the needs of countries. The published target product profiles for COVID-19 guided this methodology, which was developed to assess suppliers and assays for use in low- and middle-income markets. The procurement prioritization is performed in two phases.

The first phase of the evaluation uses a Gating Criteria, which all assays under consideration should successfully fulfil. The gating criteria include **regulatory status, clinical performance, process control and inclusion of both primers and enzymes within a kit**. Assays meeting the gating criteria are then further assessed based on a set of Prioritization Criteria. Performance, operational characteristics, and suppliers' capacity to service the market are considered, in particular:

- Product performance
- Cold chain requirements
- Shelf life
- Capacity to bundle consumables
- Workflow and usability
- Throughput
- Sample collection options
- Thermocycler interoperability and equipment requirements
- Price
- Supplier experience
- Supply availability

Each category is ranked by assigning numerical values, 2, 1, or 0, based on whether the assay is evaluated to be 'ideal', 'acceptable', or 'not preferred', respectively. The numerical rankings across all Prioritization Criteria are then tallied to enable a comparison across all assays. This matrix is intended to focus only on manual molecular assays, to provide a guide for countries for product selection, as an example of transparent product selection processes, and to provide information and data for several available products.

Please see Annex 1 for more information.

These matrices are only intended for manual kits and not intended to include automated tests.

Key product selection characteristics for antigen-based rapid diagnostic tests
Given the large number of suppliers developing antigen-based rapid diagnostics tests, a procurement prioritization methodology is helpful to identify specific suppliers and assays that best meet the needs of countries. The published target product profiles for COVID-19 guided this procurement prioritization methodology, which was developed to assess suppliers and assays for use in low- and middle-income markets. The procurement prioritization is performed in two phases.

The first phase of the evaluation uses a Gating Criteria, similar to the manual molecular assay evaluation, which all assays under consideration should successfully fulfil. The gating criteria include **regulatory status and clinical performance thresholds**. Assays meeting the gating criteria are then further assessed based on a set of Prioritization Criteria. Performance, operational characteristics, and suppliers' capacity to service the market are considered, in particular:

- Product performance
- Price
- Sample collection options
- Operational considerations including workflow, time to result, etc.
- Access to quality controls
- Additional equipment requirements
- Supplier experience
- Supply availability

Overall, seventeen prioritization criteria are included and grouped into a total of seven areas of focus. Standardized criteria are applied to each element to indicate whether a supplier has met the ideal, acceptable, or not preferred criteria for each prioritization criterion. An associated score accompanies each of these criteria, including 2, 1, and 0, respectively. Scores are tallied within each of the areas of focus and weighted by importance, with total scores calculated to enable a comparison across all assays. The matrix

is intended to guide decision making as an example of transparent product selection processes, and to provide information and data for several available products.

Please see Annex 2 for more information.

Ordering diagnostics products
There are a variety of options for countries to procure any of the diagnostics products available – procuring directly from manufacturers or through any of or their preferred procurement agent(s). The primary procurement agents of the Diagnostics Consortium for COVID-19 include the Global Fund to Fight AIDS, Tuberculosis and Malaria, Stop TB Partnership's Global Drug Facility (GDF), PAHO, UNDP, UNICEF, and WHO. Procurement agents and institutions, through the Diagnostics Consortium, are coordinating procurement to ensure transparent and equitable allocations and distribution, particularly for constrained volumes.

Furthermore, the COVID-19 Supply Portal is a purpose-built tool to facilitate national authorities and all implementing partners supporting COVID-19 National Action Plans to request critical supplies. Those requests will then be assigned to purchasing agencies of the Consortia that can execute the order and process it, utilizing their existing ordering systems.

The below provides options and information on how to procure diagnostic products through the procurement agents of the Diagnostics Consortium for COVID-19. Note that this is not an exhaustive list.

Africa Medicines Supply Platform
The AMSP is accessible to registered country users. Antigen-based rapid diagnostic tests will be listed on the website. The terms for ordering, supply and delivery are provided on the AMSP website.

The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)
Countries may be able to access funding for tests through the COVID-19 Response Mechanism (C19RM) or grant flexibilities within current grants. Regardless of funding source, countries can place orders for diagnostic tests via the WAMBO platform. Countries should contact their GFATM country representatives to register for the platform and/or initiate the order process.

PAHO
All Ministries of Health and Government Institutions of the Public Health Services Network of PAHO Member States can purchase diagnostic tests for COVID-19. Products must be eligible and approved by PAHO/WHO. Purchase requests can be channelled through the national PAHO office a request to initiate the procurement process. PAHO will provide a formal price estimate to the requesting national entity. The estimate does not imply any commitment to procure. The price estimate will include cost of goods, estimated shipping & insurance cost, and the estimated delivery time. The national entity has to approve the price estimate and request access to the PAHO Strategic Fund credit line or transfer the funds in order for PAHO to make the purchase.

More details in regards to PAHO's Strategic Fund process can be found at: www.paho.org/en/paho-strategic-fund

Stop TB Partnership's Global Drug Facility (GDF)
All countries are eligible to procure from the Stop TB Partnership's Global Drug Facility (GDF). Please see this page for step-by-step instructions on how to place an order with GDF. Information about specific products can be found in GDF's Diagnostics Catalog. For additional questions, please contact GDF at gdf@stoptb.org.

UNDP
If agreements are already in place and/or UNDP is the Global Fund Principal Receipt, countries can access Consortium-eligible tests through contacting their local UNDP partner representative.

UNICEF Supply Division
UNICEF Supply Catalogue lists over 2,000 products and is continually updating the catalogue to include more products as they become available. References for COVID-19 Diagnostics available for procurement through UNICEF are included here and here. Queries on product-specific and technical items may be sent to covid19_dx@unicef.org.

Governments and Development Partners using their own or other mobilized resources (e.g., development bank financing, etc.) can use UNICEF's Procurement Services ordering channel. Governments should contact their local UNICEF Country Office to submit a request, using this form. Other development partners should contact psid@unicef.org and similarly fill in the form detailing their request. UNICEF Country Office Programmes should continue to raise sales orders per usual ordering method via Vision.

WHO Supply Portal
All COVID-19-specific diagnostic products are available in the WHO Supply Catalogue and on the WHO Supply Portal. Users can make requests there and the Diagnostics Pillar will follow up quickly to confirm the test type, volumes, and funding source to move the procurement forward. Queries on product-specific and technical items may be sent to COVID19Enquiry-Diagnostics@who.int. Any funding source can be indicated – the Supply Portal is not restricted to only WHO funding sources.

If the purchaser is not registered to use the WHO Supply Portal, see here for more information:
https://covid19partnersplatform.who.int/

Additional resources
Falsified in vitro diagnostics (IVDs) for SARS-CoV-2
WHO Emergency Use Listing for in vitro diagnostics for COVID-19

Annex 1 – Procurement and product selection considerations for manual molecular tests[1]

Gating Criteria

Gating Criterion	Rationale	Failure to Meet Criterion	Passes Criterion
Regulatory Status and Ability to Export	The product must have WHO EUL or IMDRF[2] approval (non-self-certification). The company must also have the necessary registrations to enable sale and export out of the home country.	No WHO EUL or non-self-certification IMDRF approval or lack of appropriate registrations to export	WHO EUL or IMDRF approval (non-self-certification). The company must also have the necessary authorizations to enable export out of home country
Clinical Performance	Sensitivity ≥95% and specificity ≥99% is necessary to pass per WHO TPP. Source data expected to be of good quality and following QUADAS-II quality standards. Assays still undergoing evaluation will also be considered and re-evaluated once performance is reported.	Evaluation data below minimum sensitivity and/or specificity	Ongoing evaluation or evaluated performance ≥95% sensitivity and ≥99% specificity
Inclusion of Process Control	An endogenous or exogenous process control is necessary to ensure successful RNA or NA manual extraction and to therefore minimize false negatives.	No process control included in assay	Process control included in assay
Inclusion of All Essential PCR Reagents	The inclusion of all necessary PCR reagents essential to perform the assay is a minimum requirement. For example, those which supply only primers without the enzymes would be excluded.	Assay supplied without essential reagents	All essential assay reagents are included in the assay

[1] These product selection tools and considerations should not be considered prescriptive nor replace traditional open, competitive tendering processes. Further, they should not be considered as WHO or other agency preference, but rather serve as an informative base for product selection for countries interested. Further, countries and other end-users should adapt this tool, the criteria, and scoring mechanism as best suits their context.
[2] Australia, Brazil, Canada, China, Japan and the United States. European Union CE-IVD Emergency Use currently self-certification and does not meet minimum requirement. List of IMDRF members available here: http://www.imdrf.org/about/about.asp#man.

Prioritization Criteria

Prioritization Criterion	Rationale	Not Preferred (0)	Acceptable (1)	Ideal (2)
Quantitative Indicators and Points Ranking				
Independent Validation	Independent evaluation of high performance from FIND or other recognized organizations. Evaluation expected to be of good quality and following QUADAS-II quality standards. Assays still undergoing evaluation will also be considered and re-evaluated once performance is reported.	No; 0 points	N/A	Yes; 2 points
Clinical Sensitivity	Proportion of true positives that are correctly identified during assay evaluation using nasopharyngeal specimens as gold standard.	≤98%; 0	>98% to <99%; 1	≥99%; 2
Clinical Specificity	Proportion of true negatives that are correctly identified during assay evaluation using nasopharyngeal specimens as gold standard.	≤99%; 0	>99% to <100%; 1	100%; 2
Cold Chain Requirements	Due to potential transportation delays, logistics strain and storage of assays in non-traditional laboratory settings, additional consideration must be given for the shipping and storage cold chain requirements.	Dry ice is required for shipping and -70°C for storage; 0	Dry ice is required for shipping and -20°C (or higher temperature) for storage; 1	Cold chain not required for shipping and ≥-20°C storage; 2
Shelf Life	Prolonged shelf life for 12 months or longer is preferred for storage of kits.	<12 months; 0	12 months or greater; 1	N/A
Consumables Bundling Capability	In addition to the assay kit, additional consumables are required to run a test. These items may include the sample collection kit, extraction kit, ancillary reagents and disposable plastic ware. The capacity of the assay supplier to bundle these additional components necessary to perform a test with the assay is desired to minimize supply chain burden.	No additional consumables bundled with the assay; 0	Extraction kit bundled with assay; 1	All or most consumables necessary to perform a test bundled with the assay including the extraction kit; 2
Amplicon Contamination Mitigation Reagent	To help mitigate amplicon cross-contamination from previous amplification, UDG/UNG or similar reagent is often included in high quality assays to degrade amplicon carryover and help prevent false positive results.	No contamination mitigation reagent included in assay; 0	N/A	Contamination mitigation reagent is included in assay; 2

Workflow and Usability	Multiple factors may increase the overall complexity of assay workflow. Characteristics of an ideal work flow for use in scoring: 1. Endogenous process control 2. Ability to run single reactions without discarding unused reagent 3. Single-well set-up for entire reaction 4. Single-run for results (no sequential testing) 5. Automated results interpretation	1 or fewer ideal work flow characteristics; 0	2-3 ideal work flow characteristics; 1	4-5 ideal work flow characteristics; 2
Throughput / Test Duration	Expected duration of test from sample to result.	> 5 hours per test or <188 samples in 8 hours; 0	4-5 hours per test or ~188 samples in 8 hours; 1	<3.5 hours per test or >188 samples in 8 hours; 2
Sample Collection	Most assays have been validated with nasopharyngeal and/or oropharyngeal specimens and assumed standard for all test kits. Improvements to sample collection processes include: 1. Self-collected or self-collected under healthcare worker supervision (nasal, mid-turbinate, saliva)[3,4] 2. No cold chain requirement for sample transport[4,5] 3. BALF or sputum (lower respiratory sample)	None of the improvements; 0	1 improvement; 1	2 or more improvements; 2
Waste Disposal Requirements	Minimal waste disposal complexity based on low toxicity of reagents and test components is desirable.	Contains components that require waste disposal with high temperature incinerator (or more than a De Monfort type incinerator); 0	Standard biohazardous waste disposal or incineration of consumables, no high temperature incineration required; 1	Small environmental footprint; recyclable or compostable plastics for test cartridges and other materials after decontamination, no incineration required; 2

[3] Sample types can also be collected by healthcare worker.
[4] If validated by supplier and recommended for use.
[5] Sample stable > 12 hours post sample collection without cold chain requirement.

Thermocycler Interoperability	Utility of an assay across different suppliers' platforms is desirable, while validation for use only on specific equipment will limit usability of the assays. Common thermocyclers in LMICs include: ABI 7500/7500 FAST/7500 FAST Dx, ABI 7300; Qiagen Rotor-GeneQ, Bio-Rad CFX96, Roche LightCycler and QuantStudio5.	Validated on only one thermocycler model; 0	Validated on only one supplier's thermocycler product line (>1 instrument model); 1	Multiple suppliers and thermocycler product lines; 2
Equipment Requirements	Products may require additional laboratory equipment to successfully run assay. These include: 1. Vortex mixer 2. Microcentrifuge 3. Plate centrifuge 4. Plate shaker / rocker 5. Vacuum manifold 6. Magnet for bundled extraction kits 7. Heating block / water bath 8. -20C cold block	>6 equipment requirements; 0	3-5 equipment requirements; 1	0-2 equipment requirements; 2
Price per Test	Pricing offers vary across suppliers and can include only the assay as well as bundling with RNA extraction, collection kit or additional consumables. Current pricing spans <$7 to ~$20 USD for a bundled reagent and RNA extraction kit. Most pricing is volume dependent.	> $15 per test; 0	$10-15 per test; 1	<$10 per test; 2
Qualitative indicators				
Production Capacity & Supply Security	To sufficiently service the market, suppliers must be capable of producing significant bundled kits and willing to commit volumes for countries. Where known, production capacity is documented with minimum commitments. Supply chain constraints, likelihood of uninterrupted supply and potential sourcing risks are taken into account.	Limited supply or severe sourcing risks; 0	Significant manufacturing capacity and limited sourcing risks; 1	N/A
Footprint in LMICs	Current use of the assay and/or platforms in LMICs is advantageous due to familiarity with the products and company's ability to supply to LMICs. Assay validation with extraction methods/platforms and thermocyclers which have a large footprint in LMICs is desired.	No existing footprint of required equipment for extraction and detection and limited international assay sales; 0	Existing sales in LMICs or interest in expanding to LMICs. Limited footprint of required equipment for extraction and detection; 1	Assay currently in use in LMICs and significant footprint of required equipment for extraction and detection in LMICs; 2

Company	With many products coming into the market, it's critical to better determine the supplier's ability to service the market. Indicators to consider include the company's financial health, history of high-quality and reputable products and service, utilization of products in high-income countries, market capitalization, level of diversification, and positive relationships with consortium members. Countries and procurement entities may also consider whether other products from this company may be useful for LMICs, and whether COVID instrumentation can be leveraged in the future so that this investment would have benefits over time. Finally, the supplier's capacity for training customers on the use of assay will also be considered.	Unknown supplier with little to no LMIC experience or experience in high-income markets; 0	Supplier with some international sales and LMIC experience; 1	Large supplier with large market-cap and extensive LMIC experience; 2

Annex 2 – Procurement and product selection considerations for antigen-based rapid diagnostic tests[6]

Gating Criteria[7]

Criteria	Rationale	UNACCEPTABLE (Does not meet minimum requirements)	MINIMUM REQUIREMENT
Regulatory Status	Level of Stringent regulatory authority (SRA) authorization to permit sale and distribution of assay.	Research Use Only (RUO), or no emergency use authorizations by WHO EUL or IMDRF approval or emergency use authorization[8]	The product must have WHO EUL or IMDRF approval or emergency use authorization[8] (non-self-certification). The company must also have the necessary authorizations to enable export out of home country
Performance	Clinical evaluation data are critical for review of product performance with RT-PCR used as a comparator.	Low clinical performance with <80% sensitivity or <97% specificity	Acceptable clinical performance[9] with ≥80% sensitivity and ≥97% specificity from studies meeting minimum/optimal data presentation requirements as indicated in Annex A and B

[6] These product selection tools and considerations should not be considered prescriptive nor replace traditional open, competitive tendering processes. Further, they should not be considered as WHO or other agency preference, but rather serve as an informative base for product selection for countries interested. Further, countries and other end-users should adapt this tool, the criteria, and scoring mechanism as best suits their context.
[7] Note: Products meeting minimal criteria will be scored.
[8] *Australia, Brazil, Canada, China, Japan and the United States. European Union CE-IVD Emergency Use currently self-certification and does not meet minimum requirement.*
[9] *Minimum performance limit is based on WHO Interim Guidance 11 September 2020*

Prioritization Criteria

Prioritization Criterion	Rationale	NOT PREFERRED (0)	ACCEPTABLE (1)	IDEAL (2)
Assay Indicators and Points Ranking				
Performance (30%)[10]				
Source of Data[11] **(5%)**	The source of data should be considered (Independent vs. internal/corporate sponsored).	Manufacturer	Independent validation[12]	Point estimates from a published robust systematic review (e.g. Cochrane)
Quality of Data (5%)	Quality of data should consider study design (e.g. Reference standard used, the delay between sample collection and test execution, number of days since symptom onset, distribution of Ct value), number of subjects enrolled and the setting of enrolment. Prospective clinical studies are generally superior to retrospective studies. (if multiple studies available give preference to higher quality independent study).	Does not meet FDA or WHO EUL data submission requirements	In line with FDA EUA data submission requirements (Annex B)	In line with WHO EUL data submission requirements (Annex B)
Sensitivity (2.5%)	As the concentration of virus in specimens is the greatest predictor of test sensitivity, the clinical sensitivity of the test should be expressed within a defined Ct≤33.	Sensitivity not expressed as Ct≤33	N/A	Sensitivity expressed as Ct≤33
Clinical Sensitivity[13] **(5%)**	Proportion of true positives that are correctly identified during assay evaluation within Ct≤33	≤85%	>85% to <90%	≥90%
	Proportion of true positives that are correctly identified during assay evaluation.	80 - 85%	>85% to <90%	≥90%
Clinical Specificity (10%)	Proportion of true negatives that are correctly identified during assay evaluation.	97 - 98%	>98% to <99%	≥99%

[10] Consistent source of data across all criteria.
[11] Scoring will be applied to the most preferred data source (point estimates > independent validation > manufacturer data).
[12] Independent validation needs to be in line with FDA EUA or WHO EUL data submission requirements.
[13] Scoring will applied for data available but preference will be for data with Ct cutoff at 33.

Analytical sensitivity (2.5%)	Analytical sensitivity is determined through determination of the Limit of Detection (LoD) presented as $TCID_{50}$/ml *(Should only consider data from independent verification for $TCDID_{50}$).* Analytical sensitivity can also be expressed using known protein concentration on viral copies/ml **(when data becomes available)**.	>10^3 $TCID_{50}$/ml	10^2 – 10^3 $TCID_{50}$/ml	<1 x 10^2 $TCID_{50}$/ml
Sample collection (10%)				
Sample Type	Most assays have been validated with nasopharyngeal and/or oropharyngeal specimens and assumed standard for all test kits. Improvements to sample collection processes include: • Anterior nares, mid-turbinate and/or saliva/oral fluid)[14] • Self-collected under HCW supervision and/or self-collected[4]	None of the improvements	N/A	Yes
Sample Collection kit	In order to achieve true-POC implementation, all consumables required to obtain a result (e.g. sample collection kit, reagents, etc) should be included along with the assay. Bundling of these additional components with the antigen assay by the test supplier themselves is a priority.	No sample collection kit included	N/A	Sample collection kit included
Operation/programmatic considerations (13%)				
Workflow / Usability	Multiple factors increase overall complexity of antigen testing workflow. Ideal workflows would require no preparation steps and no additional processing steps between sample collection, placing swab/sample in the buffer and squeezing and/or breaking off swab, applying to the cartridge/strip, and reading result (4 steps ideal, inclusive of sample collection). Additional step may include filling buffer tube, addition of secondary solution, timed waiting step, or pipetting. Steps such as opening of tubes, unsealing pouch, or opening sample collection package should not be considered.	6 or more steps	5 steps	4 steps

[14] If validated by supplier and recommended for use.

Time to result	Duration of test from sample application to the test well to result.	30 min or above	15 - <30 min	<15 min
Shipping and storage conditions	The capacity to withstand temperature stress are critical to the ease-of-use of Ag tests. All companies expected to provide accessible Point-of-Care solutions to LMICs - any cold chain requirements are not preferred characteristics. Acceptable criteria include no cold chain requirements – with shipping and storage capable at room temperature.	Cold chain	No cold chain required (2-30C)	Greater temperature extreme (30C-40C)
Batching capability	Ideally individual tests can be run in parallel (batch testing).	No	N/A	Yes
Waste / Disposal requirements	Minimal waste disposal complexity based on low toxicity of reagents and test components is desirable.	Contains components that require waste disposal with high temperature incinerator (or more than a De Monfort type incinerator)	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
Remote connectivity capacity/ Data management capabilities	Decentralized testing is notoriously difficult to monitor, and connectivity will be critical for tracking the epidemic response. Ideal data management solutions may be integrated data management solutions with built-in functionality for test read, data capture, and connectivity solution. Acceptable solutions may include standalone solutions including app-based tools supplied by the supplier for data capture and connectivity, while not-preferred products lack any supplier-offered data management capabilities.	No supplier-offered data management solution	Data management solution included as pay per use model	Data management solution available at no additional cost

Quality Control (2%)				
Quality control reagents	The controls are used to verify the user's ability to properly perform the test and interpret the results. The Positive Control will produce a positive test result as well as a visible test line (T) for RDTs. The Negative Control will produce a negative test result. Good laboratory practice suggests the use of positive and negative controls to ensure that: • Test reagents are working, and • The test is correctly performed.	None included	Available for separate purchase	Included within each box
Price (30%)				
Price per Test (25%)	Pricing offers vary across suppliers and can include only the assay as well as bundling with swabs. Current pricing spans <$5 to ~$20 USD for a bundled kit including test, swab, and controls. Most pricing is volume dependent. The cost of the full test kit – including assay, controls, and swabs – should be lower than $3 Ex Works.	> $5 per test (EXW price for combined test kit, controls, and swab required to perform one test)	$3-5 per test (EXW price for combined test kit, controls, and swab required to perform one test)	<$3 per test (EXW price for combined test kit, controls, and swab required to perform one test)
Incoterms[15] (5%)	Simplification of logistics is preferred to ensure transparency of pricing and ease of distribution. More comprehensive incoterms are preferred, though may come with trade-offs and ultimately subject to country / procurer circumstances.	Limited supplier responsibility (EXW, FCA)	Moderately inclusive incoterm (CPT, CIP)	Comprehensive incoterms (DAP, DPU, DDP)

[15] Incoterms 2020. International Chamber of Commerce. https://iccwbo.org/resources-for-business/incoterms-rules/incoterms-2020/

Additional equipment needed for testing (5%)				
Device	Some tests will require additional equipment like readers, which is not preferred.	Reader required	N/A	No reader required
Need for replacement/spare parts	POC Devices are typically supplied as a single instrument without ancillary equipment requirements. Due to a large deployed fleet, need for replacement parts and/or entire devices should be built into the supplier's maintenance plans.	Replacement device purchase required if breakdown or overuse	N/A	None, swap out or replace ancillary device when needed under service and maintenance agreement **OR** No device required
Device Production Capacity & Supply Security	In order to sufficiently service the market, suppliers must leverage an extensive device footprint or be capable of producing significant volumes of devices and be willing to place in LMICs. Where known, production capacity will be documented along with known commitments to LMICs. Supply chain constraints, likelihood of uninterrupted supply and potential sourcing risks are taken into account.	Limited available devices or severe sourcing risks	Available device supply, minimal sourcing risks, though with limited manufacturing capacity	Available device supply, significant manufacturing capacity, and limited sourcing risks **OR** No device required
Device Pricing	Pricing offers vary across suppliers and may include placement terms in lieu of direct per-device pricing.	Inaccessible (>US $500)	Affordable pricing (<US $500)	Direct placement by manufacturer **OR** No device required

Qualitative indicators (10%)[16]				
Assay Production Capacity & Supply Security	In order to sufficiently service the market, suppliers must be capable of producing significant volumes and willing to commit volumes to LMICs. Where known, production capacity will be documented with minimum commitments to LMICs. Supply chain constraints, likelihood of uninterrupted supply and potential sourcing risks are taken into account. Assessments will be conducted relative to other suppliers in the space.	Limited available assay supply, severe sourcing risks[17], no LMIC commitments **<5 M / month**	Available assay supply, minimal sourcing risks[17], though with limited manufacturing capacity. May include LMIC commitments of limited volumes **5-10 M / month**	Available assay supply, significant manufacturing capacity, limited sourcing risks[17], and LMIC commitments **>10 M / month**
Company	Many new companies without a history of success in the manufacture, sales and support of in vitro diagnostics are entering the market with SARS-CoV-2 Ag tests. Procurers should consider the range of other products offered by the company (especially lateral flow tests), what regulatory approvals they have for non-emergency diagnostic products, and their manufacturing and post-market surveillance capacity.	Unknown supplier with no other lateral flow assays approved by stringent regulatory authorities or WHO PQ for LMICs	Supplier with LMIC experience limited to one or two regions for sales and support of SRA and/or WHO PQ'ed lateral flow assays	Supplier with extensive LMIC experience and ability to service majority of regions / geographies. Especially for sales and support of SRA and/or WHO PQ'ed lateral flow assays

[16] Comprehensive details on the qualitative indicators should be added in order to provide justification for scoring.
[17] Single or only few raw materials suppliers, supplies obtained from company that lack QMS, manufacturing location in country with risk of nationalizing supply, news of large procurement requests exceeding manufacturing capacity.