

C19RM Health Product Segmentation Framework

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This document describes the Health Product Segmentation Framework, which is relevant for the COVID-19 Response Mechanism (C19RM). It provides guidance which is subject to change over time in response to rapidly evolving supply and demand dynamics of health products needed to control and contain COVID-19. This version is the current version in effect.

Additional information is available in the COVID-19 Response Mechanism Technical Information Note (link forthcoming), the <u>COVID-19 Response Mechanism Guidelines</u> and the <u>COVID-19 Response Mechanism Funding Request Instructions</u>.

The C19RM Health Product Segmentation Framework classifies health products eligible for funding through C19RM based on two considerations:

- Product use, whether "optimal" or "limited use/specialized"; and
- Recommended procurement channel.

Product use

The product use classification reflected within this framework is aligned with the C19RM Fast-track and Full Funding Request options designated within the funding request application guidance and templates. Specifically, the **products designated here as "Optimal" are eligible under both the Fast-track and Full Funding Request options**, along with the costs associated with their effective deployment. Procurement of "Limited use/specialized" products is expected to remain restrictive and to require sufficient justification. Products designated as "limited use/specialized" are not eligible for approval through a C19RM Fast-track Funding Request, although they can be submitted for consideration through a C19RM Full Funding Request.

Recommended procurement channel

Health and non-health products needed for the COVID-19 response include a diverse set of products with different market characteristics, which require deliberate approaches to secure better market outcomes (such as lower prices or improved lead times). A three-category framework for health products has been developed to articulate this:

- Strategic: products that are scarce on the global market. For such products, pooling of demand or co-ordination of order placement is needed to be able to secure volume that, if not done in a coordinated and timely way, may be lost to high income country markets. This may include very close and timely coordination for an ACT-A partner volume agreement that had to be made to secure volumes for low- and middle-income countries:
- **Mainstream**: products with specific quality assurance requirements, which may require enhanced visibility to have assurances on volumes secured and delivered; and
- Local sourcing advised: products which are generally low value bulky and/or hazardous products, such as alcohol and bleach, or those for which contracting of a local contractor is preferred, for example, for supply of some oxygen interventions.

For strategic products, as described in Section 2 of the Guide to Global Fund Policies on the Procurement and Supply Management of Health Products,¹ countries may be required to use the Global Fund's Pooled Procurement Mechanism (PPM)/wambo.org for as long as the supply dynamics and constraints remain as described above.

For mainstream products, countries are highly encouraged to use the Global Fund's PPM/wambo.org. This will allow for countries to benefit from negotiated terms and pricing while simplifying orders, especially for those products currently scarce on the global market.

The tables below, by product category and COVID-19 intervention, provide the classification of eligible health products for C19RM by product use and procurement channel categories. There are seven tables:

- Table 1: Diagnosis and Testing
- Table 2: Surveillance (Genomic Sequencing) and Epidemiologic Investigation
- Table 3: Infection Prevention and Control
- Table 4: Case Management, Clinical Operations and Therapeutics: Medical oxygen
- Table 5: Case Management, Clinical Operations and Therapeutics: Pharmaceuticals
- Table 6: Laboratory Systems
- Table 7: Health Product and Waste Management Systems

¹ https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf

Table 1: Diagnosis and Testing

Health Product	Product use	Procurement
COVID-19 Diagnostic Reagents and Consumables	category	channel category
RAPID DIAGNOSTIC TESTS		
SARS-CoV-2 Rapid Antigen Diagnostic Test Kit	Optimal	Strategic
AUTOMATED PCR TESTS	Optimal	Otratogio
Abbott RealTime SARS-CoV-2 RT-PCR Kit	Optimal	Mainstream*
Cepheid Xpert® Xpress SARS-CoV-2	Optimal	Strategic
Hologic Aptima SARS-CoV-2 assay	Optimal	Mainstream*
Roche Cobas SARS-CoV-2 RT-PCR Kit	Optimal	Mainstream*
MANUAL PCR TESTS	Op.	
BGI Real-time fluorescent RT-PCR kit for detecting	0	NA ' 4 #
2019- nCoV	Optimal	Mainstream*
Qiagen QIAamp Viral RNA extraction kit	Optimal	Mainstream*
Thermo Fisher MagMAX Viral/Pathogen Nucleic Acid	·	B.A. Caratana and
Isolation Kit	Optimal	Mainstream*
Thermo Fisher TaqPath COVID-19 CE-IVD RT-PCR Kit	Optimal	Mainstream*
SAMPLE COLLECTION		
Sample collection kit: swab and viral transport medium	Optimal	Mainstream
Sample collection: triple packaging boxes for transport	Optimal	Mainstream
Cepheid Xpert Nasopharyngeal swab collection kit 100	Optimal	Mainstream
OTHER CONSUMABLES		
Extraction consumables	Optimal	Mainstroam
(e.g. deep-well plate, microplate)	Optimal	Mainstream
Filtered Pipette Tips Sterile	Optimal	Mainstream
Other consumables	Optimal	Mainstream
COVID-19 Molecular Test Equipment		
AUTOMATED EXTRACTORS	, , , , , , , , , , , , , , , , , , , ,	
BioMerieux EMAG (easyMAG) Equipment	Limited use/ Specialized	Mainstream*
GeneXpert equipment (I, II, IV-2, IV-4, XVI-16, tablet/	Limited use/ Specialized	Mainstream*
desktop computer, barcode reader and aux. batteries)	·	
KingFisher™ Flex Purification System	Limited use/ Specialized	Mainstream*
Qiagen QIAsymphony SP Equipment	Limited use/ Specialized	Mainstream*
Roche MagNA pure Equipment	Limited use/ Specialized	Mainstream*
THERMOCYCLERS, INCLUDING RT-PCR ANALYZERS) 	
Applied Biosystems [™] 7500 Real-Time, Fast Real-Time	Limited use/ Specialized	Mainstream*
and Fast Dx Real-Time PCR Instrument Systems	·	Main atus and *
BioRad CFX96 PCR system	Limited use/ Specialized	Mainstream*
Qiagen Rotor-Gene 5 Plex PCR system	Limited use/ Specialized	Mainstream*
QuantStudio [™] 5 Real-Time PCR System 96-well and 384-well	Limited use/ Specialized	Mainstream*
Roche LightCycler 480 PCR system	Limited use/ Specialized	Mainstream*
SLAN-96P PCR system	Limited use/ Specialized Limited use/ Specialized	Mainstream*
OTHER	Limited use/ Specialized	iviaiiistitaiii
Magnetic stand: Manual extraction	Limited use/ Specialized	Mainstream*
Tabletop PCR workstation with UV light	Limited use/ Specialized	Mainstream*
UV cross linker	Limited use/ Specialized	Mainstream*
UV transilluminator	Limited use/ Specialized	Mainstream*
Other NEAR Point of Care equipment	Limited use/ Specialized	Mainstream*
* Where contractual arrangements are already in place for PCP to	•	

^{*} Where contractual arrangements are already in place for PCR testing and supply of COVID-19 reagents, continued Local Sourcing is advised (as opposed to Mainstream).

Table 2: Surveillance (Genomic Sequencing) and Epidemiological Investigation

Health Product	Product use category	Procurement channel category
SARS-CoV-2 Rapid Antibody Test kit	Limited Use/ Specialized	Mainstream
Container, sharps	Limited Use/ Specialized	Mainstream
Needles and syringes	Limited Use/ Specialized	Mainstream
Reagents for sequencing	Limited Use/ Specialized	Mainstream
Sample collection	Limited Use/ Specialized	Mainstream
Sequencing analyzers	Limited Use/ Specialized	Mainstream
Triple packaging boxes for transport	Limited Use/ Specialized	Mainstream

Table 3: Infection Prevention and Control

Health Product	Product use	Procurement channel category
Core Personal Protective Equipment (PPE)*	category	Chamilei Calegory
Apron	Optimal	Mainstream
Face shield	Optimal	Mainstream
Gloves, examination/surgical	Optimal	Mainstream
Goggles	Optimal	Mainstream
Gowns	Optimal	Mainstream
Masks, Medical/Surgical	Optimal	Mainstream
Respirator, FPP2/N95 and airflow test set	Optimal	Mainstream
Non-Core PPE*		
Boot cover	Limited use/ Specialized	Mainstream
Boots	Limited use/ Specialized	Mainstream
Coverall	Limited use/ Specialized	Mainstream
Heavy-duty apron	Limited use/ Specialized	Mainstream
Heavy-duty gloves	Limited use/ Specialized	Mainstream
Scrubs	Optimal	Local sourcing advised
Surgical cap	Limited use/ Specialized	Mainstream
Disinfectants		
Alcohol-based hand rub	Optimal	Local sourcing advised
Chlorine	Optimal	Local sourcing advised
Chlorohexidine	Optimal	Local sourcing advised
Hand wash (liquid)	Optimal	Local sourcing advised
Soap	Optimal	Local sourcing advised

^{*} The "core" and "non-core" designation for PPE relates to the definition in the Guide to Global Fund Policies on Procurement and Supply Management of Health Products, where Quality Assurance Requirements are specified, applicable from 1 July 2021. The Guide is available from this site: https://www.theglobalfund.org/en/sourcing-management/.

Table 4: Case Management, Clinical Operations and Therapeutics: Medical Oxygen

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Health Product	Product use	Procurement
	category	channel category
Medical oxygen – consumables		
Airway: Oropharyngeal airway, Guedel	Optimal	Mainstream
Airway: Nasopharyngeal airway	Optimal	Mainstream
Colorimetric end tidal CO2 detector	Optimal	Mainstream
Cricothyrotomy set	Optimal	Mainstream
Endotracheal tube	Optimal	Mainstream
Flow splitter (for oxygen concentrator)	Optimal	Mainstream
Flowmeter (medical oxygen)	Optimal	Mainstream
Humidifier (non-heated, reusable)	Optimal	Mainstream
Infusion giving set	Optimal	Mainstream
Laryngoscope (adult/child, neonate)	Optimal	Mainstream
Nasal Cannula (high flow)	Optimal	Mainstream
Nasal Catheter (high flow)	Optimal	Mainstream
Nasal prongs (adult, child, neonate, single use)	Optimal	Mainstream
Oxygen mask	Optimal	Mainstream
Pulse oximeter probes (tabletop, handheld)	Optimal	Mainstream
Resuscitator (adult, child)	Optimal	Mainstream
Suction devices (electrical)	Optimal	Mainstream
Tubing (suction, oxygen administration)	Optimal	Mainstream
Medical Oxygen – equipment		
Mechanical ventilation	0.00	NA - Constant
(for transport, for critical/intensive care)	Optimal	Mainstream
Non-invasive ventilation (HFNC, BiPAP and CPAP	Ontined	Mainatuaan
with tubing and patient interfaces)	Optimal	Mainstream
Oxygen analyzer	Optimal	Mainstream
(electrochemical, battery-powered, handheld)	Optimal	Mairistream
Oxygen analyzer (ultrasonic, battery-powered)	Optimal	Mainstream
Oxygen concentrator	Optimal	Mainstream
(stationary/bedside or portable, with accessories)	Optimai	Mairistream
Pulse oximeter	Optimal	Mainstream
COVID-19 equipment spare parts / warranty,	Optimal	Local sourcing advised
maintenance and service	·	-
Surge suppressor	Optimal	Local sourcing advised
Voltage stabilizer	Optimal	Local sourcing advised
Medical Oxygen – liquid oxygen		
Medical gas cylinder, portable (compressed		
oxygen or compressed medical air, with valves and	Optimal	Local sourcing advised
regulators)		
Pressure swing adsorption oxygen generator		
plants (incl. spare parts/accessories,	Optimal	Local sourcing advised
warranty/maintenance/service)		
Other Health Equipment		
Blood gas analyzer	Limited use/Specialized	Mainstream
Electrocardiogram (ECG) digital monitor and	·	Mainstream
recorder	Limited use/Specialized	iviaii istieaiii
Electronic drop counter, IV fluids	Limited use/Specialized	Mainstream
Infusion pump	Optimal	Mainstream
Patient monitor (with and without EKG/ECG)	Optimal	Mainstream
Thermometer, non-contact	Limited use/Specialized	Mainstream
	Elittica asc/opedialized	IVI all istical i
Ultrasound	Limited use/Specialized	Mainstream

Table 5: Case Management, Clinical Operations and Therapeutics: Pharmaceuticals

Health Product	Product use category	Procurement channel category
Dexamethasone and other steroids	Optimal	Local sourcing advised
Low dose heparin sodium solution and low molecular weight heparins for injection	Optimal	Local sourcing advised
Compound sodium lactate solution	Optimal	Local sourcing advised
Paracetamol	Optimal	Local sourcing advised

Table 6: Laboratory Systems

Health Product	Product use category	Procurement channel category
Laboratory equipment		
Autoclave for laboratory	Limited Use/ Specialized	Mainstream
Biological Safety Cabinet BSL II	Limited Use/ Specialized	Mainstream
Centrifuges	Limited Use/ Specialized	Mainstream
Glove box	Limited Use/ Specialized	Mainstream
Incubator	Limited Use/ Specialized	Mainstream
Laboratory freezer	Limited Use/ Specialized	Mainstream
Laboratory refrigerator	Limited Use/ Specialized	Mainstream
Microcentrifuge	Limited Use/ Specialized	Mainstream
Thermoblock	Limited Use/ Specialized	Mainstream
Refrigerated bench top centrifuge	Limited Use/ Specialized	Mainstream
Vortex	Limited Use/ Specialized	Mainstream

Table 7: Health Product and Waste Management Systems

Health Product	Product use	Procurement channel
	category	category
Cold Chain Consumables		
Cold box	Limited Use/ Specialized	Mainstream
Data logger	Limited Use/ Specialized	Mainstream
Ice pack	Limited Use/ Specialized	Mainstream
Remote temperature monitoring system	Limited Use/ Specialized	Mainstream
Vaccine carrier	Limited Use/ Specialized	Mainstream
Cold Chain Equipment		
Vaccine freezer	Limited Use/ Specialized	Mainstream
Vaccine refrigerator	Limited Use/ Specialized	Mainstream
Vaccine combined refrigerator and freezer	Limited Use/ Specialized	Mainstream
Waste Management		
Autoclave	Limited Use/ Specialized	Mainstream
Biohazard bags	Limited Use/ Specialized	Mainstream
Container, sharps	Limited Use/ Specialized	Mainstream
Incinerator, medical/general waste	Limited Use/ Specialized	Mainstream
Reagents	Limited Use/ Specialized	Mainstream