

MOBIMED
We Stock Your Medical Supplies

COVID 19

Managed Supply Services

INTRODUCTION

A key focus as the COVID-19 Pandemic [SARS-Co-V-2; coronavirus disease] continues its surge throughout the world touching every community province, state and country in its path. This pandemic like many before it has placed the heavy burden of assuring the public through businesses, hospitals and governments that they have command over resources for citizens' safety, medical care and supplies, and that they have the ability to maintain critical health care delivery of vital services (e.g., respiratory, surgical, critical care, dialysis etc.).

Health care facilities, providers, businesses and governments do not have the option to avoid or wait and make crisis care decisions when the situation arises. Yet here we are again, with only minimal crisis plans in place. The world is scrambling to get equipment, hoarding supplies, lack of personnel and insufficient budgets to meet demands.

Many facilities, businesses and emergency medical agencies have been waiting on state and government level actions or plans rather than planning at the ground level or health care facility level.

Many hospitals have failed to maximize their conventional (usual customary care) and contingency planning. Nor have they ensured the integration of crisis care into existing surge capacity plans rather they have described such plans as a separate entity, therefore making success elusive. Businesses have found themselves without any Pandemic plan in place for loss of business, remote work or protection of staff to provide continuity of service.

"Extreme surge" (ES), as we are currently facing will subside during the summer and can be expected to return at a far greater level (due to reoccurrence, no vaccine, no medication) between late September and early October according to the World Health Organization. The ES involves significant adaptations of staff, space, supplies and the respective usages must be anticipated and planned.



COVID 19

Managed Supply Services

TO WHOM IT MAY CONCERN:

Dear Sir or Madam,

SanPete Financial Groups' MOBIMED Medical Supply Division can assist you with getting your Pandemic Plan in place and with setting up recurring drop shipment of supplies at your designated levels and intervals.

Managing your supply shipment will save you time, budgetary concerns and give you total control of your inventory.

We can help to ensure that you are able to provide consistency of safe environments, health care and good community service to all citizens and to primarily provide you peace of mind during any ensuing pandemic or disastrous event.

We look forward to working with you and your teams to provide the COVID 19 medical supplies and equipment you require.

Warm Regards,

Yvonne E. Gamble

Chief Executive Officer

cc.

Gwendolyn Hinton

VP Finance & Client Services

COVID 19

PRODUCT COMPLIANCE

All products are shipped direct from the United States, China and the United Kingdom, and are FDA approved and C.E. certified.

MEDICAL SUPPLY GENERAL PROCEDURES

1. Send Letter of Intent, item number, quantity and compliance spec for each item.
2. Show Proof of Funds. Discuss Terms, Conditions and Freight Costs.
3. We will prepare Purchase Order specifications based on products. We will provide FDA and C.E. Certifications.
4. Sign required documents, remit required payment (50% minimum down).
5. Your shipment will be tracked with notification of delivery.

CORONAVIRUS

MED SUPPLIES

WE WANT YOU

SAFE &

HEALTHY



**HAND
SANITIZERS**



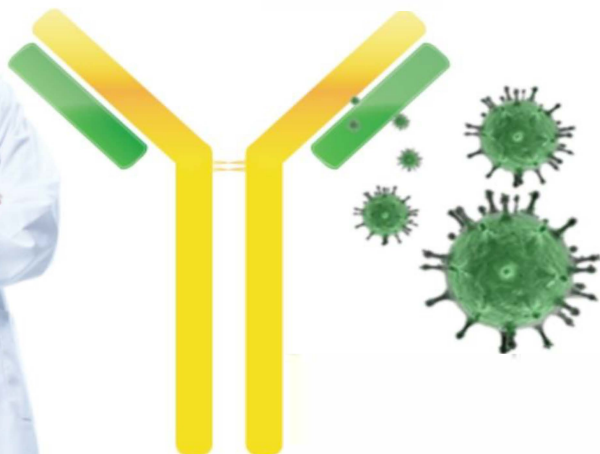
**FLUID RESISTANT
SURGICAL MASK
W/SHIELD**



**KN95
MASKS**



GLOVES



EMAIL ORDER

Rosette Aliu - newedrac@yahoo.com
Ency Litsoane - ency@ubambano.org.za
Samantha Chui - support@chuimarketing.com
Yvonne Gamble - service@mobimed.us

All Products






FDA or C.E. Certified

+1.832.819.5260

See Our Supply List



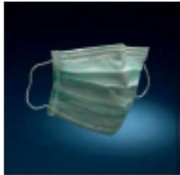




CORONAVIRUS MEDICAL SUPPLIER CATALOGUE

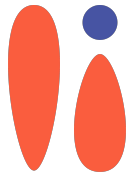
SANQUI Medical & Health Minimum Order 5,000	N95	Particulate Respirator FDA & CE 99.6% Certified	\$3.60 ea;	
3M 1860 Minimum Order 5,000	3M 1860	Surgical Mask NIOSH Approved: N95. Meets CDC guidelines FDA >99% BFE (Fluid resistant)	\$2.70 ea.	
PRUNUS Minimum Order 5 Based on model See Specifications	Boaray 5000D	Boaray 5000D Ventilator 20-2000ml (VCV); Applicable to adult, pediatric and infant	\$25,000 — \$75,000 Based on Model	
Minimum Order 50	RBE-57	Canister RBE-57, Hood 6 EA/Case	\$56.58 ea; 6 per case	
Leading Chinese Manufacturer Minimum Order 5,000	Nitrile Gloves	Disposable Nitrile Gloves, 6 Mil / 100 Pack	\$12.00 per 100 Pack	

STRICTLY CONFIDENTIAL

Leading US and Chinese Manufacturers







Manufacturer	Model Number	Description	Pricing	Product Image
Leading US Manufacturer Minimum Order 500	IDC/GAF 4630000	PPE Goggles	\$1.30 - \$15.00	
Leading Chinese Manufacturer Minimum Order 5,000	Nitrile Gloves	Disposable Nitrile Gloves	\$12.00 box; 100 gloves per box	
Minimum Order 5,000	K1840	3M High Fluid Resistant Procedure Mask, Ear Loop level 3	\$0.25 ea; 50 per box	
Minimum Order 1,000	Hand Sanitizer	Instant Hand Antiseptic 75% Ethyl Alcohol 500 ml	\$6.90 ea	
Minimum Order 10 •10 +US \$65.21 •20+US \$63.27 •50+ US \$61.27 •100+ US \$9.27 •150+ US \$53.27	Handheld Non-Contact	Non-Contact Digital Thermometer-Forehead Laser Infrared	\$25.00 ea 10,000 minimum	

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Item	Min.Order	Cost/Unit	Product Image
KN 95 (CE Mark - WKH KANGBANG FFP2 Certified Particulate filter to 99.6%	5,000	\$3.25	
Surgical 3 Ply Mask YY0469-2011 Standard Similar to EN16683 Type 1, with Fluid Resistance like Type 3	5,000	\$0.75	
Quick Test Kit Leading US & Chinese Manufacturer See Specifications	1,000	\$30.00 - \$40.00 each based on total quantity	
Sterile Gloves (pair)	1,000	\$16.00/ box of 100	
Hand Sanitizer # PB128 - 8oz	1,000	\$3.60	
Hand Sanitizer - 32oz (1L)	1,000	\$14.40	

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Hand Sanitizer - 20L Refill	500	\$72.00	
"Thermometer - Digital Forehead"	50	\$38.00	
Full body "Tyvek" Level 2 See Specifications	5,000 25 per box	\$20.00	
Level 3/4 surgical gown	20,000	\$30.00	
Isolation Gowns Level 4 See Specifications	20,000	Sterile \$32.00 Non-Sterile \$20.00	

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Boaray 5000D Ventilator



- 20-2000ml (VCV); Applicable to adult, pediatric and infant
- Various ventilation modes for different needs of all patients
- 15 inch TFT touch screen & big font view for easy observation
- Touch screen & Navigation knob for simple operation
- Simultaneous display of 4 waveforms and 2 loops
- Optional CO₂ monitoring helps verify correct intubation and stability of metabolism
- Optional SpO₂ monitoring avoids deficiency of oxygen
- Synchronized nebulizer (optional)
- Low noise and water-free medical air compressor (optional)
- Expiratory valve could be taken off for autoclavable disinfection to avoid cross-infection
- Active exhalation valve with anti condensation design
- World leading brands of key components of ventilator ensure high accuracy and stable performance
- Advanced proportional solenoid technology realize accurate ventilation control
- Multi-safety mechanism and three-priority alarm of visual and audio for different risks

Specification	Boaray5000D
Patient type:	Adult, Pediatric and infant ($\geq 5\text{kg}$)
Ventilation modes:	VCV, PCV, SIMV(V)+PS, SIMV(P)+PS, SPONT/CPAP, Sigh PRVC, DualPAP, NPPV, Manual, Standby,
Tidal Volume:	20-2000 mL
Ventilation frequency:	1-100 bpm
Inspiration time:	0.1-10S (increment:0.1S)
FiO ₂ :	21%-100%
Flow trigger:	0.5-20L/Min
Pressure trigger:	-20-0cmH ₂ O
Pressure control:	5-70 cm H ₂ O
Pressure support:	0-70 cm H ₂ O
Electronic PEEP:	0-50 cm H ₂ O (increment: 1 cm H ₂ O)
Nebulizer:	30 minutes
Direct access function:	100% O ₂ 2 min, Inspiration hold, Expiration hold, Manual, Freeze, Lock
Monitoring:	Volume:V _{TI} , V _{TE} , MV, MVspont. Pressure:Ppeak, Pmean, Pplat, Pmin, PEEP,Freq Fspont, I:E, FiO ₂ , Compliance, Resistance, RSB, P0.1, NIF, Auto PEEP, Rcexp,Cdyn Co ₂ module (optional): EtCO ₂ SpO ₂ module (optional): SpO ₂ , PR
Waveform:	P-T, F-T, V-T, Optional: SpO ₂ -T, EtCO ₂ -T
Loop:	P-V, F-V, F-P, Optional: Volume-EtCO ₂
Trend:	Peak, FiO ₂ , PEEP, MV, V _{TE} , V _{TI}
System Log:	500 events (setting and alarm)
Alarm:	Audio and visual alarms with three levels Volumes: V _{TE} high/low, MV high/low; Pressure: Paw high/low O ₂ supply pressure high/low, Air supply pressure high/low Apnea, Continuous high airway pressure Freq high/low, FiO ₂ high/low SpO ₂ low (optional), EtCO ₂ high/low (optional) Power: AC power failure, Low battery power, Exhausted battery failure
Physical Specification	
Dimensions (H×W×D):	Host:645*735*610(mm) Trolley:225*805*555(mm)
Communication Interface:	RS232
Screen:	15 inch TFT touch screen
Net weight:	Host:45kg,Trolley:22.5kg
Power:	100-240VAC, 50/60Hz, 1A(Max)
Lithium Battery:	Minimum 120 minutes

Full Body Tyvek Specifications Level 2

Technical Data Sheet

Brand Name: Derma Care
Product Name: Coveralls
Code: MT-428

Description: Disposable Coverall
With Hood And Elastic Cuff

Color: White

Approvals SGS

Standards

EN ISO 14325:2004 Protective clothing- general requirements.

EN 1149-1:2006



EN 13034:2005 Protective clothing against liquid chemicals- Performance requirements for chemical protection clothing offering limited protective performance against liquid chemicals



EN ISO 13982- 1:2004+ Protective clothing for use against solid particulates-Part1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates



**Description:**

For clinical medical personnel in the work of contact with patients with potential infectious blood, fluids, secretions for provide barrier and protection.

Waterproof against blood, bacteria and viruses, antistatic, moisture permeable, whole body protection.

Application occasions:

- ICU (after EO sterilization);
- Diagnosis and treatment of suspected or confirmed infected patients;
- Transfer or accompany the diagnosis of patients with suspected or confirmed infections;
- Sample collection of suspected or confirmed infections;
- Laboratory infection sample detection;
- Environment cleaning disinfection;
- Corpse disposal;
- Fever /respiratory/ emergency/ pediatrics clinics;

Specifications:

Materials: 63gsm breathable film lamination material

Color: White

Size: S/M/L/XL/XXL

Packaging: 50pcs/box

Case Dimension: 60*45*50cm




One Box Gross Weight : 13.5 KG

Current Daily Supply: 50K PCS/DAY



Level 4 Protective Coverall - Instructions

USE: Garments object of this instruction for use are according to european standards and they are in compliance with the following usage; they are not suitable for all non mentioned usage. (in particular concerning all kind of risks relative to third category according to European Directive (EU) 2016/425)

EN 13034:2005+AI:2009 - Protection against liquid chemical, light spray (type 6)	
EN ISO 13982-1:2004+AI:2010 - Protection against airborne solid particulates (type 5)	
EN 14126:2003+AC:2004 - Infective agents (Type 5B, 6B)	
EN 1149-5:2018 - Electrostatic charges	
EN ISO 13688:2013 - Protective clothing - general requirements	

LIMITATIONS: Exposition to certain chemicals or high concentrations may require higher barrier properties, either in terms of the performances of material or in the construction of the suit. The user shall be the sole judge of the suitability for the type of protection required and the corrected combinations of coveralls and additional equipment.

WAYS OF DRESSING:

- Make sure that the size corresponds with the user. Do not make any modifications on product.
- Check that the product has no defect and is in good condition (no holes, unsewed parts, etc.)
- Open the zip, dress up taking care not to break the material. Close the zip and sealed the flap. In case of airborne solid particulates it is advisable to cover the zipper and to surround the extremity of the sleeves and the leggings with adhesive ribbon.
- The protection characteristics are valid only if the item is correctly dressed and closed
- Protect uncovered parts of body (hands, respiratory areas, foot) with protective gloves, boots, eventual mask etc. attached to the coverall (if necessary adding adhesive stripe) and offered the same level of protection in order to provide for full body protection

LIFETIME: It is suggested to use the product within a period of five years from the date of production written on label.

WARNINGS:

- Choose products compatible with area of work.
- The disposable item should be replaced after every use.
- If any breaking, punctures etc. occur, leave the working area and wear new coverall.
- The prolonged wearing of chemicals protective suits may cause heat stress. Heat stress and discomfort can be reduced or eliminated by using appropriate undergarments or suitable ventilation equipment.
- The person wearing the electrostatic dissipative protective clothing shall be properly earthed. The resistance between the person and the earth shall be less than 1080 e.g. by wearing adequate footwear;
- Electrostatic dissipative protective clothing shall not be open or removed whilst in presence of flammable or explosive atmospheres or while handling flammable or explosive substances;
- Electrostatic dissipative protective clothing shall not be used in oxygen enriched atmospheres without prior approval of the responsible safety engineer;
- The electrostatic dissipative performance of the electrostatic dissipative protective clothing can be affected by wear and tear, laundering and possible contamination;
- Electrostatic dissipative protective clothing shall permanently cover all non-complying materials during normal use (including bending and movements).
- This coverall meets the requirement Ljmn, 82/90 s 30% Ls 8/10 s 15%.
- The test method is based on a testing principle similar to the inward leakage test principle for respiratory equipment, for type 1 and type 2 chemical protective clothing and for protective clothing against radioactive contamination. The method provides a measure of the inward leakage into protective clothing by dry aerosol particles (generated from a sodium chloride solution) having a mass-median aerodynamic diameter of 0,6 Qm
- These garments are flammable - Keep away from fire.
- Abandon the place of work immediately in case of damage of the product.
- The user shall not take off the garment when he is still in the risk area.

Level 4 Protective Coverall - Instructions

Evaluation and testing of complete suit	Result	
Resistance to liquid penetration Spray test Type 6 (EN ISO 17491-4 met. A- EN 13034)	Pass	
Resistance to aerosol penetration Inward leakage type 5 (EN ISO 13982-2 - EN ISO 13982)	Pass	
Seams: strength (EN ISO 13935-2)	Class 3	
Evaluation and testing of fabric	Result	
Resistance to penetration to liquid (EN ISO 6530 - EN 13034)	H ₂ SO ₄ 30%	Class 3
	NaOH 10%	Class 3
	o-xilene	Class 3
	Butan-1-ol	Class 3
Repellency to liquid (EN ISO 6530 - EN 13034)	H ₂ SO ₄ 30%	Class 2
	NaOH 10%	Class 3
	o-xilene	Class 2
	Butan-1-ol	Class 2
Abrasion Resistance (EN 530-method 2)	Class 4	
Trapezoidal tear resistance (EN ISO 9073-4)	Class 2	
Tensile strength (EN ISO 13934-1)	Class 1	
Puncture resistance (EN 863- EN 13034)	Class 2	
Flex cracking resistance (EN 7854)	Class 6	
Charge decay (test condition EN 1149-3)	Pass	
Bursting strength (13938-1)	Class 3	
Resistance to penetration by blood-borne pathogens - phi-x174 bacteriophage test - ISO 16603/16604	Class 6	
Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids - ISO 22610 (test micro-organism: staphylococcus aureus)	Class 3	
Resistance to penetration by contaminated liquid aerosols - ISO DIS 22611 (test microorganism: staphylococcus aureus)	Class 2	
Resistance to penetration by contaminated solid particles - EN ISO 22612 (test microorganism: spores of bacillus subtilis)	Class 3	
PH (EN 340-ISO 3071)	Pass	

Product Specification Sheet

Product Name: Antibacterial Hand Sanitizer Gel-70% Ethyl Alcohol

Product Code: 80114-BULK TOTE

Product Description: Topical, antimicrobial gel applied to hands.

Active Ingredients
Ethyl Alcohol 70%
Inactive Ingredients: Glycerin, Propylene Glycol, Carbomer, 2-amino methyl-1 propanol solution, water USP

Microbiological Testing Limits		
Test	Limit	Testing Method
Total Plate Count	$<10^7$ cfu/g	USP <2021>
Yeast and Mold	$<10^5$ cfu/g	USP <2021>

Other Test Limits	
Test	Limit
pH	6.5-9.0

Organoleptic Properties	
Color	Clear
Condition	Liquid Gel
Aroma	Alcohol-like

Packaging:	BULK TOTE
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Shelf-Life and Storage Requirements:	The product shelf-life is three (3) years. Keep only in the original container in a cool, well ventilated place away from direct sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F. Keep in fireproof place.
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 Quality Assurance Signature of Approval	Date: 04/06/2020 Version: 01
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Coronavirus (COVID-19) Instant Test Kits for Medical Professional Use



- Rapid results in 10 minutes
- Small sample sizes
- Sold in packs of 100
- Following the incubation period, IgM may appear in blood within 3-5 days. IgG will appear as soon as 1-2 weeks.
- Shelf life of 24 months from manufacture date
- Forensic / Medical Professional Use Only
- Tests should be conducted by a licensed phlebotomist, or a medical professional
- Verification of use case prior to shipping is mandatory

Warning: This Coronavirus instant test kit has not been reviewed by the FDA and results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.



RAPID ANTIBODY TEST

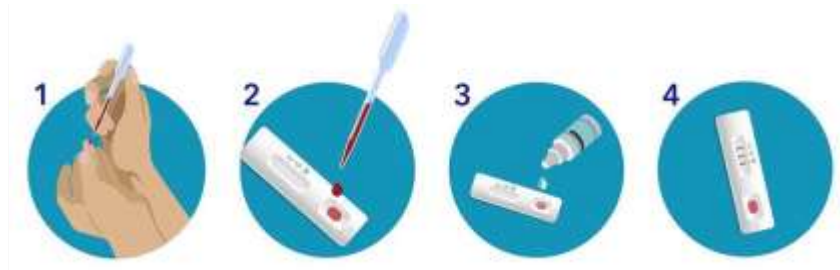
Understanding the Emergency Use Authorization PEUA-200094, and our Antibody test FDA Registered Establishment Number 2031229. Made in AMERICA COVID-19 Rapid Test.

Dr. Stephen Hahn, Director FDA KNOW YOUR TESTS:

- What test is it
- What is the process
- Where is it manufactured
- What are the reagents
- Where are reagents manufactured
- What is the cross reactivity
- What is the sensitivity rating
- What are the requirements
- What is the total cost
- What is the test application time investment
- Does the test have a CPT code process
- Is the test eligible for insurance reimbursement

We offer the COVID-19 finger prick antibody 5-10 minute test now. We also offer the Molecular test through mail in or CLIA certified POC machine. This cartridge has been deployed in use for the intended goal of a quick, easy, efficient, and AFFORDABLE test to the mass public, for the 80% that will NOT require further treatment or testing.

Simple, fast, efficient, accurate:



The COVID19 IgG/IgM Rapid Test

The COVID19 IgG/IgM Rapid Test is a 10-minute instant point-of-care test device for the qualitative detection of IgG and IgM antibodies specific to 2019-nCoV in human whole blood, serum or plasma specimens.

IMPORTANT

- This test is pending review by the FDA.
- This test is not for the screening of donated blood.
- This test is for research use only or for emergency use during the COVID19 pandemic.

INTENDED USE

The COVID19 IgG/IgM Rapid Test Cassette is intended to be used in conjunction with other test and/or clinical and epidemiological information:

- For the in vitro qualitative detection of IgM and IgG antibodies specific to 2019n-CoV (detected in China in 2019) in whole blood / serum / plasma collected directly from symptomatic patients. The test **may** cross react with other viruses not being tested.
- For the presumptive identification of viral infections in patients who may be infected with 2019nCoV (detected in China in 2019) in conjunction with clinical and epidemiological risk factors. The test **may** cross react with other viruses not being tested.
- To provide **epidemiologic information** for surveillance of 2019n-CoV (detected in China in 2019)

Testing with the COVID19 IgG/IgM Rapid Test Cassette should **only** be performed **in conjunction with** other laboratory approved testing and/or clinical observations for the presumptive identification of viral infections in patients who may be infected with 2019nCoV (detected in China in 2019).

NOTE: The USFDA updated their guidance, issued on March 16, 2020, to allow the distribution of this product for diagnostic use in laboratories or by healthcare workers at point-of-care facilities.

All test results are presumptive and should be confirmed by an approved molecular assay. A presumptive negative test does not preclude 2019n-CoV infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, a presumptive positive result does not rule out infections caused by other viruses.

ABOUT THE TEST AND COVID 19 (2019nCoV)

In response to the global pandemic caused by 2019n-CoV, the COVID19 IgG/IgM Rapid Test Cassette was developed as a 10-minute simple field test using a lateral flow immunoassay that will allow field personnel with minimal training to perform. The test detects the presence of IgG and IgM antibodies specific to 2019n-CoV (detected in China in 2019) generally available in whole blood/ serum / plasma after infection by 2019n-CoV.

Early January 2020, a novel coronavirus (2019-nCoV) was identified as the infectious agent causing an outbreak of viral pneumonia in China, where the first cases had their symptom onset in December 2019.¹

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases.² Six coronavirus species are known to cause human disease.¹ Four viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals.¹ The two other strains - severe acute respiratory syndrome coronavirus (SARS-COV) and Middle East respiratory syndrome coronavirus (MERS-COV) - are zoonotic in origin and have been linked to sometimes fatal illness.⁴

Coronaviruses are zoonotic, which means they can be transmitted between animals and people. Common signs of infection include respiratory symptoms, fever, and cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.⁵

Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing. ⁵

HOW THE TEST WORKS

In response to the global pandemic caused by 2019n-CoV (COVID19), the COVID19 IgG/IgM Rapid Test Cassette was developed as a 10-minute simple field test using a lateral flow immunoassay that will allow field personnel with minimal training to perform. The test detects the presence of IgG and IgM antibodies specific to 2019n-CoV (detected in China in 2019) generally available in whole blood/ serum/ plasma after infection by 2019n-CoV.

The COVID19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane- based, lateral flow immunoassay for the detection of IgG and IgM antibodies to 2019-nCoV in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component.

In the IgG component, anti-human IgG is coated in the IgG test line region on the membrane. During testing, when the specimen is added to the test cassette, it reacts with 2019-nCoV antigen-coated particles inside the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG coated in the IgG test line region. If the specimen contains IgG antibodies to 2019-nCoV, a complex will be formed resulting in a colored line that will appear in the IgG test line region. Similarly, anti-human IgM is coated in the IgM test line region and if the specimen contains IgM antibodies to 2019-nCoV, the conjugate-specimen complex reacts with anti-human IgM on the membrane. A colored line appears in IgM test line region as a result.

Therefore, if the specimen contains 2019-nCoV IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains 2019-nCoV IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain 2019-nCoV antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred, and the test has been activated correctly.

THE REAGENTS

The test contains anti-human IgM and anti-human IgG as the capture reagent, 2019-nCoV antigen as the detection reagent. A goat anti-mouse IgG is employed in the control line system.

PRECAUTIONS

1. **Biohazard.** Biological samples such as blood have the potential to transmit infectious diseases. Follow all applicable local, state, and federal regulations.
2. Use routine laboratories precautions. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use the test if protective pouch is damaged.
4. For research use only. Do not use after expiration date.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Please ensure that an appropriate amount of samples are used for testing. Too much or too little of sample size may lead to deviation of results.
8. Used test should be discarded according to local regulations.
9. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

PROCEDURE

SPECIMEN COLLECTION AND PREPARATION FOR TESTING

The COVID19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or finger prick), serum or plasma.

To collect Finger prick Whole Blood Specimens (when ready to perform the test):

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin of 1 finger with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Collect the blood from the finger using the dropper provide or by using a capillary tube.
- Transfer the blood specimen to the sample well on the test device

To collect Whole Blood using Venipuncture and preparation of Serum and Plasma:

- Collect blood using general guideline for venipuncture.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.

Testing Preparation

- Testing should be performed immediately after the specimens have been collected.
- Do not leave the specimens at room temperature for prolonged periods.
- Serum and plasma specimens may be stored at 2-8°C for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20°C.
- Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
- Whole blood collected by finger prick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

RUNNING THE TEST

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.

For **Serum or Plasma** specimen:

- To use a dropper: Hold the dropper vertically, draw the specimen to the **fill line** (approximately 10µL), and transfer the specimen to the specimen well (**S**), then add **2 drops of buffer** (approximately 80 µL), and start the timer.
- To use a pipette: Transfer **10 µL** of specimen to the specimen well(S), then **add 2 drops of buffer** (approximately 80 µL), and start the timer

For **Venipuncture Whole Blood** specimen:

- To use a dropper: Hold the dropper vertically, draw the specimen about **1 cm above the fill line** and transfer **1 full drop** (approx. 20µL) of specimen to the sample well(S). Then add **2 drops of buffer** (approximately 80 µL) and start the timer.
- To use a pipette: Transfer **20 µL** of whole blood to the specimen **well(S)**, then **add 2 drops of buffer** (approximately 80 µL), and start the timer

For **Finger prick Whole Blood** specimen:

- To use a dropper: Hold the dropper vertically, draw the specimen about **1 cm above the fill line** and transfer **1 full drop** (approx. 20µL) of specimen to the sample **well(S)**. Then add **2 drops of buffer** (approximately 80 µL) and start the timer.
- To use a capillary tube: Fill the capillary tube and transfer **approximately 20µL of finger prick whole blood specimen** to the specimen well (**S**) of test cassette, then **add 2 drops of buffer** (approximately 80 µL) and start the timer. See illustration below.

Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer beyond 6 months after opening the vial.



Internal procedural controls are included in the test cassette. The control line is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The COVID19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibody to 2019-nCoV in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to 2019-nCoV can be determined by this qualitative test.
2. The COVID19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to 2019-nCoV in the specimen and should not be used as the sole criteria for the diagnosis of 2019-nCoV infections.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of 2019-nCoV infection.
5. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.
6. The test will show negative results under the following conditions: The titer of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test, or the novel coronavirus antibody has not appeared at the time of sample collection (Asymptomatic stage).

PERFORMANCE CHARACTERISTICS

Clinical Performance

The clinical performance of the "COVID19 IgG/IgM Rapid Test Cassette" was evaluated in Shanghai, China with clinical samples derived from blood samples collected from 2019n-CoV infectious patients and 2019n-CoV non-infectious patients confirmed by PCR.

The study included testing of 20 known positive samples and 50 known negative samples.

Of the 20 known positive samples, the IgG test yields a 100% agreement of 20 out of 20, while the IgM test yields an 85% agreement of 17 out of 20.

Of the 50 known negative samples, the IgG test yields a 98% agreement of 49 out of 50, while the IgM test yields a 96% agreement of 48 out of 50. The data are illustrated in the table below.

Sensitivity and Specificity

IgG Result

Method	Results	PCR		Total Results
		Positive	Negative	
2019-nCoV IgG/IgM Rapid Test	Positive	20	1	21
	Negative	0	49	49
Total Result		20	50	70

IgG test results yields 20 positive results from 20 know positive samples.

IgG test results yields 49 negative samples from 50 known negative samples.

Relative Sensitivity: 100% (95%CI*: 86.0%-100%) *Confidence Interval

Relative Specificity: 98.0% (95%CI*: 89.4%-99.9%)

Accuracy: 98.6% (95%CI*: 92.3%-99.96%)

IgM Result

Method	Results	PCR		Total Results
		Positive	Negative	
2019-nCoV IgG/IgM Rapid Test	Positive	17	2	19
	Negative	3	48	51
Total Result		20	50	70

IgM test results yields 17 positive results from 20 know positive samples.

IgG test results yields 48 negative samples from 50 known negative samples.

Relative Sensitivity: 85.0% (95%CI*: 62.1%-96.8%) *Confidence Interval

Relative Specificity: 96.0% (95%CI*: 86.3%-99.5%)

Accuracy: 92.9% (95%CI*: 84.1%-97.6%)

Cross-reactivity

The "COVID19 IgG/IgM Rapid Test Cassette" (Whole Blood/Serum/Plasma) has been tested against anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

- Triglyceride: 50 mg/dL - Ascorbic Acid: 20mg/dL - Hemoglobin: 1000mg/dL-
Bilirubin: 60mg/dL - Total cholesterol : 6mmol/L



Supporting videos:

- https://www.youtube.com/watch?time_continue=4&v=DH-RXleVQXY&feature=emb_logo
- https://www.youtube.com/watch?v=tVKUK5RzW8E&feature=emb_logo

Our tests as compared to other tests available. Others available upon request.

BIBLIOGRAPHY

1. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020. [Accessed 26 Jan 2020]. <https://www.who.int/china/news/detail/09-01-2020-who-statement-regarding-cluster-of-pneumonia-cases-in-wuhan-china>
2. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. *Adv Virus Res* 2011;81:85-164.

PMID:22094080 DOI:[10.1016/B978-0-12-385885-6.00009-2](https://doi.org/10.1016/B978-0-12-385885-6.00009-2)

1. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. *Trends Microbiol* 2016;24:490-502.

PMID:27012512 DOI:[10.1016/j.tim.2016.03.003](https://doi.org/10.1016/j.tim.2016.03.003)

1. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. *Nat Rev Microbiol* 2019;17:181-192. PMID:30531947 DOI:[10.1038/s41579-018-0118-9](https://doi.org/10.1038/s41579-018-0118-9)
2. World Health Organization (WHO). Coronavirus. <https://www.who.int/health-topics/coronavirus>

Order Process

Ordering Terms of Service



Send Letter of Intent, item number, quantity and compliance spec for each item.



Show Proof of Funds.
Discuss Terms, Conditions,
Freight Costs.



We will prepare P.O.
specifications based on
products. We will provide FDA
or C.E. Certifications.



Sign required documents, remit
required payment.



Your shipment will be tracked
with notification of delivery.

Order Process

SHIPPING

Freight Delivered **ONLY** to your address.
Shipment 3 - 6 weeks from date of order.

Freight charges will appear in Terms & Conditions.

All orders will be shipped to the address you provide.



RETURN AND REFUND POLICY

Return and Refund policy, based on Manufacturers Policy.

Please contact manufacturer to facilitate return and refund.



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USA Yvonne Gamble +1.832.819.5260
USA Samantha Chui +1.888.264.9529
GHANA Rossette Aliu +233 24 459 8017
SOUTH AFRICA Ency Litsoane +27 83 235 0859



twitter.com/mobimed



USA Yvonne Gamble service@mobimed.us
USA Samantha Chui support@chuimarketing.com
GHANA Rosette Aliu newedrac@yahoo.com
South Africa Ency Litsoane ency@ubambano.org.za



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