Domestic Version
7.9.2020

Responding to the COVID-19 Crisis as America Looks for Ways to Safely Reopen

The Point of Care Solution for Coronavirus Testing.

www.greenstorygroup.com

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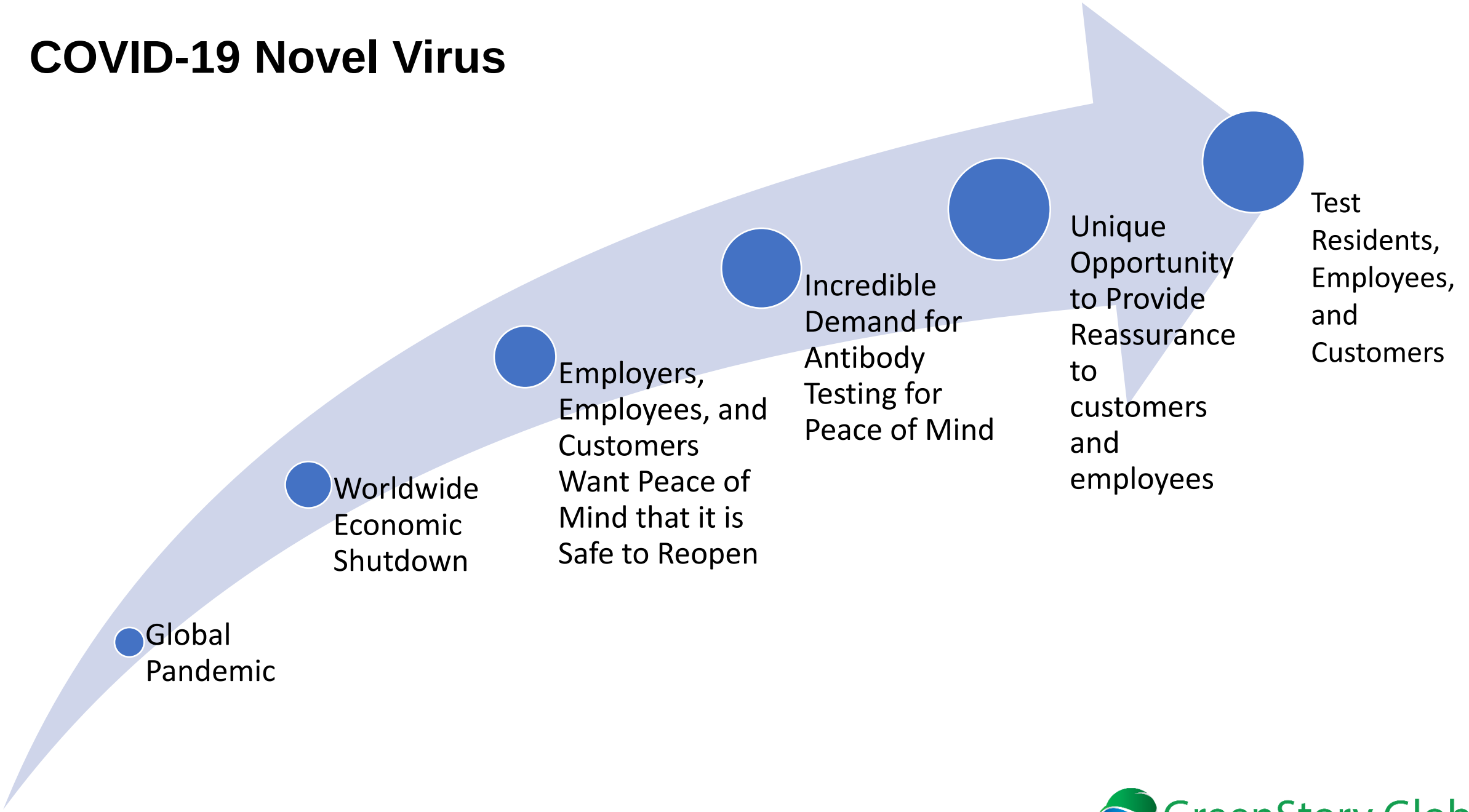
COVID-19 Novel Virus



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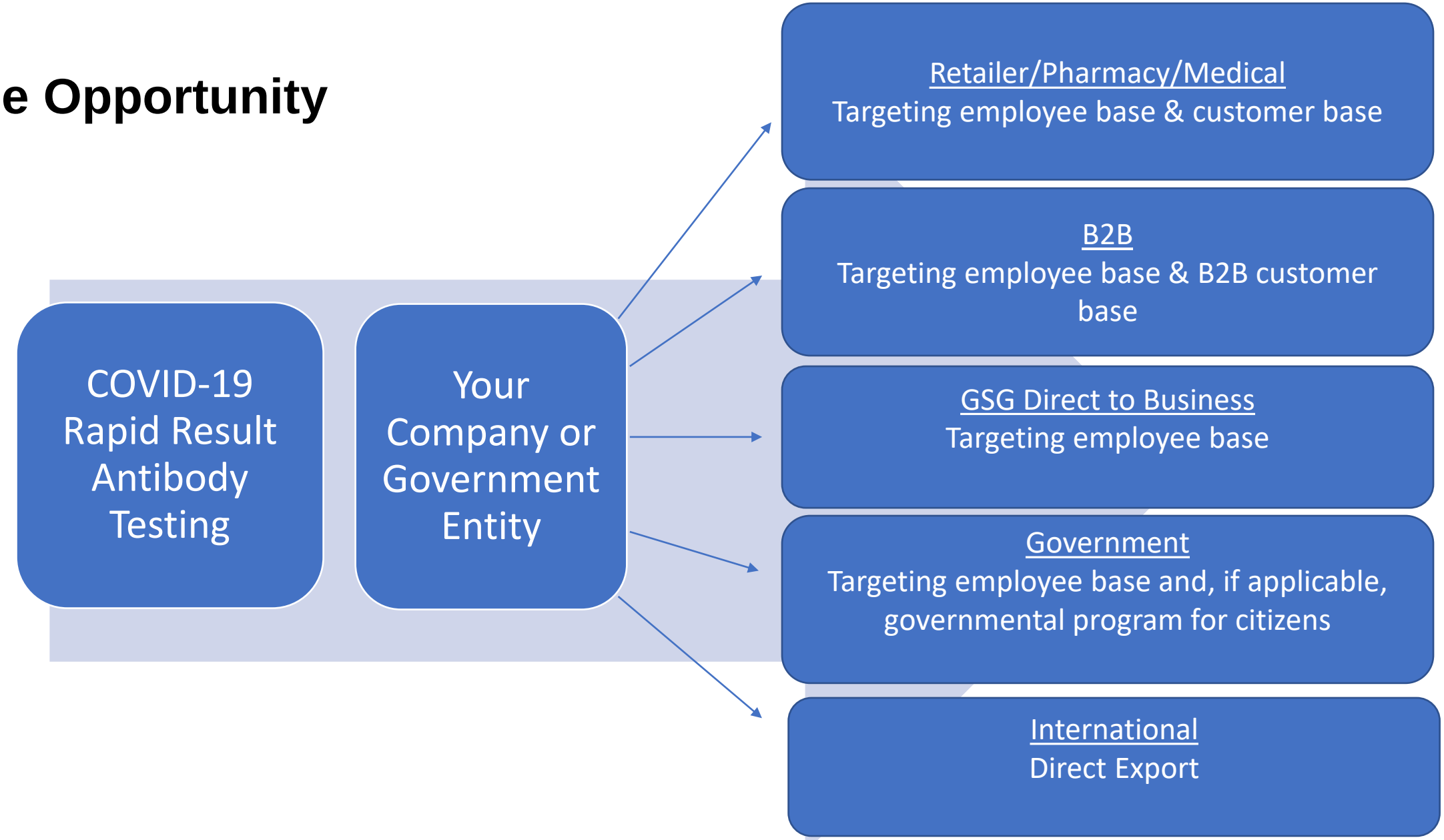
The Opportunity



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What are IgG, IgM, and IgA? And Why Are they Important?

- **IgM** antibodies are those created by the human body as part of the body's immediate defense against the SARS-CoV-2 virus.
- **IgG** antibodies are those created to provide long term protection against the resurgence of SARS-CoV-2 in the body.
- **IgA** is an antibody that plays a crucial role in the immune function of mucous membranes. The amount of IgA produced in association with mucosal membranes is greater than all other types of antibodies combined
- Each microbial organism, from viruses like SARS-Covid and influenza to bacteria such as MRSA, has a unique antigenic fingerprint on the cell membrane, which your body recognizes as alien.
- Once the immune response is initiated, the body begins to manufacture targeted immunoglobulins, of which IgG, IgM, and IgA are types.
- Vaccines work by inducing that immune response to attenuated pathogens (measles, mumps, rubella vaccine is an example, as is the flu nasal mist) or non-infective antigenic material that is injected or inhaled into the body (hepatitis A, flu shot, polio, and rabies are examples).
- This immunity is how we develop protection from recurrent infections by the same organism.
- The presence of these antibodies indicate that the body has responded to the virus, indicating that a confirmatory test should be used to determine if the virus is still active in the subject being tested.

Winning the war against COVID-19

Given the novelty of the SARS-CoV-2 virus and associated COVID-19 illness, the primary public health concern is to identify who has been exposed to the virus and who has not. This increased accuracy will help direct much needed medical resources to those who need it. In addition to the more accurate and reliable test, the biological elements necessary to manufacture this total antibody detection test can be synthesized in-house by the U.S.-based manufacturer and in doing so help eliminate a critical manufacturing supply chain challenge.

A reliable supply chain is critical to the successful mitigation of COVID-19. Creating a public health response to an epidemic like COVID-19 is a lot like fighting a war. Wars are won by logistics, not by tactics and strategies. The inability to produce the reactive agents (reagents) that create a line on a serological test in large quantities has been the single largest limitation in bringing test kits to market in the quantities needed to provide the public health professionals the data that they need in order to fight this battle. Our reagent in the Antibody Tests can be produced in quantities sufficient to turn on America's large-scale manufacturing capacity to meet this need.

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Return to Work Strategy

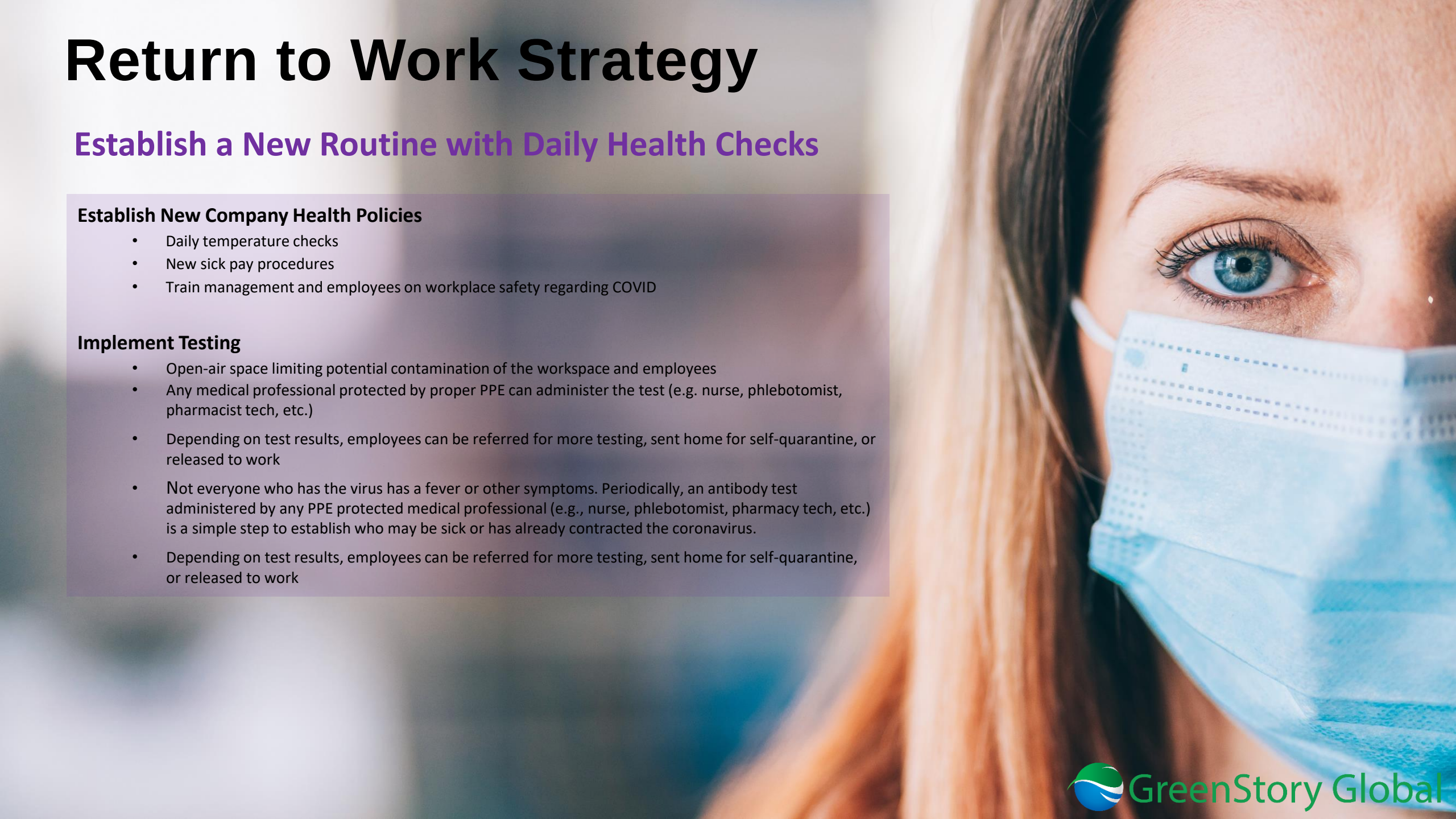
Establish a New Routine with Daily Health Checks

Establish New Company Health Policies

- Daily temperature checks
- New sick pay procedures
- Train management and employees on workplace safety regarding COVID

Implement Testing

- Open-air space limiting potential contamination of the workspace and employees
- Any medical professional protected by proper PPE can administer the test (e.g. nurse, phlebotomist, pharmacist tech, etc.)
- Depending on test results, employees can be referred for more testing, sent home for self-quarantine, or released to work
- Not everyone who has the virus has a fever or other symptoms. Periodically, an antibody test administered by any PPE protected medical professional (e.g., nurse, phlebotomist, pharmacy tech, etc.) is a simple step to establish who may be sick or has already contracted the coronavirus.
- Depending on test results, employees can be referred for more testing, sent home for self-quarantine, or released to work



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Testing is
Easy, Fast, and
Accurate
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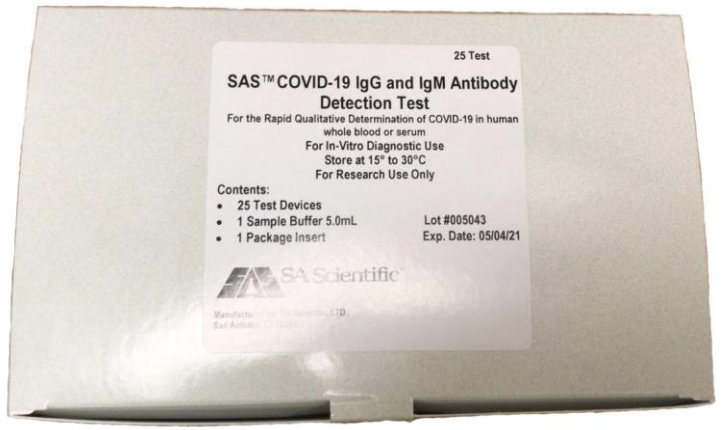
What's Included in the Box?

- 25 Individually Wrapped Test Cassette Devices
- Disposable Pipette
- Package Insert
- 5 mL Buffer
- Quick Reference Guide

Kits do NOT include:

- Lancet
- Alcohol swab

Why? The FDA deemed these items necessary to performing the test. By not including them, it deters someone from using it as an at-home test.



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What's a Master Kit?

- 1,000 Individually Wrapped Test Cassette Devices
- Disposable Pipettes
- Package Inserts and Flat Boxes to Make Packs of 25 tests
- 40 bottles of 5 mL Buffer
- Quick Reference Guide

Kits do NOT include:

- Lancet
- Alcohol swab

Why? The FDA deemed these items necessary to performing the test. By not including them, it deters someone from using it as an at-home test.

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Performing the Test

1. Wash non-dominant hand with soap and water.
2. Wipe fingertip with alcohol swab.
3. Prick skin with lancet.
4. Allow a drop of blood to form.
5. Compress bulb and hold pipette close to drop of blood while slowly releasing blood to collect blood in pipette.
6. Hold pipette tip over the test chamber and compress bulb to fill chamber with blood sample.
7. Add diluent and wait 10-15 minutes.
8. Results must be read by appropriately-trained healthcare provider.

WATCH A DEMONSTRATION VIDEO HERE.

Who should perform the test? Any medical professional can administer the test: nurse, nurse practitioner, physician's assistant, phlebotomist, pharmacist, or pharmacy tech.

Any facility that performs a flu shot or any form of on-site rapid medical testing would qualify.

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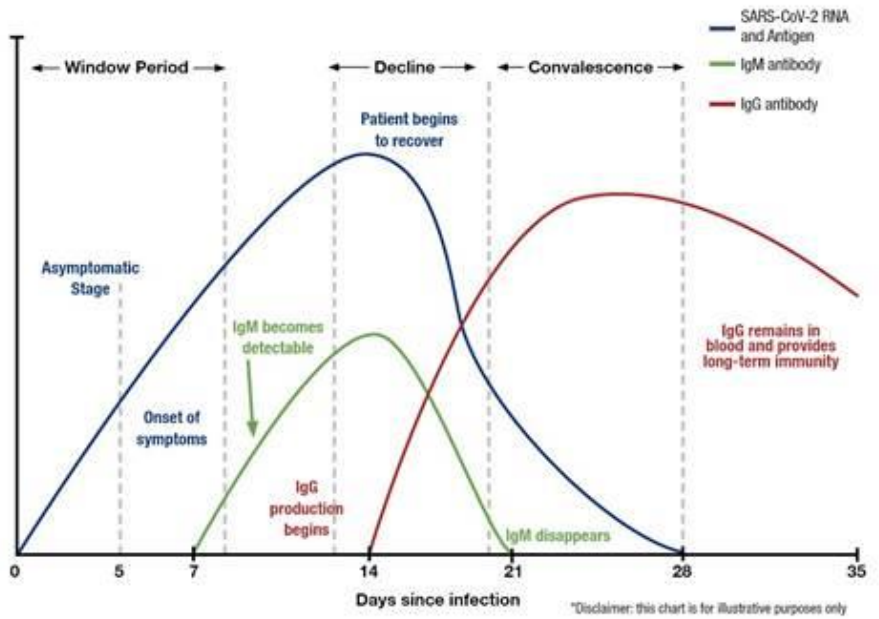
What do the Test Results Mean?

- The presence of IgM (line M) indicates the patient in the early stage of the virus and is starting to develop antibodies. The healthcare professional may advise the patient to be retested in the near future to confirm they have by then developed IgG as well. Ideally, the patient would be advised to go for an immediate PCR test to confirm 100% whether they have the virus or not. At a minimum, it would be recommended they self-isolate and do another antibody test in a week.
- The presence of both IgM and IgG indicates the patient is in the active stage of the virus
- The presence of IgG (line G) indicates the patient is in the late stage or has already had the virus
- The presence of the control line (C) indicates the test worked properly



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Unlike many competitors, our tests are both HIGHLY SENSITIVE AND HIGHLY SPECIFIC.

- The best antibody tests are both highly sensitive (meaning they detect a wide range of IgA, IgM, or IgG antibodies that recognize different parts of a viral protein) and highly specific (meaning the detected antibodies are for only that virus).
- Coronaviruses that cause colds, for example, also circulate around the globe. Antibody tests with low specificity and high sensitivity might detect antibodies against cold viruses and give a false positive. But a test with high specificity and low sensitivity could miss antibodies, resulting in a false negative.

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CLIA

Clinical Laboratory Improvement Amendments (CLIA) regulations establish quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health.

The basis of the complexity of CLIA tests are categorized into three levels: waived tests, moderate, and high complexity.

Waived testing is designated by CLIA as simple tests that carry a low risk for an incorrect result.

During the Presumptive Emergency Use Authorization (PEUA):

Point of Care = Point of Administering the Test → Photo of Test Results Sent Electronically to CLIA Lab for Instant Interpretation*
**Individual states can override this and allow CLIA Waived Testing*

Once the Full Emergency Use Authorization is Granted (EUA):

It is assumed that the Rapid Results tests in this catalog will be CLIA waived tests.**

Point of Care = Point of Administering the Test AND Point of Interpreting the Results
***Note if NOT CLIA Waived, the process outlined above for the PEUA period will apply*

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Working with GreenStory Global

Quick Turnaround

We understand the sensitivities that are demanded with customer health delivery initiatives. We'll work at your pace and on your schedule to support you.

Solutions Approach

We share a common mission for your organization – enabling a safer tomorrow through the strategical deployment of health mitigating technology and services.

Certified & Verified

From manufacturing through our various distribution channels, our medical & testing supply partners are carefully vetted through our rigorous due diligence process

Trusted & Experienced

We've combined a team of industry professionals at the top of their respective fields. Experience ranging from Healthcare delivery, Surgical Procedure, Medical Device Sales, Manufacturing, and Logistics.

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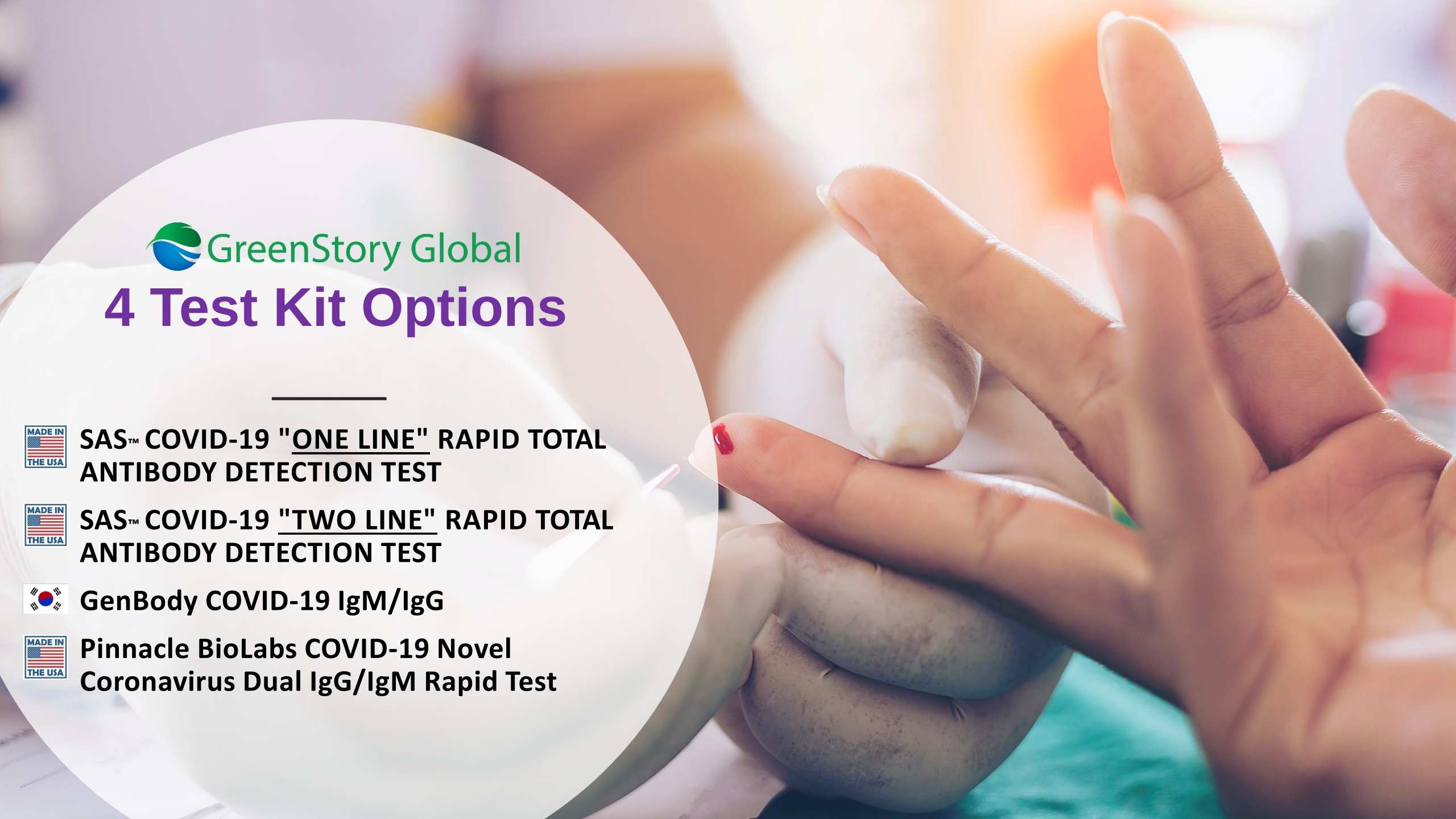
4 Test Kit Options

- SAS™ COVID-19 "ONE LINE" RAPID TOTAL ANTIBODY DETECTION TEST
- SAS™ COVID-19 "TWO LINE" RAPID TOTAL ANTIBODY DETECTION TEST
- GenBody COVID-19 IgM/IgG
- Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test



All 4 Test Kit Options Feature:

- Point of Care Testing: no special requirements for training, lab equipment, or facilities
- Simple, easy, accurate testing
- Only 2 drops of whole blood
- Results in 15 minutes or less
- No painful nasal swabbing
- Storage at 15°-30°C
- Not a single false positive has been reported
- Zero returns to date
- What's included in the box: 25 tests, diluent/buffer solution, pipettes, instructions
- **Available for sale and use now**

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	SAS COVID-19 One-Line Rapid Total Antibody Detection Test	SAS COVID-19 Two-Line Rapid Total Antibody Detection Test	GenBody COVID-19 IgM/IgG	Pinnacle Biolabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test
Tests for	IgG/IgM/IgA	IgG/IgM	IgG/IgM	IgG/IgM
Results in	10-15 minutes	10-15 minutes	10 minutes	10-15 minutes
Sensitivity	98%	96%	91.7%	94%
Specificity	99%	97%	97.5%	98%
FDA Status	PEUA201175, 5/21/2020	PEUA201388, 5/22/2020	PEUA201049, 5/15/2020	EUA202009
Shipping Lead Time	30-45 days	30-45 days	30-45 days	30-45 days
Manufacturing Capacity/Month	5M	3.5M	5M	8M
Shelf Life	1 year	2 years	2 years	2 years
Ships From	Texas 	Texas 	South Korea 	Utah 

Center for Medicare and Medicaid set reimbursement rates for COVID-19 test between $42.13 - $51.31, based upon the AMA CPT Code 86328.

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About SA Scientific

American manufacturer of over 400 FDA-approved products, including lateral flow test kits for human infectious diseases like COVID-19 (EUA in progress), hMPV, RSV, Adenovirus, Rotavirus, Strep A, Influenza A and B, Legionella. Founded by a research scientist in 1984, SA Scientific's philosophy is to combine high-quality ingredients with proven research techniques to create high-quality products at a reasonable cost. With research, production and quality control capabilities under one roof, SA Scientific's vertical integration gives them complete control of quality and production scheduling.

FDA and USDA Registered Facilities

All SAS products are manufactured according to Good Manufacturing Practices (GMP) in their registered facilities. Their tests meet or exceed the specifications of various government agencies responsible for reagent quality and standardization.

Their location in the heart of the South Texas Medical Center and close to the University of Texas Health Science Center provides additional resources to refine and perfect their tests.

- Manufacturing is 100% US-based
- Headquartered and manufactured in San Antonio, TX
- All SAS products are manufactured in accordance with Good Manufacturing Practices (GMP)
- 5000 sq. feet of dedicated wet labs:
  - 4 R&D Labs
  - Production Chem Lab
  - Quality Control Lab
  - Quality Assurance Lab
  - 15,000 sq. feet of <15% Dry Rooms
  - 3 assembly rooms
- Multiple manufacturing sites ensures production & delivery continuity in case of experienced downtime

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SAS™ COVID-19 "ONE LINE" RAPID TOTAL ANTIBODY DETECTION TEST

Seen here: one individually-wrapped cassette, one bottle of diluent (enough for 25 tests), and an instruction insert.

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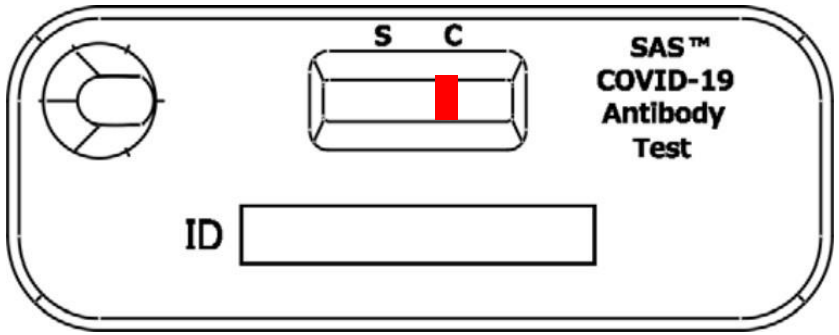
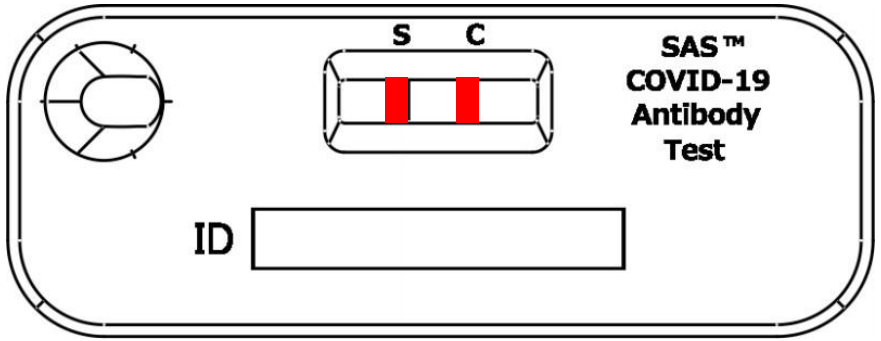
SAS™ COVID-19 "ONE LINE" RAPID TOTAL ANTIBODY DETECTION TEST



Negative

The test is negative if a colored line appears only in the C area (control).



Positive

The test is positive for SARS-CoV-2 antibody if a colored line appears in the S area (sample).

Invalid Results: The test is invalid if no colored line appears in the C area even if a colored line appears in the S area. Colored lines that appear after 15 minutes are invalid and should be ignored

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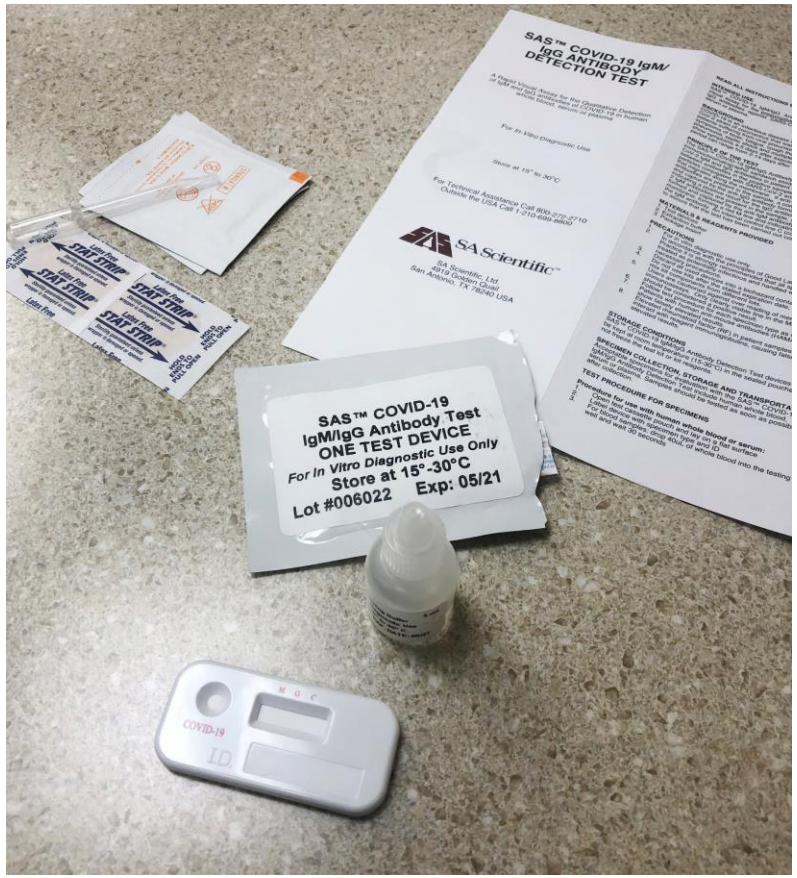
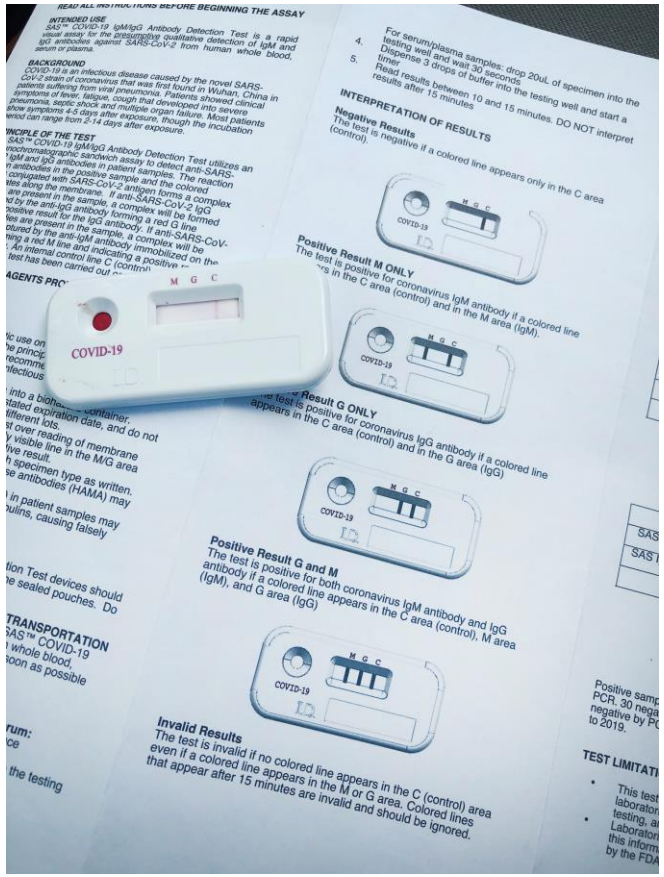
SAS™ COVID-19 "TWO LINE" RAPID TOTAL ANTIBODY DETECTION TEST

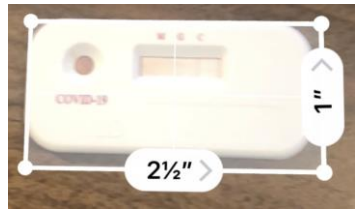


Seen here: one individually-wrapped cassette, one bottle of diluent (enough for 25 tests), and an instruction insert. *Pipette, alcohol wipe, and bandage provided by the testing facility.*



This patient's test results were negative – only the Control line showed up.

[Watch this test being performed HERE](#).



Cassette measures 2.5"x1", or 6.35cm x 2.54cm

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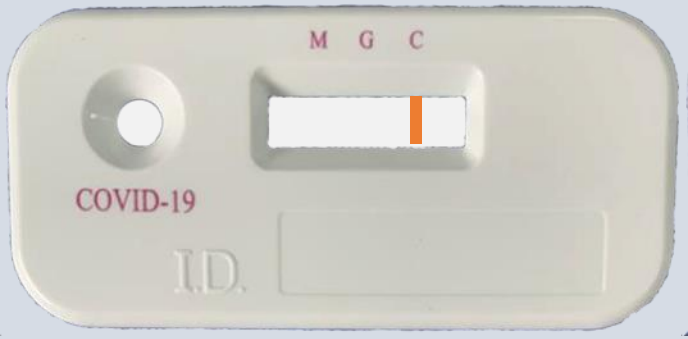
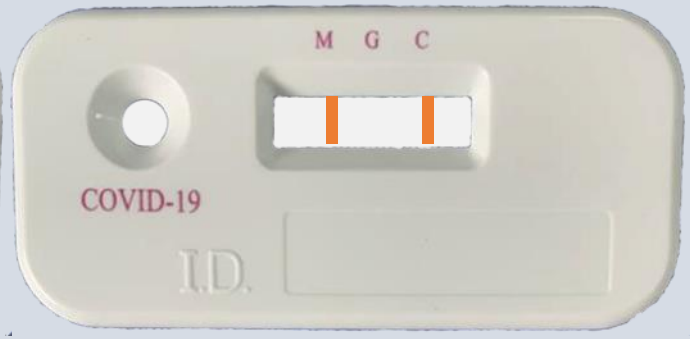
SAS™ COVID-19 "TWO LINE" RAPID TOTAL ANTIBODY DETECTION TEST

Results in Minutes:



IgG Negative
IgM Negative



IgG Negative
IgM Positive

IgG Positive
IgM Positive

IgM only: Healthcare professional should advise the patient to avoid contact with others and seek follow-up testing to prevent spreading the virus to others.

IgM and IgG: Indicates patient is in active state. Healthcare professional should advise the patient to avoid contact with others and seek follow-up testing to prevent spreading the virus to others.

Read the Test's CLINICAL PERFORMANCE REPORT HERE.

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Documentation

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

SA Scientific Ltd.

(DUNS# 88-335-0811)

Main Site: 4919 Golden Quail

San Antonio, Texas 78240 United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Design, manufacture and distribution of in-vitro diagnostic test kits used in the diagnosis and management of disease status, fertility testing and pregnancy testing and for including near patient in-vitro diagnostic devices.

Certificate Number:
0092543

Initial Certification Date:
2019-07-05

Certification Effective Date:
2019-07-05

Certification Expiry Date:
2022-07-04

ISO 13485:2016 CERTIFICATION

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

Intertek

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request. Validity of this certificate may be verified at http://www.intertek.com/business-assurance/certificate-validation/

CT-MDSAP-2016-NA-EN-LT-P-30.apr.18

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SAFETY DATA SHEET

SAS™ COVID-19 IgG and IgM Antibody Detection Test Kit

SECTION I: PRODUCT/COMPANY IDENTIFICATION

Cat. No. (s)	Chemical/Common Name	Formula
048025	SAS™ COVID-19 Antibody Test	Mixture

Description

SAS™ COVID-19 IgG and IgM Antibody Detection Test is a rapid, visual assay for the presumptive qualitative detection of COVID-19 antibodies from whole blood or serum samples of symptomatic patients.

The SAS ™ COVID-19 IgG and IgM Antibody Detection Test Kits are manufactured by SA Scientific, Ltd.

SA Scientific, Ltd.
4919 Golden Quail
San Antonio, Texas 78240

SDS Coordinator
Telephone Number: (800) 272-2710
Emergency Phone: (800) 272-2710

SECTION II: HAZARDOUS IDENTIFICATION

Product Hazard Classification: Pursuant to OSHA's Hazardous Communications Standard 29 CFR 1910.1200, these products are not considered to contain hazardous materials.

Label elements, including hazard and precautionary statements
Pictogram: None.
Signal word: None.
Health: Minimal risk if used as directed.
Fire: Not considered a fire hazard.
Reactivity: Minimal risk. Reagents do not contain hazardous materials according to WHMIS, EU and OSHA criteria.
Physical Hazards: If not used as directed, it may be harmful if ingested and/or it may cause eye and skin irritation.
Special Hazards: Avoid ingesting reagents, as toxicity has not been determined.

Potential Health Effect Summary
WHMIS criteria: None considered hazardous materials.
EU criteria: None considered hazardous materials.
OSHA criteria: None considered hazardous materials.

Carcinogenicity Summary
ACGIH criteria: None of the ingredients are listed.
NTP criteria: None of the ingredients are listed.
OSHA criteria: None of the ingredients are listed.

SECTION III: PRODUCT COMPOSITION

Strip contains reagents in dry form (Nitrocellulose membrane, fiberglass pad, antibodies and colloidal gol contains recombinant protein for SARS-CoV-2(2019-nCoV)).

Extraction Buffer: Buffer contains 0.1% Sodium Azide.

Chemical Name	CAS No.	%
Sodium Azide	26628-22-8	0.1

Kit does not contain chemical mixtures at levels greater than 1.0% of a hazardous compound or 0.1% or more of a carcinogen as per ACGIH, NTP or OSHA criteria.

SECTION IV: FIRST AID MEASURES

After skin contact: Immediately, wash affected area thoroughly with soap and water. Remove contaminated clothing and shoes, if necessary. Seek medical attention, if irritation develops or persists.
After eye contact: Immediately, flush eyes under gently running water for at least 15 minutes, making sure that the eyelids are held open. Seek medical attention, if irritation or redness develops.
After ingestion: Rinse mouth with plenty of water to dilute the substance. Immediate medical attention is required.
After inhalation: Move person into fresh air. Seek medical attention.

SECTION V: FIRE FIGHTING MEASURES

Extinguishing Media: Not combustible. Use extinguishing media suitable for surrounding materials.
Special Fire and Explosion Hazards: May react with lead and copper plumbing to form explosive metal azides. Drains should be flushed thoroughly with water after disposing of buffer to prevent azide buildup.
Hazardous Combustion Products: None
Protective Equipment for Firefighters: Wear self-contained breathing apparatus and full protective gear.

SECTION VI: ACCIDENTAL RELEASE MEASURES

Personal Precautions: Avoid skin and eye contact by wearing appropriate lab personal protective equipment (PPE)
Environmental Precautions: Absorb into inert solid or dilute with a large quantity of water and flush into an approved wastewater treatment system. Use good laboratory practices.

SECTION VII: HANDLING AND STORAGE

Handling Precautions: Use good laboratory practices.
Recommended Storage Conditions: Store at 15°- 30° C to maintain efficacy.
Other Precautions/Special Hazards: Avoid eye and skin contact.

MSDS

SECTION VIII: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure Limits: US OSHA: None established. **ACGIH:** None established.
DFG MAK: None established. **Engineering Controls:** Use in well ventilated area.
Eye Protection: Safety glasses should be worn to prevent eye contact.
Skin Protection: Impervious gloves should be worn to prevent skin contact.

SECTION IX: PHYSICAL AND CHEMICAL PROPERTIES

Form: Test strip contains reagents in dry form; extraction buffer is a liquid.
Color: Test strip is white; extraction buffer is clear, colorless.
Odor: Not identified.
Boiling Point/Boiling Range: N/A
Flash Point: N/A
Auto-ignition Temperature: N/A
Flash Point: N/A
Decomposition Temperature: N/A
Viscosity: N/A

SECTION X: STABILITY AND REACTIVITY

Stability: Stable under normal temperatures and pressures.
Hazardous Incompatibilities: N/A
Hazardous Decomposition: Not available.

SECTION XI: TOXICOLOGICAL INFORMATION

Toxicity Data for Hazardous Ingredients: N/A
Primary Routes of Exposure: Skin or eye contact.
Potential Effects of Acute Exposure: Low order of acute toxicity.
Potential Effects of Chronic Exposure: None identified
Symptoms of Overexposure: No specific symptoms identified
Carcinogenicity: No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
Other Effects: None Identified

SECTION XII: ECOLOGICAL INFORMATION

Ecotoxicity: No results of ecological studies are available.
Biodegradability: No results of biodegradability studies are available.
Mobility: No results of mobility studies are available.

SAFETY DATA SHEET
SAS™ COVID-19 IgG and IgM Antibody Detection Test

MADE IN THE USA

SECTION XIII: DISPOSAL CONSIDERATIONS

Waste Disposal: Disposal practice must be in compliance with company, local, state and federal lav regulations. If needed, Contact local, state or country environmental agency for specific rules.
Recommended Product Disposal: Sodium Azide may react with lead and copper plumbing to form explosive metal azides. Drains should be flushed thoroughly with water after disposing of buffer to prevent azide buildup.

SECTION XIV: TRANSPORT INFORMATION

Transportation is not regulated under ICAO, IATA, US DOT, Canadian TDG or European ADR/RVD.

SECTION XV: REGULATORY INFORMATION

Product is not classified as a dangerous preparation according to 1999/45/EC and 200/58/EC. Under US Federal and State Regulations.

SECTION XVI: OTHER INFORMATION

Employers should use this information as a supplement to other information gathered by them and should make independent judgment of the suitability of this information to ensure proper use and to protect the health and safety of employees. This information is provided without warranty and any use of this product not in conformance with this Safety Data Sheet, or in combination with any other product or process is the responsibility of the user. SA Scientific, Inc. shall not be held liable for any damage resulting from the handling or use of this product.

SAS™ COVID-19 IgG and IgM ANTIBODY DETECTION TEST

INSERT

A Rapid Visual Assay for the Qualitative Detection of IgG and IgM antibodies of COVID-19 in human whole blood or serum

For *In-Vitro* Diagnostic Use

Store at 15° to 30°C

For Technical Assistance Call 800-272-2710
Outside the USA Call 1-210-699-8800

SA Scientific™

SA Scientific, Ltd.
4919 Golden Quail
San Antonio, TX 78240 USA

Kit package insert

READ ALL INSTRUCTIONS BEFORE BEGINNING THE ASSAY

INTENDED USE
SAS™ COVID-19 IgG and IgM Antibody Detection Test is a rapid visual assay for the presumptive qualitative detection of IgG and IgM antibodies against SARS-CoV-2 from human whole blood or serum.

BACKGROUND
COVID-19 is an infectious disease caused by the novel SARS-CoV-2 strain of coronavirus that was first found in Wuhan, China in patients suffering from viral pneumonia. Patients showed clinical symptoms of fever, fatigue, cough that developed into severe pneumonia, septic shock and multiple organ failure. Most patients show symptoms 4-5 days after exposure, though the incubation period can range from 2-14 days after exposure.

PRINCIPLE OF THE TEST
The SAS™ COVID-19 IgG and IgM Antibody Detection Test utilizes an immunochromatographic sandwich assay to detect anti-SARS-CoV-2 IgG and IgM antibodies in patient samples. The reaction between antibodies in the positive sample and the colored particle-conjugated with SARS-CoV-2 antigen forms a complex that migrates along the membrane. If anti-SARS-CoV-2 IgG antibodies are present in the sample, a complex will be formed and captured by the anti-IgG antibody forming a red G line indicating a positive result for the IgG antibody. If anti-SARS-CoV-2 IgM antibodies are present in the sample, a complex will be formed and captured by the anti-IgM antibody immobilized on the membrane, forming a red M line and indicating a positive result for the IgM antibody. An internal control line C (control) area is built-in to assure that the test has been carried out correctly.

MATERIALS & REAGENTS PROVIDED
1. Test devices
2. Extraction buffer
3. Package insert

PRECAUTIONS
1. For in vitro diagnostic use only.
2. In accordance with the principles of Good Laboratory Practice it is strongly recommended that all specimens be treated as potentially infectious and handled with all necessary precautions.
3. Discard all used devices into a biohazard container.
4. Do not use kits after the stated expiration date, and do not mix kit components from different lots.
5. Users are cautioned against over reading of membrane immunoassays. Only clearly visible line in the S area should be considered a positive result.
6. Follow test procedure for each specimen type as written.
7. Patients with human anti-mouse antibodies (HAMA) may show falsely elevated results.
8. Elevated rheumatoid factor (RF) in patient samples may interact with reagent immunoglobulins, causing falsely elevated results.

STORAGE CONDITIONS
SAS™ COVID-19 IgG and IgM Antibody Detection Test devices should be kept at room temperature (15-30°C) in the sealed pouches. Do not freeze the test kit or kit reagents.

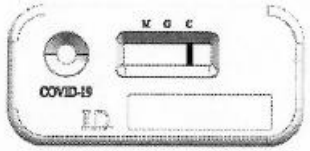
SPECIMEN COLLECTION, STORAGE AND TRANSPORTATION
Acceptable specimens for evaluation with the SAS™ COVID-19 IgG and IgM Antibody Detection Test include human whole blood or serum. Samples should be tested as soon as possible after collection.

TEST PROCEDURE FOR SPECIMENS

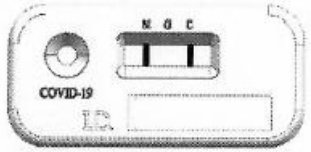
Procedure for use with human whole blood or serum:
1. Open test cassette pouch and lay on a flat surface
2. Label device with specimen type and ID
3. For blood samples: drop 40uL of whole blood into the testing well and wait 30 seconds
   For serum samples: drop 20uL of serum into the testing well and wait 30 seconds
4. Dispense 3 drops of buffer into the testing well and start a timer
5. Read results between 10 and 15 minutes. DO NOT interpret results after 15 minutes

INTERPRETATION OF RESULTS

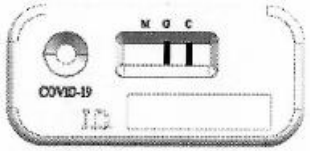
Negative Results
The test is negative if a colored line appears only in the C area (control).



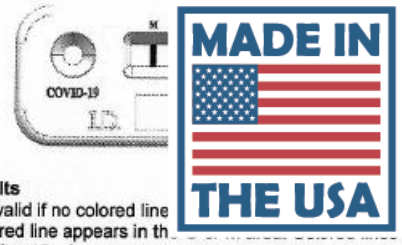
Positive Result M ONLY
The test is positive for coronavirus IgM antibody if a colored line appears in the C area (control) and in the M area (IgM).



Positive Result G ONLY
The test is positive for coronavirus IgG antibody if a colored line appears in the C area (control) and in the G area (IgG)



Positive Result G and M
The test is positive for both coronavirus IgM antibody and IgG antibody if a colored line appears in the C area (control), M area (IgM), and G area (IgG)



Invalid Results
The test is invalid if no colored line [illegible] ea even if a colored line appears in th[illegible] that appear after 15 minutes are invalid and should be ignored.

PERFORMANCE CHARCTERISTICS

Clinical Performance

	PCR Positive	Negative
SAS IgM/IgG Positive	45	4
SAS IgM/IgG Negative	2	126
Total	47	130
	PPA	96%
	NPA	97%

Positive samples have been confirmed COVID-19 positive by PCR. 30 negative samples have been confirmed COVID-19 negative by PCR and remaining 100 samples were drawn prior to 2019.

TEST LIMITATIONS

- This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.
- Laboratories and healthcare providers must include this information in their patient test report as provided by the FDA guidance:
  - This test has not been reviewed by FDA
  - Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow up testing with a molecular diagnostic should be considered to rule out infection in these individuals
  - 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.
  - Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E
  - Not for the screening of donated blood

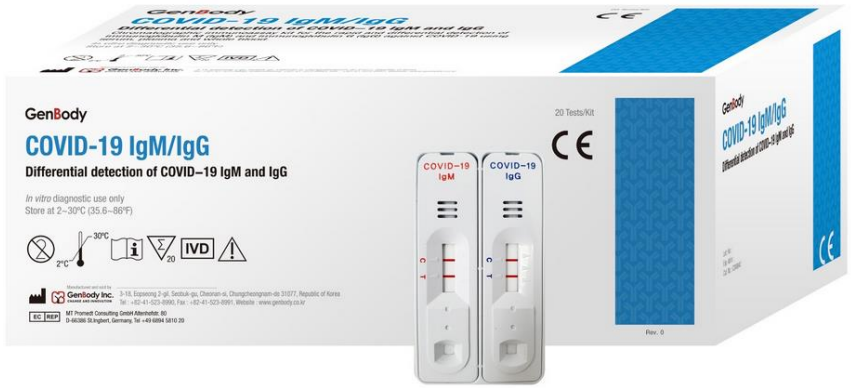
About GenBody

Founded in 2012 with the pursuit for human and global health, GenBody Inc. creates innovative technologies for the development of raw materials for diagnostic use. They offer diagnostic total solution such as rapid diagnostic tests (RDTs), fluorescent immuno-diagnostic tests, ELISA, molecular diagnostic tests (MDx) and clinical chemistry.

With over 20 years combined experience in the diagnostic industry and through vast bio-networks between several key institutes, universities, and hospitals, our core strength is in R&D. They specialize in developing monoclonal antibodies and recombinant antigens in-house at their facility in South Korea.

They also have patented technologies including fluorescent immuno-diagnostics, which will be one of the major IVD technologies of the future.

Their Mission statement is to bring Technology to Your life.
They continuously develop innovative diagnostics and pharmaceutical technologies for improving your quality of life.



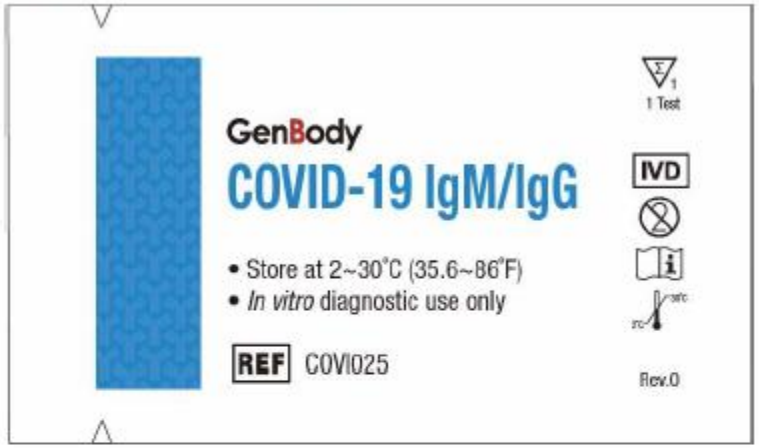
MADE IN S.KOREA
PREMIUM QUALITY

GreenStory Global

GenBody COVID-19 IgM/IgG

- Pouch Front view

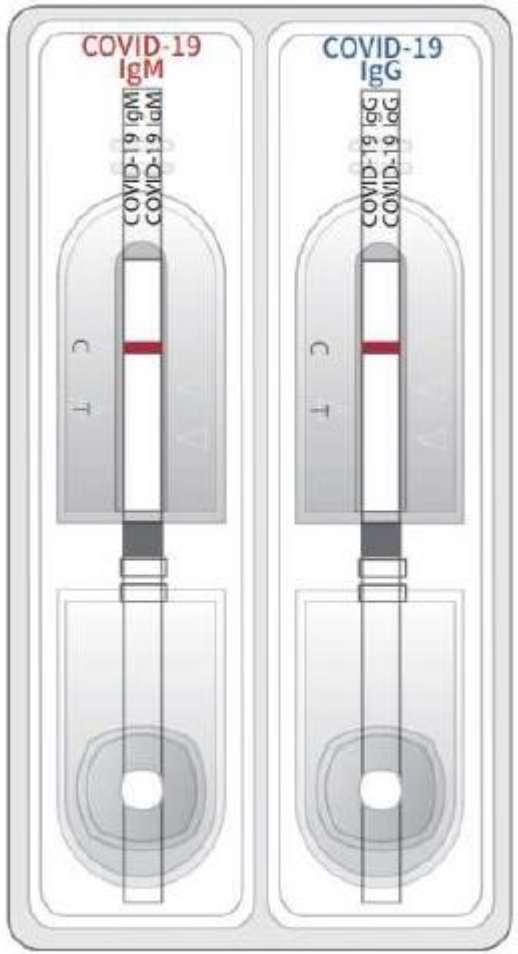
Dimensions(Height(H) X Width(W)): 70 X 120 mm



- Pouch Back view

Dimensions(Height(H) X Width(W)): 70 X 120 mm

Device view



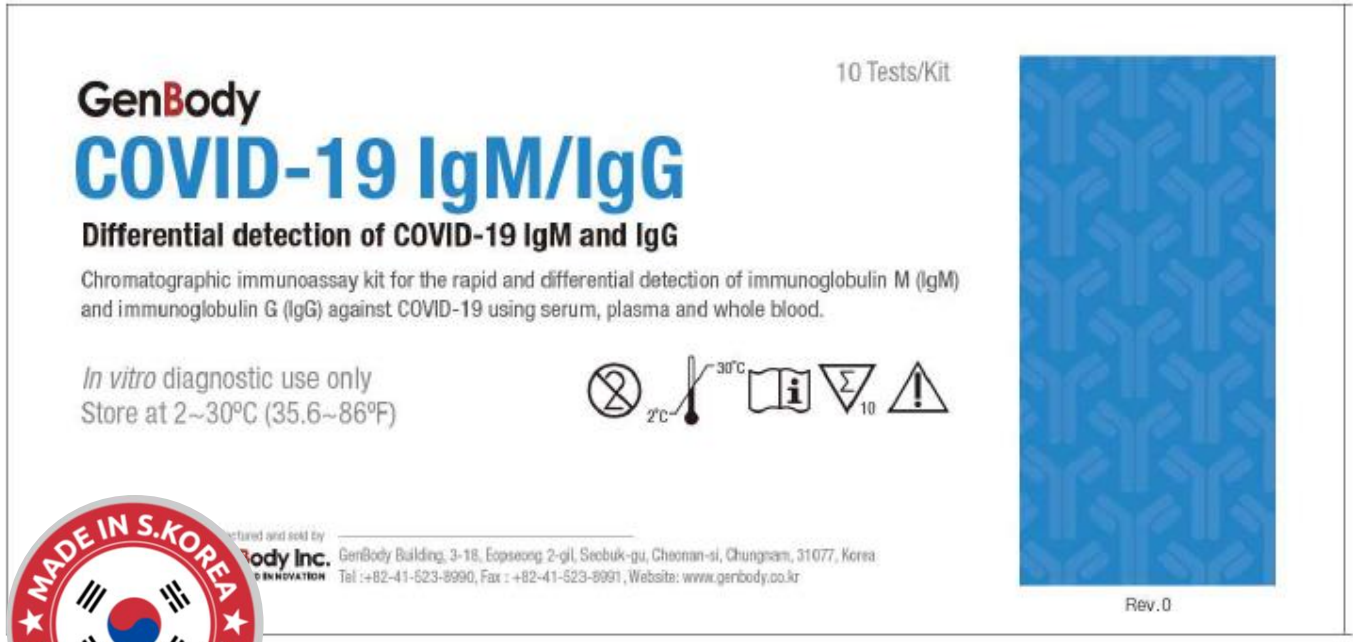
MADE IN S.KOREA PREMIUM QUALITY

GreenStory Global

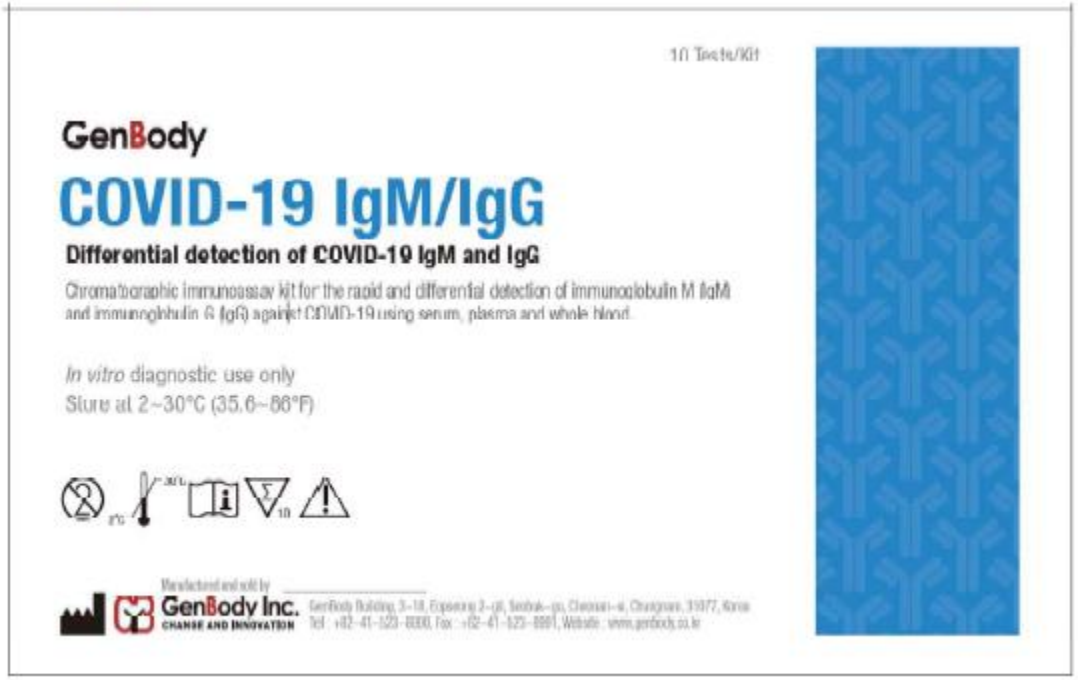
- Full view

- Back view

- Front view



- Top view



GenBody Inc. (주)젠바디 3-18, Eopseong2-gil, Seobul-gu, Cheonan, Chungnam, 31077, KOREA
Tel :+82-41-523-8990, Fax : +82-41-523-8991, contact@genbody.co.kr contact@genbody.co.kr

MATERIAL SAFETY DATA SHEET

Printing data : 2020/06/01 Reviewed on : : 2020/06/01

1. Product and Company Identification

Product name :

NO	Cat. No.	Product Name	Description
1	COVI040	GenBody COVID-19 IgM/IgG	20T/Kit

Application of the Product: Clinical Laboratory Application
Manufacturer/Supplier : GENBODY INC.
8-18, Eopseong2-gil, Seobuk-gu, Cheonan, Chungnam, 31077, KOREA
TEL: 82-41-523-8990
FAX: 82-41-523-8991

2. Composition/Information on Ingredients

Name	CAS#	% by weight	Exposure Limits
Sodium azide	26628-22-8	<1.00%	-

3. Hazards Identification

Physical State and Appearance : Liquid.
Emergency : No specific hazard.
Routes of Entry : Absorbed through skin. Inhalation. Ingestion.
Skin Contact : Irritation of the product in case of skin contact: Not available. Sensitization of the product: Not available.
Aggravating conditions : Repeated or prolonged exposure is not known to aggravate medical condition.
Potential Chronic Health Effects : Carcinogenic effects: Classified None. by OSHA, None. by NIOSH [Bovine Serum Albumin]. Classified None. by NIOSH [Sodium Phosphate (dibasic)]. Classified None. by NIOSH [Magnesium Nitrate]. Classified None. by NIOSH [Sodium Chloride]. Classified None. by NIOSH [Sodium Phosphate (monobasic)].
Mutagenic effects: Not available.
Teratogenic effects: Not available.

Not available

ction 11)

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Inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion : Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything mouth to an unconscious person. If large quantities of this material are swallowed, call aphysician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.
Skin Contact : In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.
Eye Contact : Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water at least 15 minutes. Cold water may be used. Get medical attention.

5. Fire-Fighting Measures

Extinguishing Media

Suitable : Not applicable. Use an extinguishing agent suitable for surrounding fires.
Flammability of the Product : Non-flammable.
Autoignition Temperature : Not applicable.
Flash Points : Not applicable.
Flammable Limits : Not applicable.
Fire Hazards in Presence of Various Substances : Not applicable.
Explosion Hazards in Presence of Various Substances : Not considered as a product presenting risks of explosion.
Special Remarks on Fire Hazards : Not available.

6. Accidental Release Measures

Environmental Precautions and Clean-up Methods : Absorb with an inert material and put the spilled material in an appropriate waste disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.
Small Spill and Leak : Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

7. Handling and Storage

Handling : Avoid breathing vapors or spray mists.
Storage : Keep container tightly closed. Keep container in a cool, well-ventilated area.

8. Exposure controls and Personal protection

Engineering measures : Provide exhaust ventilation or other engineering controls to keep the airborne

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concentrations of vapors below their respective occupational exposure limits.

Personal protective equipment

Skin and Body : Lab coat.
Hands : Gloves.
Eyes : Safety glasses.
Feet : Not applicable

Personal Protection in Case of a Large Spill : Splash goggles. Full suit. Boots. Gloves. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Consult local authorities for acceptable exposure limits.

9. Physical and Chemical Properties

Physical state : Liquid.
Color : Colorless.
Odor : Not available.
Odor Threshold : Not available.
Taste : Not available.
Molecular Weight : Not applicable.
Molecular Formula : Not applicable.
pH : Neutral
Boiling Point : The lowest known value is 100°C (212°F)(water)
Melting Point : May start to solidify at 0°C (32°F) based on data for: water.
Critical Temperature : The lowest known value is 374.8°C(706.7°F)(water).
Vapor Pressure : The highest known value is 8.2 kPa (28.8 mmHg) (at 20°C)
Volatility : 0%(w/w). (water). Weighted average: 0%(w/w).
VOC : =0°C(%).
Evaporation rate : 0.88 (water) compared to (n-butyl acetate= 1).
Specific Gravity : Not available.
Solubility : Easily soluble in cold water, hot water, methanol, acetone.
Ionicity (in Water) : Amphoteric. (water).
Dispersion Properties : See solubility in water, methanol, acetone.
Physical Chemical Comments : Not available.

10. Stability and Reactivity

Stability : The product is stable.
Hazardous Decomposition Products : Not applicable.
Hazardous Polymerization : Will not occur.
Explosion Hazards in Presence of Various Substances : Not considered as a product presenting risks of explosion.

11. Toxicological information

Chronic Effects on Humans : Carcinogenic effects: Classified None. by OSHA, None. by NIOSH [Bovine Serum Albumin]. Classified None. by NIOSH [Sodium Phosphate (dibasic)]. Classified None. by NIOSH [Magnesium Nitrate]. Classified

None. by NIOSH [Sodium Chloride]. Classified None. by NIOSH [Sodium Phosphate (monobasic)].

Other Toxic Effects on Human	:	No specific information is available in our database regarding the other toxic effects of this material for humans.
Special Remarks on Toxicity to Animals	:	Not available.
special Remarks on Chronic Effects on Humans	:	Not available.
Special Remarks on Other Toxic Effects on Humans	:	Not available.

12. Ecological information

BOD and COD	:	Not available.
Biodegradable/OECD	:	Not available.
Mobility	:	Not available.
Products of Degradation	:	Not available.
Toxicity of the products of Biodegradation	:	Not available.
Special Remarks on the Products of Biodegradation	:	Not available.

13. Disposal considerations

Methods of disposal; Waste of residues; Contaminated packaging	:	Waste must be disposed of in accordance with federal, state and local environmental control regulations.
Waste Stream	:	Not available.

Consult your local or regional authorities.

14. Transport information

DOT regulations :
Hazard class : – None hazard

Land Transport ADR/RID (cross-border)
ADR, RID class : –

Maritime transport IMDG :
IMDG Class : – None hazard
Marine pollutant : No

Air transport ICAO-TI and IATA-DGR : None hazard
ICAO/IATA Class : – None hazard

15. Regulations

Chemicals known to cause cancer:
None of the ingredients is listed.
Chemicals known to cause reproductive toxicity:
None of the ingredients is listed
Cancerogenity categories
EPA (Environmental Protection Agency):
None of the ingredients is listed
IARC (International Agency for Research on Cancer):
None of the ingredients is listed

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NTP (National Toxicology Program) :
None of the ingredients is listed

TLV(Threshold Limit Value established by ACGIH) :
None of the ingredients is listed
MAK(German Maximum Workplace Concentration) :
None of the ingredients is listed
NIOSH-Ca(National Institute for Occupational Safety and Health) :
None of the ingredients is listed
OSHA-Ca(Occupational Safety & Health Administration) :
None of the ingredients is listed

Hazard-determining components of labelling :
sodium azide
Risk phrases:
Harmful if swallowed
safety phrases:
This material and its container must be disposed of in a safe way.
Wear suitable protective clothing.
If swallowed, seek medical advice immediately and show this container or label.
National regulations:
Water hazard class: Generally not hazardous for water.

16.Other information

The above information is believed to be correct but does not purport to by all inclusive and shall be used only as a guideline of GENBODY INC. shall not be held liable for any damage resulting from handing or from contact with above product. Final determination of suitability of any material is the sole responsibility of user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that are the only hazards that exist.

DECLARATION OF CONFORMITY

MANUFACTURER : GenBody Inc.
3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungcheongnam-do 31077, Republic of Korea

EUROPEAN REPRESENTATIVE EC REP : MT Promedt Consulting GmbH
Altenhofstr. 80
D-66386 St. Ingbert, Germany

PRODUCT : GenBody COVID-19 IgM/IgG

CATALOG NO. : COVI025

EDMA code/ Term : 15 04 80 90 00 Other Viral Antigen/Antibody Detection

CLASSIFICATION : Others
(Neither Listed in Annex II of IVDD, nor self-testing device)

CONFORMITY ASSESSMENT ROUTE : IVDD ANNEX Ⅲ

We here with declare that the above mentioned products meet the provisions of the council directive 98/79/EC for In Vitro diagnostic medical device. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED: IVD directive 98/79/EC, EN ISO 13485:2016, EN ISO 15193:2009, EN13612:2002, EN ISO 23640:2015, EN 14136:2004, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13975:2003, EN ISO 15194:2009, EN 13641:2002, EN 15223-1:2016, EN 62366:2008

PLACE, DATE OF ISSUE : Chungcheongnam-do, Republic of Korea, Mar 02, 2020

SIGNATURE : C. K. Chong
Chom-Kyu Chong, Ph.D.

CE

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 005332 0002 Rev. 00

Certificate Holder: **Genbody Inc.**
3-18 Eopseong 2-gil, Seobuk-gu
Cheonan-si, Chungcheongnam-do 31077
REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: **Design, Development, Manufacture and Distribution of In-Vitro Diagnostic Medical Device; Immunoassay and Molecular Diagnostic Reagents used in the Determination of Infectious Diseases, Metabolism and Hormone**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Brazil ANVISA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization

DUNS No: **68-945-1998**

Effective Date: **2019-04-25**

Expiry Date: **2022-04-24**

Date of Issue: 2019-04-29

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

TÜV®

ZERTIFIKAT ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認證證書 ◆ CERTIFICATE ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認證證書 ◆ CERTIFICATE ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認證證書 ◆ CERTIFICATE

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 005332 0002 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Facility(ies):

Genbody Inc.
3-18 Eopseong 2-gil, Seobuk-gu, Cheonan-si,
Chungcheongnam-do 31077, REPUBLIC OF KOREA

GenBody Inc.
3-12, Eopseong 2-gil, Seobuk-gu, Cheonan-si,
Chungcheongnam-do 31077, REPUBLIC OF KOREA

Facility Scopes:

GenBody Inc.
3-18 Eopseong 2-gil, Seobuk-gu, Cheonan-si,
Chungcheongnam-do 31077, REPUBLIC OF KOREA

Design, Development, Production and Distribution of In-Vitro Diagnostic Medical Device; Immunoassay and Molecular Diagnostic Reagents
DUNS No: 68-945-1998

GenBody Inc.
3-12, Eopseong 2-gil, Seobuk-gu, Cheonan-si,
Chungcheongnam-do 31077, REPUBLIC OF KOREA

Production of In-Vitro Diagnostic Medical Device; Immunoassay and Molecular Diagnostic Reagents
DUNS No: 68-945-1998

Date of Issue: 2019-04-29

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 005332 0001 Rev. 00

Holder of Certificate: **Genbody Inc.**
3-18 Eopseong 2-gil, Seobuk-gu
Cheonan-si, Chungcheongnam-do 31077
REPUBLIC OF KOREA

Facility(ies):
Genbody Inc.
3-18 Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungcheongnam-do 31077, REPUBLIC OF KOREA

GenBody Inc.
3-12, Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungcheongnam-do 31077, REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of In Vitro Diagnostic Medical Device – Immunoassay and Molecular Diagnostic Reagents**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74951612

Valid from: 2019-03-13
Valid until: 2022-03-12

Date, 2019-03-13

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV SÜD CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MADE IN S.KOREA ★ PREMIUM QUALITY ★

인정번호(No.) :KTR-ABBA-7312

의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

■ 업체명/허가번호(Company name of Applicant / License No.)
(주)젠바디/제 6504 호

GenBody Inc.

■ 대표자 (Representative)
김진수 (Jin Soo Kim)

■ 업체 소재지 (Company address of Applicant)
충청남도 천안시 서북구 업성2길 3-18 , 3-12

3-18, 3-12, Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 31077, Korea

■ 제조소명 (Name of Manufacturer)

제조자 : (주)젠바디(GenBody Inc.)

■ 제조소 소재지 (Address of Manufacturer)

제조자 : 충청남도 천안시 서북구 업성2길 3-18, 충청남도 천안시 서북구 업성2길 3-12

3-18, 3-12, Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 31077, Korea

■ 품목군 (Category)
체외진단 의료기기용 시약류(Reagent for In-Vitro Diagnostic Device)

의료기기 제조 및 품질관리기준에 적합함을 인정합니다.
(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product group listed above)

발행일자(Date of Issue) : 2020. 01. 07
유효기간(Date of Expiration) : 2023. 01. 06

대전지방식품의약품안전청장
DAEJEON REGIONAL FOOD AND DRUG ADMINISTRATION

KTR 한국화학융합시험연구원장
KOREA TESTING & RESEARCH INSTITUTE

GreenStory Global

국세청 nts.go.kr

발급번호 Issuance number	사업자등록증명 Certificate of Business Registration (법인사업자) (Corporate Taxpayer)	처리기간 Processing time
5320-924-7831-782		즉시 Immediately

상호(법인명) Name of company	주식회사 젠바디 (GenBody Inc.) Genbody Inc.
사업자등록번호 Business registration number	312-86-44225
성명(대표자) Name of representative	김진수 Kim Jinsoo
주민(법인)등록번호 Resident(Corporation) registration number	161511-0146253
사업장소재지 Business Address	충청남도 천안시 서북구 업성2길 3-18, (주)젠바디(업성동) 3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea
개업일 Date of business commencement	2012년(Year) 10월(Month) 17일(Day)
사업자등록일 Date of business registration	2012년(Year) 10월(Month) 18일(Day)
업태 Business type	제조업 Manufacturing
종목 Business item	진단용 항원항체 원료 Manufacture of Medicinal Chemicals and Antibiotics

공동사업자 Joint business owner	성명(법인명) Name(Name of company)	주민(사업자)등록번호 Resident(Business) registration No.
	해당사항 없습니다 (No Data)	

위와 같이 증명합니다.

I certify that above information is true and correct to the best of my knowledge and belief.

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담당부서 Department	민원봉사실 Taxpayer Service Center
담당자 Staff in Charge	전선빈 Jeon Sunbin
연락처 Telephone No.	041-559-8224

2020 년 1 월 21 일
Year Month Day

천안세무서장 (인)
Head of Cheonan District Tax Office (Stamp)

국세청 National Tax Service

* 본 증명의 위·변조 여부는 발급일로부터 90일 이내 「국세청 홈택스(www.hometax.go.kr) 또는 모바일 홈택스 > 민원증명(증명발급) > 민원증명 원본확인」에서 발급번호로 확인, 또는 문서 하단의 바코드로 확인이 가능합니다. (공문서를 위·변조하거나 행사한 자는 10년 이하의 징역에 처할 수 있습니다.)
* 본 증명은 홈택스(www.hometax.go.kr)에서 대민 온라인 서비스를 통해 발급된 증명서입니다.

About Pinnacle Biolabs

MADE IN THE USA

- Pinnacle Biolabs has partnered with Biomerics for production.
  - Biomerics also manufactures for Johnson & Johnson and Becton Dickinson.

- On-line production facilities in Utah and Texas. Costa Rica for international manufacturing.

- Pinnacle Biolabs is well established in the Rapid Test space (pregnancy tests, colon cancer screening, etc.) with retail sales at Walmart, Rite Aid, CVS, and more.

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Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test

Results in Minutes:

All components proudly

MADE IN THE USA

[Read Pinnacle BioLabs' COVID-19 Coronavirus Dual IgG/IgM Rapid Test Product Specifications Master Sheet HERE].

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Package Insert

Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test Package Insert

Intended Use

The Pinnacle BioLabs COVID-19 Novel Coronavirus (COVID-19)IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is a lateral flow immunoassay for the qualitative detection and differentiation of IgG and IgM of Novel Coronavirus(COVID-19) in human whole blood, serum or plasma. This test is intended to be used as an aid in the diagnosis of infection with Novel Coronavirus. Any reactive specimen with the Novel Coronavirus(COVID-19)IgG/IgM Rapid Test must be confirmed with alternative testing method(s) as this test is currently distributed under an Emergency Use Authorization by the FDA. **For professional use only. This test has not been reviewed by the FDA. Negative results do not rule out SARS- CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. 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. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E. Not for the screening of donated blood.**

Summary and Explanation of the Test

Coronavirus (CoV) belongs to the genus Nestovirus, Coronaviridae, and is divided into three genera: α, β, and γ. The α and β gene are only pathogenic to mammals. The γ gene mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route.

So far, there are 7 types of human coronaviruses (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and Novel Coronavirus(COVID-19 (2019)), is an important pathogen of human respiratory infections. Among them, a COVID-19 was discovered in 2019 due to Wuhan virus pneumonia cases. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough, dyspnea and so on. It can quickly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc., and even life-threatening.

Test Principle

The Pinnacle BioLabs COVID-19 Novel Coronavirus (COVID-19)IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant COVID-19 antigen conjugated with colloid gold (COVID-19 conjugates) and quality control antibody gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band

Test Principle (continued)

(C band). The T1 band is pre-coated with monoclonal anti- human IgG for the detection of IgG anti-COVID-19, T2 band is pre-coated with reagents for the detection of IgM anti-COVID-19 and the C band is pre-coated with quality control antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. COVID-19 IgM antibodies if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored T2 band, indicating COVID-19 IgM positive test result.

COVID-19 IgG antibodies if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored T1 band, indicating a COVID-19 IgG positive test result.

Absence of any test bands (T1 and T2) suggests a negative result. The test card also contains a quality control band C. Regardless of the presence or absence of a detection band, the red quality control band C should appear. The quality control band is a color band of the quality control antibody immune complex. If the quality control band C does not appear, the test result is invalid, and the sample needs to be tested again with another test card.

Kit Components

- *25 Individually wrapped test cassette device(s)*
- *Disposable pipette(s)*
- *5 mL buffer*
- *Package insert*
- *Quick Reference Guide*

Materials Not Provided

- *Timer*

Storage and Stability

Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse test. The kit should be stored at 2~30°C in cool and dry place, protected from light. After opening the aluminum foil pouch, the test card will become invalid due to moisture absorption. Therefore, it is important that the test is performed and resulted within one hour of opening the individually wrapped foil cassette.

Specimen Collection and Preparation

The kit can be performed using a whole blood (finger-stick) specimen [recommended], or plasma or serum samples prepared from commonly used anticoagulants (EDTA, heparin, sodium citrate). Testing should be performed immediately after specimen collection. **For Serum and Plasma Only:** If the test cannot be performed immediately, the serum and plasma specimen to be tested can be stored at 2 ~ 8 °C for 5 days. For long-term storage, store at -20 °C. Avoid repeated freeze-thaw specimens. Anti-coagulated whole blood specimens should not be stored for more than 72 hours at room temperature; not more than 7 days at 2-8 °C. Before testing, slowly return the refrigerated or frozen specimens to room temperature and mix them gently. When clearly visible particulate matter is present in the specimen, it should be centrifuged to remove sediment before testing. If the specimen contains a large amount of lipid, hemolysis or turbidity, please do not use it, so as not to affect the result judgment.

Assay Procedure

1. Place the test device on a clean, flat surface. After washing your hands, choose the non-dominant hand and face it palm side up. Remove the cap from the finger-stick device and use the disposable finger-stick device to stick the ring finger. It is recommended to wipe off the first droplet of blood with the provided gauze pad. **For Serum and Plasma Only:** Bring the specimen and test components to room temperature if refrigerated or frozen.

2. Fill the pipette dropper with the blood specimen. Holding the dropper vertically, dispense 1 drop (about 10 µL) of whole blood (include finger blood),serum, plasma into the sample well, making sure that there are no air bubbles. Then add 2 drops (about 70-100 µL) of Sample Diluent immediately.

3. Set up timer for 15 minutes. Read and record results at the 14-15 minute mark. **It is important not to read results after 15 minutes.**

Negative Result

If only the C band is present, the absence of any burgundy color in the both test bands (T1 and T2) indicates that no COVID-19 antibody is detected in the specimen. The result is negative.

Presumptive Positive Result
(Must be verified by HHS approved facility)

In addition to the presence of the C band, if the T1 band is visible, the test indicates the presence of the COVID-19 IgG antibody. The result is a presumptive positive and additional confirmation testing is immediately needed.

In addition to the presence of the C band, if the T2 band is visible, the test indicates the presence of the COVID-19 IgM antibody. The result is a presumptive positive and additional confirmation testing is immediately needed.

In addition to the presence of the C band, if both the T1 and T2 bands are visible, the test indicates the presence of both COVID IgG and IgM antibodies. The result is a presumptive positive and additional confirmation testing is immediately needed.

Invalid Result

If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands. Repeat the assay with a new device.

Package Insert

Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test Package Insert (continued)

Performance Characteristics

1. Positive Coincidence Rate: The test results of positive quality control are all positive. 2. Negative Coincidence Rate: The test results of negative quality control are all negative. 3. Analytical Specificity: The test results of specimen from non- infected by novel coronavirus should be negative.
4. Analytical Sensitivity: The detection result is positive when detection of a novel coronavirus IgG strongly positive serum 1:50 dilution sensitivity reference : The detection result is positive when detection of a novel coronavirus IgM strongly positive serum 1:50 dilution sensitivity reference.
5. Intra-Assay: There is no different test results of the same quality control in the same batch. 6. Inter-Assay: There is no different test results of the same quality control from different batch.

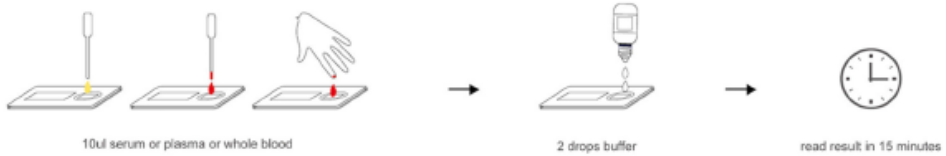
Limitations of the Test

1. The Assay Procedure and the Assay Result Interpretation must be followed strictly when testing. Failure to follow the procedure may give inaccurate results. 2. This kit is only used for in vitro diagnosis and is only used for qualitative detection of Coronavirus IgG and/or IgM antibodies in blood samples. 3.Positive and negative results indicate the presence of IgG and/or IgM antibodies with/without detectable concentrations of Coronavirus in blood samples, but cannot be used as the sole criterion for the determination of Coronavirus infection. Other methods (such as nucleic acid testing) should be used for identification when necessary, and comprehensive judgment should be made based on the test results. All positive results should be deemed presumptive positives and appropriate follow-up testing should be immediately sought.

Warnings and Precautions

1. Before using the kit, please read the instructions carefully and control the reaction time strictly. 2. Inadequate blood supply may deliver inaccurate results. Be sure to deliver adequate blood supply to the sample well. It is strongly encouraged to use the accompanying pipette, ensuring 10 µL is delivered to the sample well of the cassette. 3. Do not allow the product to get wet. 4. Do not dilute the specimen for testing. 5. Dispose of kit in accordance with infectious disease protocol. 6. Special Statement from the US Food and Drug Administration: For professional use only. This test has not been reviewed by the FDA. Negative results do not rule out SARS- CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. 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. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E. Not for the screening of donated blood.

Sample Collection



Results Interpretation

Excluding the pipette bulb, ensure the pipette is filled half way up the conduit with no bubbles or visible air

Failure to deliver adequate blood supply to the sample well may lead to inaccurate results. The following guide shows sample collection from WB/S/P.

If using the device outside of a clinical laboratory setting, it is recommended to use the included pipette. To deliver adequate blood supply, exclude the bulb and draw 50% up the remainder of the conduit, pursuant to the image to the left.

References

1. Catherine I. Paules MD; Hilary D. Marston, MD, MPH; Anthony Fauci, MD. Coronavirus Infections - More than the common cold. JAMA 2020; 323 (8)

2. Prof Roujian Lu MSc, Xiang Zhao Md, Juan Li PhD, et al. Genomic characterization and epidemiology of 2019 Novel Coronavirus implications for virus origins and receptor binding. The Lancet, Volume 395 Issue 10224.

3. B. Coutard, C. Valle, X. de Lamballerie, et al. The spike glycoprotein of the new coronavirus 2019- nCOV contains a burin-like cleavage site absent in CoV of the same clade. Antiviral Research, Volume 176. April 2020.

Index of Symbols

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalog #

Pinnacle BioLabs
315 Deaderick Street
15th Floor
Nashville, TN 37238
United States of America
www.PBLabs.com
1.800.609.6419

PINNACLE BIOLABS

MADE IN THE USA

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Independent Studies

George Mason University
Microbiome Analysis Center
Department of Biology
Science and Technology Campus, MSN 4D4
10900 University Boulevard, Manassas, Virginia 20110
703-993-1057
703-993-8430 FAX

April 8, 2020

Pinnacle BioLabs
315 Deaderick Street
UBS Tower 15th Floor #1550
Nashville, TN 37238

RE: Clinical Trial using Pinnacle BioLabs Covid-19 Immune kits

I would like to thank you and Pinnacle BioLabs for supplying the Covid-19 Dual IgG/IgM Rapid Immune test to George Mason University to be used in their current surveillance trial. Your rapid response to our request will greatly expedite the studies implementation.

We will be initially focused on monitoring asymptomatic volunteers in an attempt to determine the true infection rate in the population and the course of viral dynamics and seroconversion in this cohort. Additionally, we will be assaying a number of serum and saliva samples from hospitalized patients in Italy and determine the course of viral dynamics and seroconversion in that cohort.

We will be comparing your configuration to several other diagnostic tests and will be suppling you with a report on the results of the study.

Again we would like to thank both you and the Pinnacle BioLab team for responding to this unprecedented crisis in the nation.

Sincerely,
Patrick M. Gillevet

Director, Microbiome Analysis Center
Professor, Department of Biology
Associate Dean of Research, College of Science

[Read the Delaware Final Study here].

[Read the Delaware follow-up from Dr. Richard Pescatore, Chief Physical at the Delaware Department of Health and Social Services Division of Public Health here].

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Section 1: Identification

Trade Name: **Pinnacle BioLabs Covid-19 Novel Coronavirus Dual IgG/IgM Rapid Test**

Part Number: **Suitable for Part Numbers: COV25 UPC; 5mL COV25; 1mL COV25**

Manufactured by: **Pinnacle BioLabs**
Street Address: **315 Deaderick Street, 15th Floor**
City, State, Zip, Country **Nashville, TN 37238 United States of America**
Telephone Number: **1-800-609-6419**
Fax Number: **1-800-609-9321**

Section 2: Hazard(s) Identification

Emergency Overview- NOT HAZARDOUS

Device: Lead and other heavy metals-not used in/on device.
Desiccant granules sealed within packet non-toxic but can be irritant.

Bottle(s): 1x Phosphate buffer solution (PBS) preserved with < 0.02% Sodium Azide. The product contains no substance which at their given concentration are considered to be hazardous to health according to Directive 67/548/EEC.

Section 3: Product Composition/Information on Ingredients

Diagnostic test strip(s) with/without plastic cassette packaged in foil pouch with desiccant packet. Kit also includes plastic bottle with wash buffer.

Section 4: First Aid Measures

Rinse eyes if contacted by desiccant granules or buffer solution. If ingested, contact a physician.

Section 5: Fire Fighting Measures

As appropriate to plastic and paper (water, carbon dioxide, dry chemical, foam).

Section 6: Accidental Release Measures

Not applicable to device. Spilled buffer should be wiped up directly and the area cleaned.

Section 7: Handling and Storage

Room temperature (59-86°F / 15-30°C) storage for product longevity-more extreme conditions do not present safety hazard.

Section 8: Exposure Controls/Personal Protection

Not applicable to device. Applicable PPE for use environment.

Section 9: Physical/Chemical Properties

Appearance:	Test strip or plastic cassette in foil pouch	Buffer in plastic bottle
Physical Properties:	Odorless, solid	Odorless, liquid

Other (boiling point, solubility, pH, etc.): not applicable

Safety Data Sheet

Section 10: Stability and Reactivity

Stability: Stable

Reactivity: No dangerous reactions known for device.
See insert or Certificate of Analysis for use of individual products.
Sodium Azide is at a concentration (< 0.02%) much lower than that which is potentially reactive with metals and other substances.

Hazardous Polymerization: will not occur.

Hazardous Decomposition Products and Incompatibility-not known.

Section 11: Toxicological Information

Route of exposure: skin contact, eye contact, inhalation: granules within desiccant packet non-toxic but can be irritant.

Section 12: Ecological Information

No applicable information.

Section 13: Disposal Consideration

Device itself may be disposed as solid waste. Devices tested with patient samples should be handled as potentially biohazardous materials in accordance with federal, state and local regulations. The amount of Sodium Azide in the wash buffer will not cause disposal problems.

Section 14: Transport Information

Proper Shipping Name: None

Kits and devices: not dangerous, not hazardous and not restricted to transport by IATA.

Section 15: Regulatory Information

Not restricted for safety reasons.

Section 16: Other Information

The above information is believed to be correct but is not intended to be all inclusive and shall be used only as a guide.

Documentation

MADE IN THE USA

PINNACLE BIOLABS

CE

Declaration of Conformity

Product Designation: Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test

Model No(s): CV25
EAN: 029741887695

We herewith declare that the products listed above are in compliance with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning In-Vitro-Diagnostic Directive 98/79/EC. The Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Conformity Assessment Procedure: Annex III (IVD 98/79/EC)

Classification of the product:

General, Not a referred product in Annex II, List A and List B
EDMA Code: 15.04.80.90.00 - Other Virology (Infectious immunology)
Other Viral Antigen/Antibody Detection

Applied Harmonized Standards:

EN 13640:2002	Stability Testing of in Vitro Diagnostic Reagents
EN ISO 14971:2019	Medical devices - Application of risk management
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General Requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use

EU Authorized Representative: Zhuhai Encode Medical Engineering CO., LTD
℅ Prolinx GmbH
Brehmster, 56
40239, Dusseldorf, Germany

Company Name: Pinnacle BioLabs
315 Deaderick Street
15th Floor
Nashville, TN 37238

Megan Peters, Director of Operations

Signature

20 February, 2020
Date

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 23493 rev.4

e que le système de management de la qualité développé par
certifies that the quality management system developed by

BIOMERICS, LLC
6030 W Harold Gatty Drive
Salt Lake City, UT 84116, UNITED STATES

pour les activités
for the activities

fabrication de matériaux polymères, préparations de composés, injection et sous-traitance d'assemblage de produits médicaux

manufacturing of polymeric materials, compounding, injection molding and contract assembly of medical products

réalisées sur le(s) site(s) de
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BIOMERICS, LLC
6030 W Harold Gatty Drive, Salt Lake City, UT 84116 USA

conforme aux exigences des normes internationales
plies with the requirements of the international standards

ISO 13485:2016

date : **January 14th, 2019 (included)**
te : **June 17th, 2021 (included)**
ary 14th, 2019

GMED

On behalf of the President
Béatrice LYS
Technical Director

selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

493-3

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Together, we can lead the way to helping reopen America safely

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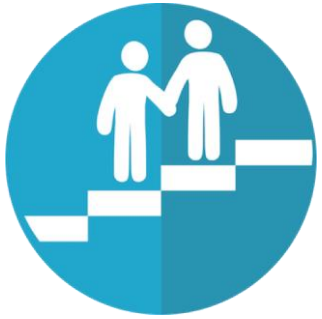
Working with GreenStory Global!

Quick Turnaround

We understand timing is critical and things need to get done quickly. Our process is efficient.

Certified Supplies

All supplies and suppliers are properly vetted and certified.



Partnership Approach

Our relationship selling approach ensures we share the same mission – enabling a safer tomorrow.

Experienced Team

Team of industry professionals with decades of healthcare experience.

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Pricing & Payment Terms

Pricing available upon request

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