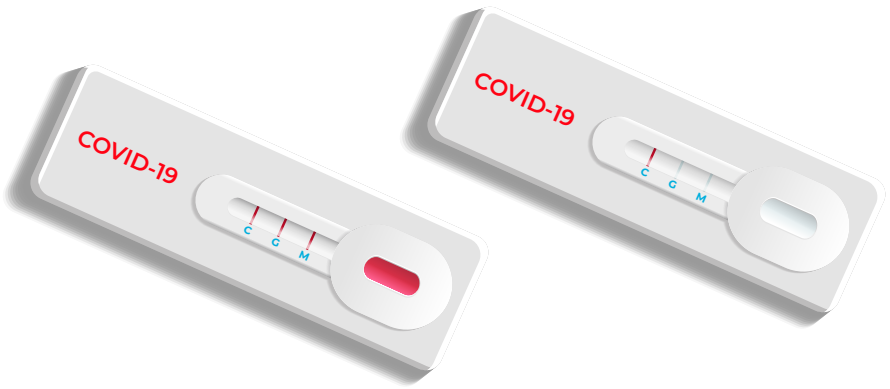
Sprise India Pvt. Ltd

SENSIT COVID-19 IgG/IgM RAPID

One Step Test for SARS Cov-2 (COVID-19) Antibody



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GSTN : 32ABECS1862J1ZC

One Step Test for
SARS CoV-2 (COVID-19)
IgM/IgG Antibody

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CDSCO APPROVED

PRODUCT CHARACTERISTICS

Results in 15 minutes or sooner

Samples needed: Fingertip blood/ Whole blood/ Serum/ Plasma

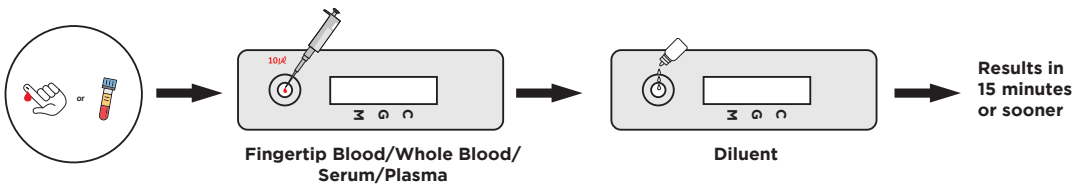
Tests both IgM and IgG to improve sensitivity

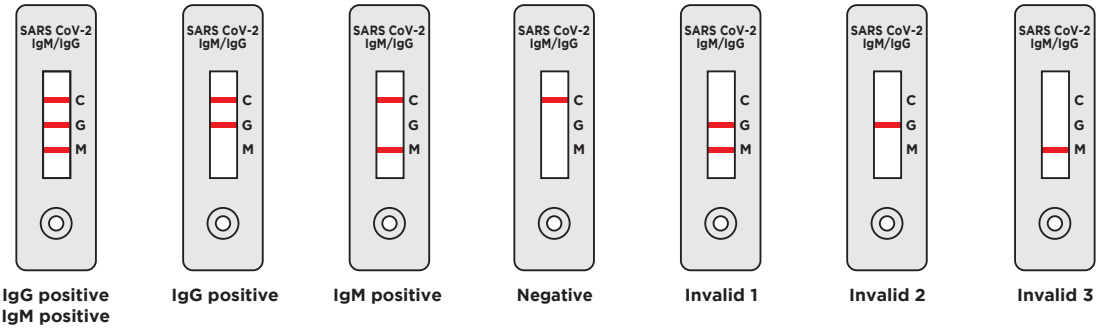
Use in combination with RT-PCR for better diagnosis

"Read Test Results Directly
No Expensive Equipments Needed"

PRODUCT CODE	HSN CODE	PRODUCT NAME	PACK SIZE
SO60-01	30029090	COVID-19 IgG/IgM RAPID TEST	1OT, 25T

OPERATION AND TEST RESULTS





APPLICATIONS

Early diagnosis and screening for COVID-19
Rapid screening for primary health institutions
Screening for public institutions
Regular screening for volunteers

Manufactured by ubio (ubiquitous.biology)

Marketed By Sprise India Pvt. Ltd

IVD CE

ICMR RGCB DISCOVERIES FOR A BETTER TOMORROW

GMP ISO 13485:2016 IAS MAKE IN INDIA

COVID-19 IgG/IgM Rapid Test

In vitro diagnostics REF S060-01

INTENDED USE

Sensit COVID-19 IgG/IgM Rapid Test Kit is a qualitative immuno chromatographic assay for the detection of IgG & IgM antibodies produced against COVID-19 virus in human whole blood/Serum/ Plasma. Sensit COVID-19 IgG/IgM Rapid Test Kit is only intended for initial screening and reactive samples should be confirmed by a supplemental assay.

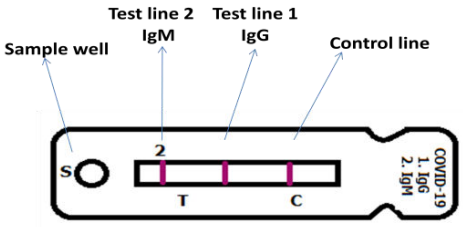
SUMMARY &TEST DESCRIPTION

COVID-19 [Coronavirus Disease- 2019] is an infectious disease caused by SARS-CoV2 [Severe Acute Respiratory Syndrome coronavirus 2] virus, which is a contagious, novel strain of Coronavirus that emerged from Wuhan, China in December 2019, which grew as a pandemic threatening human survival across the globe. The virus is thought to be of zoonotic origin and likely to have spread from large seafood and animal markets by human-animal contact in the city of Wuhan, where consumption of such products is in large. The virus causes respiratory infection with symptoms including fatigue, fever, shortness of breath, respiratory failure, renal failure and death. Patients can become infected with SARS-CoV-2 virus by person-person contact (through contact with a contaminated environment or person). The young and old (and other immune-compromised individuals) are most at risk of serious complications; however, approximately 20% of those infected can develop a critical condition.

Sensit COVID-19 IgG/IgM Rapid Test device utilizes Anti-human IgG and Anti-human IgM antibodies as the capture molecules. COVID-19 Recombinant Antigens-colloidal gold conjugate are used as detection antigen.

TEST PRINCIPLE

Sensit COVID-19 IgG/IgM Rapid Test works on chromatographic immunoassay. Basic components of test strip includes: a) Conjugate pad which contains COVID-19 Recombinant Antigens; colloidal gold conjugated; b) a nitrocellulose membrane strip containing three lines; 2: Anti-Human IgM, 1: Anti-Human IgG and C: Goat Anti-Mouse antibody.



Test sample that is added to the well (S), with adequate amount of buffer added to the same well (S) migrates from the sample pad along the conjugate pad, where COVID-19 specific IgG/IgM antibodies present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zone, where the complex accordingly will bind to the immobilized Anti-Human IgG/IgM antibodies (on test lines) producing a visible line on the membrane. If the respective antibody is not present in the sample, no reaction occurs in the capture zone and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended and thus serves as a procedural control.

CONTENTS

1. Each test kit contains 10 test devices, each sealed in a foil pouch containing following items:
   a. One COVID-19 IgG/IgM test card and dropper
   b. Desiccant
2. Assay Diluent- In dropper bottle
3. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTIONS & WARNING

1. This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
2. Test results should be read between 10 and 15 minutes after a specimen is applied to the sample well. Results read after 20 minutes may give erroneous results.
3. Do not open the sealed pouch until you are ready to conduct the assay. Once opened, the cassettes should be used immediately.
4. Do not use expired devices.
5. Bring all reagents to room temperature (15-30°C) prior to use.
6. Do not mix components from different kits. Use only the buffer supplied along with the kit.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as biohazardous waste.
10. Handle the negative and positive controls in the same manner as patient specimens for operator protection.
11. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.
12. Do not touch result window.
13. Use only for in-vitro diagnostic purpose.

SAMPLE COLLECTION & PREPARATION

- Blood Specimen: Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.
- Serum: Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.
- If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.
- For storage period longer than 5 days, freezing is recommended.
  Store at -20^{0}C
- The specimen should be brought to room temperature prior to use.

Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 10 µl of specimen to the sample well marked 'S' using the dropper provided.

3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the same well on the cassette, marked 'S'.
4. Wait for 10-15 minutes and interpret the results. Do not read results after 20 minutes. All results where control band does not appear are considered invalid

TEST RESULTS

Positive (+)

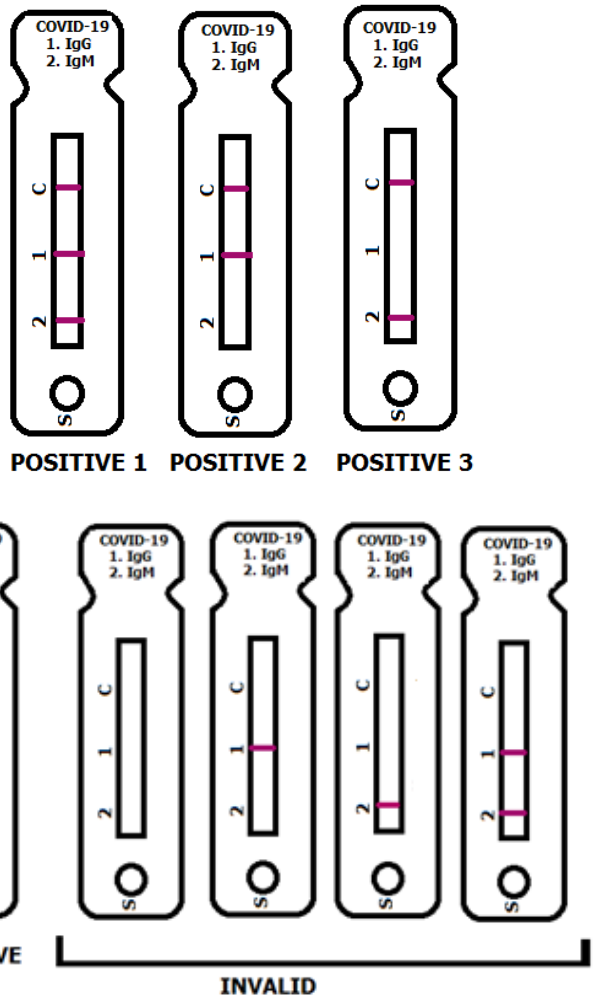
1. All Positive: Colour bands at C, 1 & 2 positions. COVID-19 IgG and IgM antibodies present in the sample.
2. Colour band at C & 1; Only COVID-19 IgG Present in the sample
3. Colour band at C & 2; Only COVID-19 IgM Present in the sample

Negative (-)

1. Negative: Colour band only at C; COVID-19 antibodies absent in the sample

Invalid:

No colour band at Control line C



LIMITATIONS

1. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of COVID-19 /SARS-CoV-2 virus specific IgG and IgM antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. Sensit COVID-19 IgG/IgM Rapid Test is limited to the qualitative detection of antibodies specific for the SARSCoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
3. A negative or non-reactive result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody utilized in the test.
4. If symptoms persist and the result from Sensit COVID-19 IgG/IgM Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.
5. The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations.
6. This test should not be used for screening of donated blood

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in COVID-19 IgG/IgM Rapid Test for single-step detection of novel Coronavirus [COVID-19] IgG and IgM antibodies are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
Σ X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use.

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Sensit COVID-19 IgM/IgG Antibody Test

Immunoglobulin M (IgM) is found mainly in the blood and lymph fluid, is the first antibody to be made by the body to fight a new infection. IgM provides the first line of defense during viral infections.

Next is the creation of the Immunoglobulin G (IgG) which is associated with long term immunity and immunological memory. Testing of COVID-19 IgM and IgG antibodies is an established and effective method for the rapid diagnosis of COVID-19 infection.

The detection of COVID-19 IgM antibodies is an indication of a recent exposure to COVID- 19, while the detection of COVID-19 IgG antibodies indicates a later stage of infection. Sensit combined antibody test can provide information on the stage of infection.

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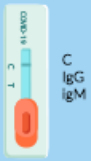
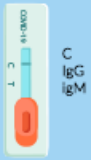
Diagnostics Results Interpretation

	Results	COVID-19 Symptoms	Results Interpretation	Need for PCR Test	Employee Status YES! NO! Join Work?
	IgM − IgG −	 Employee **DOES NOT** Show COVID-19 Symptoms	 Employee is COVID-19 **INFECTION FREE**		 Free To Join Work Place **YES!**
	IgM − IgG −	 Employee **SHOWS** COVID-19 Symptoms	 Indicates **NEW** COVID-19 Infection **Isolate Employee**	 Proceed Immediately for PCR Testing	 Seek Medical Advice For Treatment **NO!**
	IgM + IgG −	 Employee **MAY OR MAY NOT** show Symptoms	 Indicates **RECENT** COVID-19 Infection **Isolate Employee**	 Confirmation Test Recommended	 Seek Medical Advice For Treatment **NO!**
	IgM − IgG +	 Employee **DOES NOT** Show COVID-19 Symptoms	 Indicates Patient is in **LATE STAGE** of Infection or in **RECOVERY**	 Confirmation Test Recommended	 Free to Join Work After Confirmation Test **YES!**
	IgM + IgG +	 Employee **MAY OR MAY NOT** show Symptoms	 Indicates **ACTIVE** COVID-19 Infection **Isolate Employee**	 Confirmation Test Recommended	 Seek Medical Advice For Treatment **NO!**

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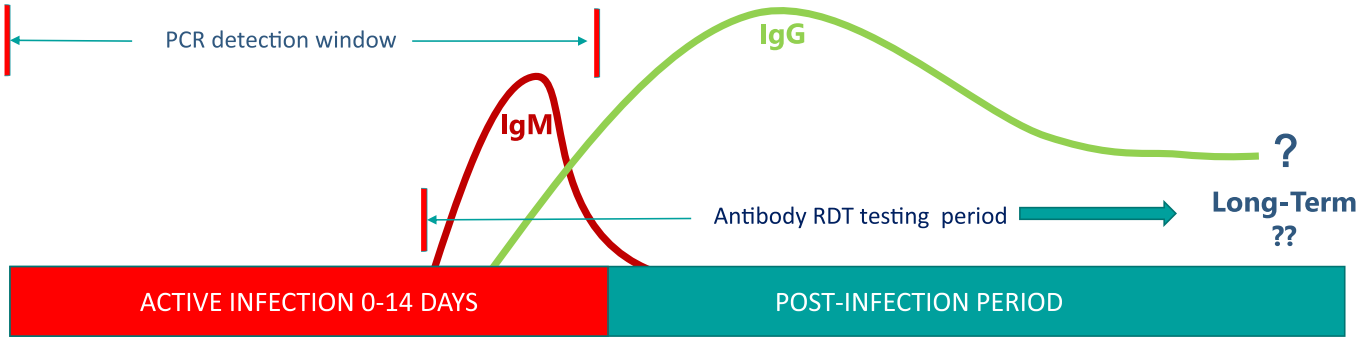
PCR and Antibody Test

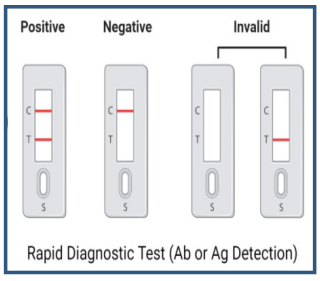


- Genetic material of the virus can be found in the nasopharyngeal area
- Antibody production likely to begin at the end of the second week of infection
- Genetic material of the virus can no longer be reliably found in the nasopharyngeal area
- **Only antibody testing** can reveal a person's past exposure to COVID-19 and potential immunity at this stage

PCR VS Rapid Test

PCR	Rapid Test
Requires trained laboratory staff and technicians to collect samples and perform the tests	No special training, nurses and frontline healthcare workers can do it
Laboratory Equipment/PCR machine/dedicated laboratories	No special equipment
Disposables tubes/swabs etc. (current global supply shortage for swabs)	Few disposables
Duration-up to 6+hrs to get result	FAST EASY-10-15 minutes


Real-Time PCR



Rapid Diagnostic Test (Ab or Ag Detection)

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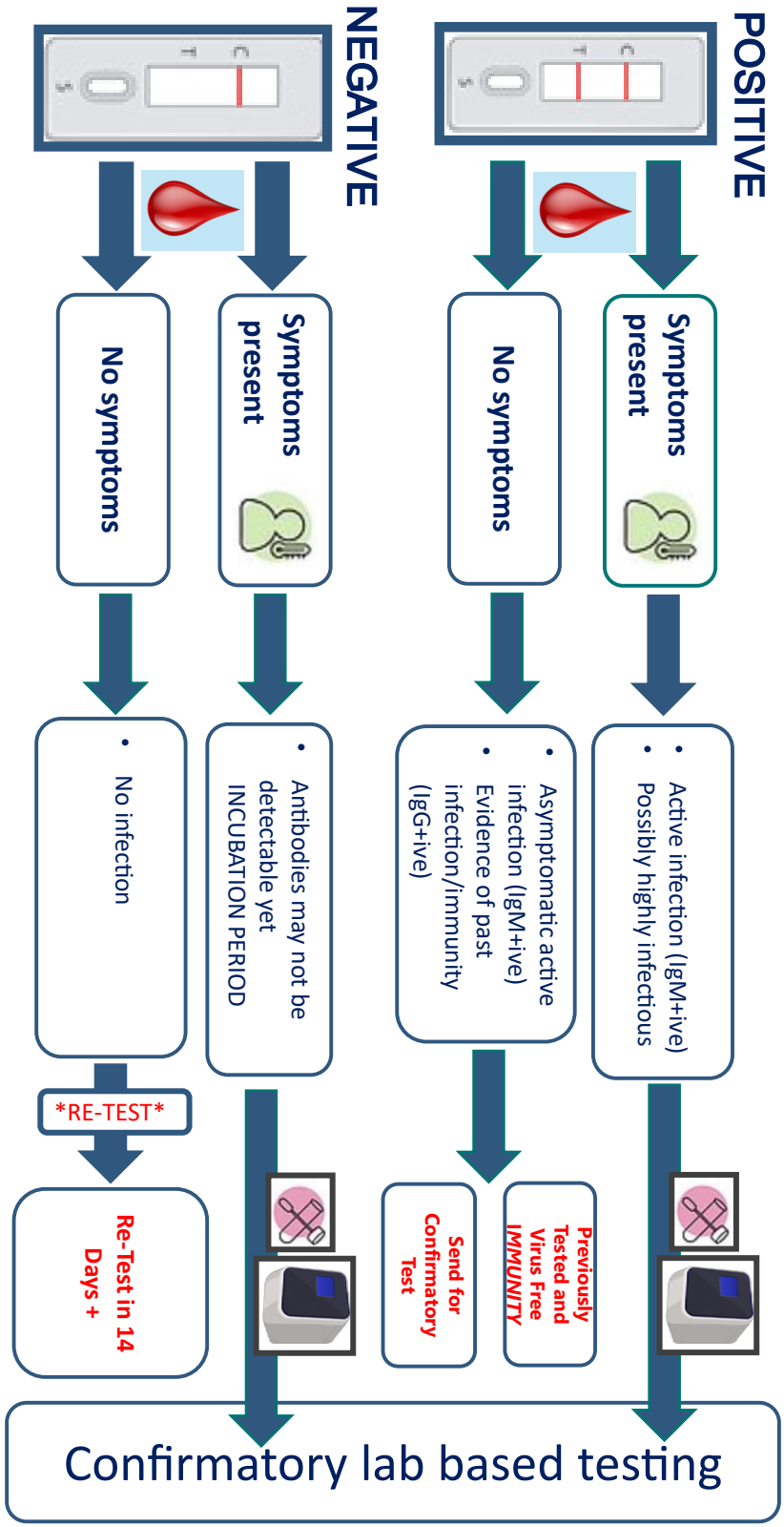
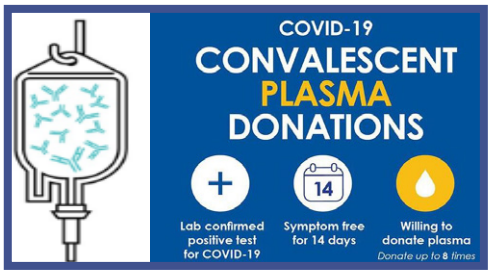
Interpreting Rapid Test COVID-19 IgM/IgG Results



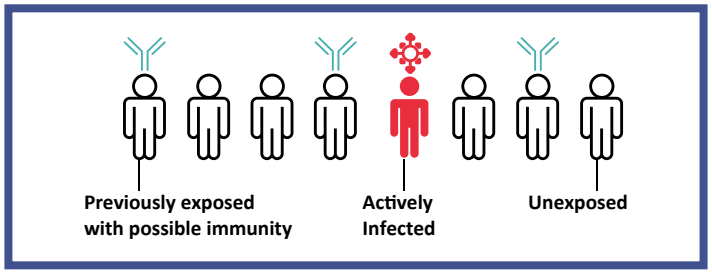
Why the Low Confidence In Rapid Test For COVID-19 screening

- **Widespread misunderstanding** of Rapid Test and their place in COVID-19 detection and surveillance
- The attempt to use Rapid Test **solely as a definitive clinical diagnosis of *active*** COVID-19 infection
- **Comparing** results of **Rapid Test directly with PCR** to measure accuracy
- It should be used for **Mass Screening Purposes**
- It Help to get results and reports can be used as **'Immunity Passports' for People to Re-enter the Workforce and Travel**
- It used to **Identify Plasma Donors**

Immunity Passports



Convalescent Plasma Donation



Calculating 'Herd Immunity'

RAPID TESTS ARE NOT A DEFINITIVE CLINICAL DIAGNOSIS OR A LIKE-FOR-LIKE ALTERNATIVE TO PCR

Our Other Testing Products

- HCG (PREGNANCY TEST) CASSETTE
- HCG (PREGNANCY TEST) STRIPS)
- LH
- MALARIA PF/PV Ag
- MALARIA PF/PAN Ag
- MALARIA PAN Ag
- MALARIA PF Ag
- SYPHILIS Ab
- HEPATITIS B Ag
- HCV AB
- HIV ½ AB
- TYPHOID IGG/IGM
- TYPHOID IGM
- BRUCELA IGG/IGM
- DENGUE IGG/IGM
- DENGUE NS1
- DENGUE IGG/IGM-NS1 COMBO
- LEPTOSPIRA IGG/IGM
- H. PYLORI AB
- H.PYLORI AG
- LEISHMANIA AB
- V. CHOLERA AG
- ROTA/ADENO STRIP
- CRP
- PCT
- INFLUENZA A+B
- ROTA-ADENO
- Covid-19 Antigen Test
- Covid RT-PCR Test

THANK YOU

Manufactured by

ubio Biotechnology Systems Pvt Ltd

Marketed By

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