ImmunoScience INDIA

ImmunoQuick

COVID-19 IgM/IgG

Rapid Test for Detection of Novel Coronavirus (COVID-19) IgM/IgG Antibodies - Device

For *In-Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

OVERVIEW

A pandemic of respiratory disease spreading from person-to-person is caused by a novel (new) coronavirus. The disease has been named "coronavirus disease 2019" (abbreviated "COVID-19"). This situation is posing a serious public health risk. COVID-19 can cause mild to severe illness; most severe illness occurs in older adults. Coronaviruses, named for the crown-like spikes on their surface (Latin: corona = crown), are positive-sense RNA viruses that belong to the Coronaviridae subfamily, in the Coronaviridae family of the Nidovirales order. They have four main subgroups-alpha, beta, gamma, and delta-based on their genomic structure. Alpha-and beta coronaviruses infect only mammals, usually causing respiratory symptoms in humans and gastroenteritis in other animals. Until December of 2019, only six different coronaviruses were known to infect humans. Four of these (HCoV-NL63, HCoV-229E, HCoV-OC43 and HKU1) usually caused mild common cold-type symptoms in immunocompetent people and the other two have caused pandemics in the past two decades. In 2002-2003, the severe acute respiratory syndrome coronavirus (SARS-CoV) caused a SARS epidemic that resulted in a 10% mortality. The Director-General, WHO has declared that the outbreak of 2019-nCoV constitutes a Procedures concerning Public Health Emergencies of International Concern (PHEIC). The COVID-19 viral disease that has swept into more than 188 countries and has killed more than 72,000 and has been officially declared a pandemic by World Health Organization. In the wake of spurt in cases of corona virus pandemic in the country, the Ministry of Home Affairs, Government of India on March 14, 2020 has decided to treat COVID-19 as a Notified Disaster.

INTENDED USE

ImmunoQuick COVID-19 is a Rapid, Qualitative, Immunochromatographic test for detection of IgM and IgG Antibodies to COVID-19 Virus in human serum/plasma/whole blood.
This test is for healthcare professional use only.

PRINCIPLE

ImmunoQuick COVID-19 Rapid Test for Detection of Novel Coronavirus (COVID-19) IgM/IgG Antibodies (Serum/Plasma/Whole Blood) consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region, if the specimen contains IgG antibodies to COVID-19. A colored line will appear in IgG test line region as a result of this. Similarly, anti-human IgM is coated in IgM test line region and if specimen contains IgM antibodies to SARS-CoV-2, the conjugate-specimen complex reacts with anti-human IgM. A colored line appears in IgM test line region as a result. Therefore, if the specimen contains COVID-19 IgG antibodies and the specimen contains SARS-CoV-2 IgM antibodies a colored line will appear in IgG and IgM test line region. If no colored line will appear in test line regions, indicating a negative result. To serve as a procedural control, a colored line should always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

CONTENTS OF KIT

1. Test Device with desiccant
2. Plastic Dropper
3. Assay Buffer
4. Package Insert

OPTIONAL MATERIAL REQUIRED

1. Timer
2. Alcohol swab
3. Lancet
4. Disposable Gloves

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Wash hands thoroughly after finishing the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the test device.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose off hygienically in biohazard waste.
5. Do not touch the membrane.
6. Treat samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.

SPECIMEN COLLECTION

1. For serum samples, Collect blood in a tube without anticoagulant and allow it to clot.
2. For plasma samples, collect blood in a tube containing anticoagulant.
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolysed specimens.
4. Whole blood samples may be collected by finger prick or venipuncture. Whole blood samples should be tested immediately or can be stored up to 24 hours at 2 to 8°C if collected in a tube containing anticoagulant.

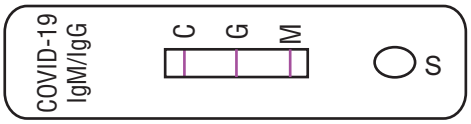
TEST PROCEDURE

1. Allow the kit components and samples reach to room temperature (20°C to 30°C) before opening the foil pouch.
2. Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle .
3. Remove the test device, desiccant and plastic dropper from the pouch and use it as early as possible.
4. Add one drop (10 µl) of serum or plasma sample or add two drops (20 µl) whole blood in well 'S' and add two drops (Approx. 60µl) of assay buffer in same well 'S'.
5. Start the timer.
6. Read the result at 15 minutes. Do not read the result after 20 minutes.

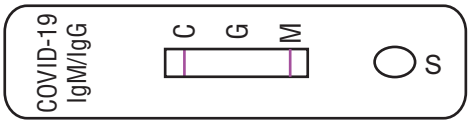
INTERPRETATION OF RESULTS

Negative: A colored line appears at the control region 'C' only.

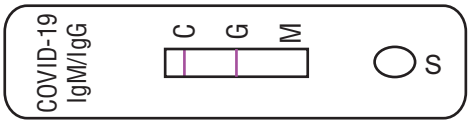
Positive for COVID-19 IgG and IgM Ab - A distinct colored line appears at the control region 'C' and at the test region 'IgG' and 'IgM'



Positive for COVID-19 IgM Ab - A distinct colored line appears at the control region 'C' and at the test region 'IgM'

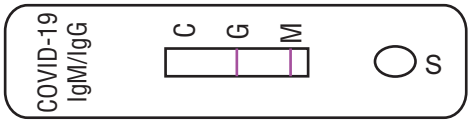


Positive for COVID-19 IgG Ab - A distinct colored line appears at the control region 'C' and at the test region 'IgG'.

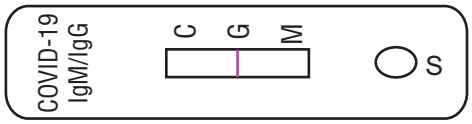


Invalid: The test should be considered invalid if,
A) no line appears at 'C' region, 'IgG' and 'IgM' region.

B) No line appears at 'C' region and line appear at 'IgM' and 'IgG' region.



C) No line appears at 'C' and at 'IgM' region and line appear at 'IgG' region.



D) No line appears at 'C' and at 'IgG' region and line appear at 'IgM' region.

NOTE: The intensity of the color of test lines will vary depending upon the antibodies present in specimen.

PERFORMANCE CHARACTERISTICS

Internal Evaluation:

75 negative samples tested, no false positive results were observed. Cross reactivity studied with dengue positive serum samples. No cross reactivity observed.

External Evaluation:

ImmunoQuick COVID-19 IgM/IgG test Devices were evaluated and approved at "ICMR - National Institute of Virology, Department of Health Research, Ministry of Health & Family welfare. Govt. of India (Pune)".

LIMITATIONS

1. There is always possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer such as technical or procedural errors associated with the testing.
2. Although the test demonstrates the superior accuracy in detecting antibodies against COVID-19 virus, a low incidence of false results can occur. Therefore, other clinically available test required in case of questionable results. As with all diagnostic test a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
3. Humidity and temperature can adversely affect results.
4. The instruction for the use of the test should be followed during testing procedure.
5. The product provides qualitative, not quantitative detection of COVID-19 IgM and IgG Antibody.

DISCLAIMER

The all precaution shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results. This test provides presumptive diagnosis of COVID-19. A confirmed COVID-19 infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

REFERENCES

1. Rabi F, Zoubi M, Kasasbeh G. et al SARS-CoV-2 and CoronavirusDisease 2019: What We Know So Far. Pathogenes.2020, pg 1-14.
2. Coronavirus general introduction available online https://www.who.int/india/emergencies/novel-coronavirus-2019 (Accessed on 30 March 2020).
3. Evaluation and Validation of an Enzyme-Linked Immunosorbent Assay and an Immunochromatographic Test for Serological Diagnosis of Severe Acute Respiratory Syndrome; Ming Guan et. al., Clin. Diagn. Lab. Immunol, July 2004, p. 699-703, Vol. 11, No. 4.
4. Recombinant Protein-Based Enzyme-Linked Immunosorbent Assay and Immunochromatographic Tests for Detection of Immunoglobulin G Antibodies to Severe Acute Respiratory Syndrome (SARS) Coronavirus in SARS Patients; Ming Guan et. al., Clin. Diagn. Lab. Immunol, Mar. 2004, p. 287-291 Vol. 11, No. 2

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
30°C 4°C	Store at 4°C to 30°C
2	Single Use
Σ	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
i	Read package insert before use

MANUFACTURED BY

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