ImmunoScience INDIA

ImmunoQuick

COVID-19 IgG

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

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

1. 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 been officially declared a pandemic by World Health Organization.

2. INTENDED USE

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

3. PRINCIPLE

COVID-19 IgG Rapid Test for Detection of Novel Coronavirus (COVID-19) IgG Antibodies (Serum/Plasma/Whole Blood) consists of an IgG component (anti-human IgG) coated on NCM and specific proteins (recombinant SARS-CoV-2 Spike protein) conjugated with colloidal gold.
During testing, when serum/plasma/whole blood samples added it flows towards NCM through sample pad and conjugate pad.
If the sample contains neutralizing antibodies to SARS-CoV-2 spike protein then it reacts with specific protein conjugated in the colloidal gold to from antigen-antibody complex. The mixture then migrates forward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. A colored line will appear in IgG test line region as a result of this. 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.
The intensity of test line (IgG) varies upon the concentration of neutralizing antibody in the specimen.

4. CONTENTS OF KIT

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

5. OPTIONAL MATERIAL REQUIRED

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

6. 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.

7. WARNINGS

1. Do not reuse the test device.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose 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.

8. SPECIMEN COLLECTION

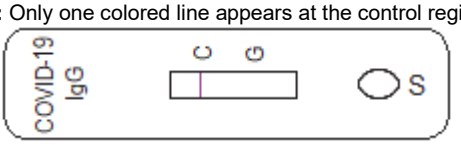
1. For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
2. For plasma samples, collect blood in a tube containing anticoagulant.
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. For whole blood samples, collect blood in a tube containing anticoagulant or a finger prick blood.

9. TEST PROCEDURE

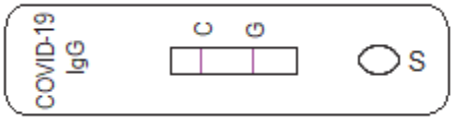
1. Allow the test device and sample reach to room temperature (20°C to 30°C) before opening the foil pouch.
2. Rotate the cap of assay buffer bottle in clockwise direction to be tighten. Again, rotate in anti-clock wise direction to pierce the nozzle.
3. Remove the test device, desiccant and plastic 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. Freshly pricked finger prick sample may also be used by putting two drops of sample (20 µl).
6. Start the timer.
7. Read the result at 15 minutes.

10. INTERPRETATION OF RESULTS

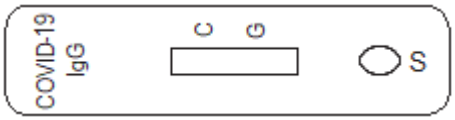
Negative: Only one colored line appears at the control region 'C' only



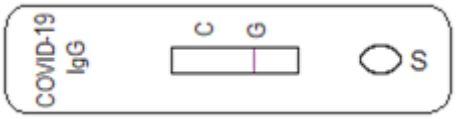
Positive: A) A distinct colored line appears at the control region 'C' and at the test region 'IgG'.



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



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



NOTE:

- The intensity of the color of test lines will vary depending upon the antibodies present in specimen.
- Antibodies against spike protein may be developed in humans normally after 15 to 30 days of vaccination.
- These tests may be/may not be found positive in patients having history of COVID-19 infection.
- Some individuals may have produced antibodies very late or very early depending upon the immune response.

11. 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 bemade 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 IgG Antibody.

12. 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.

13 REFERENCES

1. Rabi F, ZoubiM,Kasasbeh G. et al SARS-CoV- and coronavirus Disease2019: 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 Immunochromatographic tests for serological Diagnosis of Severe Acute Respiratory Syndrome (SARS), Ming Guan et. a, l Clin. Diagn. .Lab. Immunol, July. 2004, p. 699-703 Vol.11, No.4

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

MANUFACTURED BY
ImmunoScience India Private Limited
Gat No. 41, Kusgaon, Shivapur-Velhe Road,
Tal- Bhor, Pune, Maharashtra (India) -412205.