ImmunoScience INDIA

ImmunoQuick

COVID-19 Ag

Rapid Test for Detection of COVID-19 Antigen - 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. They have four main sub groups-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 immune competent 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 has been officially declared as a pandemic by World Health Organization.

INTENDED USE

ImmunoQuick COVID-19 Ag is a Rapid, Qualitative, Immunochromatographic test for detection of COVID-19 Antigen in Nasal swab (nasopharyngeal swab). This test is for healthcare professional use only.

PRINCIPLE

COVID-19 Antigen test consists of lysis buffer and Test device. The swab specimen/aspirate is added into lysis buffer and mixed to lyse the viral cells to extract the nucleic acids (RNA) into buffer.

Antigen test device consists of a strip containing NCM, colloidal gold conjugate pad and sample release pad. NCM (Nitrocellulose membrane) is coated with control specific antibodies on Control side (C) and SARS-CoV-2 specific monoclonal antibodies on Test side (T). Colloidal gold conjugate pad consists of control solution specific antibodies and SARS-CoV-2 specific monoclonal antibodies conjugated with colloidal gold nanoparticles. When sample (specimen & Lysis buffer mixture) is added on the sample port of test device, the sample migrates along with the colloidal gold nanoparticles. If sample contains Detectable levels of COVID-19 Antigen then it reacts with the conjugated monoclonal antibodies in colloidal gold particles to form Antigen antibody complex. This complex then migrates on the membrane chromatographically and reacts with the coated SARS-CoV-2 monoclonal antibodies on the test line to form a test band (colored line on test side). The unreacted complex and control specific gold particles then reacts with coated control line to form a colored band at control side. Control line shall always be appeared, indicating that the proper volume of specimen has been added, right procedure and all reagents working properly.

MATERIALS PROVIDED & ACTIVE INGREDIENTS OF CONTENTS OF KIT

1. Rapid COVID-19 Ag Test Device (1 per pouch with desiccant)
2. Lysis Buffer for COVID-19 Antigen test
3. Sample extraction Tubes for COVID-19 Antigen test
4. Package Insert
5. Nylon flocked Nasopharyngeal swab

OPTIONAL MATERIAL REQUIRED

Timer/Stop watch, Micropipette, PPEs (Disposable Gloves, mask, safety goggles, Lab coat/Apron), Biohazard dust bin.

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this pack 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

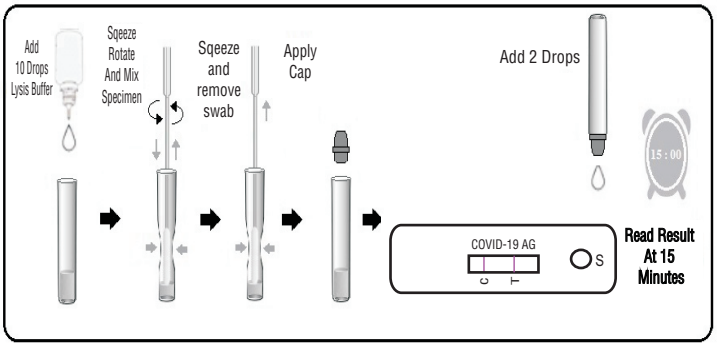
1. Do not reuse the test device.
2. Use appropriate personal protective equipment.
3. Dispose hygienically in biohazard waste as per local guidelines.
4. Do not touch the membrane.
5. Treat samples and used test as potentially infectious.
6. For in vitro diagnostic use. Not to be taken internally.

SPECIMEN COLLECTION

Nasopharyngeal swabs: sterile swab is inserted into one or both nostrils to the nasopharyngeal area. The swab is allowed to remain in the nostrils for a few seconds to absorb secretions, rotated gently, and then withdrawn. Bend shaft to follow curve of nasopharynx. For an optimal sample, repeat procedure using another nostril.

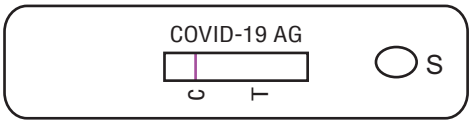
TEST PROCEDURE

1. Allow the all kit components to reach at room temperature (20°C to 30°C).
2. Add 10 drops (Approx. 300 µl) of lysis buffer provided in the kit in a sample extraction tube.
3. Label the tube with sample ID/Patient ID.
4. Collect the swab specimen and put it in the sample extraction tube containing lysis buffer. Rotate and mix the swab specimen in lysis buffer.
5. Squeeze the sides of the tube to obtain as much liquid as possible. Dispose of swab properly.
6. Apply the cap on sample extraction tube. Use this dissolved specimen as a sample.
7. Keep device on flat surface and add 2 drops (approx. 60 µl) of sample (Dissolved swab specimen in lysis buffer) by using a sample extraction tube in sample port of COVID-19 Antigen test device.
8. Start The timer.
9. Read Results at 15 minutes. Do not read the results after 20 minutes.

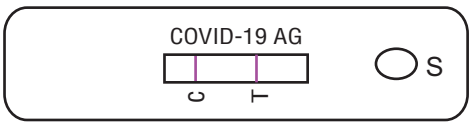


INTERPRETATION OF RESULTS

COVID-19 Antigen Negative: A colored line appears at the control region 'C' only.

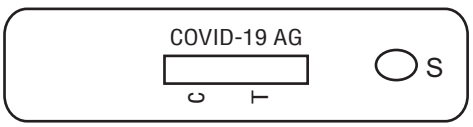


COVID-19 Antigen Positive: A colored line appears at Test region 'T' as well as control region 'C'.

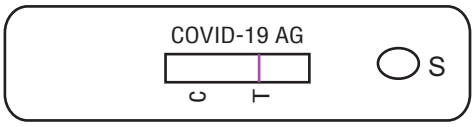


Invalid: The test should be considered invalid if,

1. No line appears at 'C' region and 'T' region,



2. No line appears at ‘C’ region and line appears at ‘T’ region.



NOTE: The intensity of the color of test line will vary depending upon the levels of antigen present in specimen.

PERFORMANE CHARACTERISTICS :

Internal Evaluation:
Total 105 COVID-19 Antigen positive samples and 125 negative samples were tested. The test shows 95 % correlation with positive sample. While, the test shows 100% correlation with negative samples. Cross reactivity studied with Influenza A, Influenza B positive samples. No cross reactivity observed.

External Evaluation:
ImmunoQuick COVID-19 Ag test evaluated and approved at “ICMR - VRDL”, Department of Health Research, Ministry of Health & Family welfare. Govt. of India ".

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 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 Antigen.

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 Coronavirus Disease 2019: What We Know SoFar. 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
	Keep away from Sunlight
	Keep Dry

MANUFACTURED BY

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