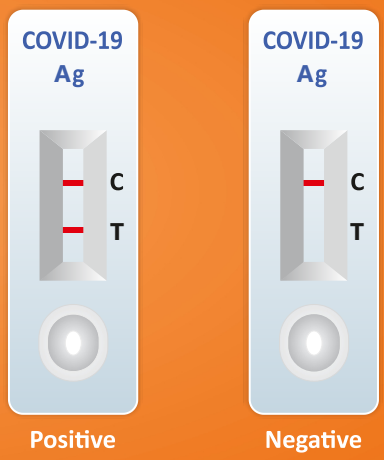
COVID-19 Antigen Test

Q-line Rapid



- Q-Line® Rapid COVID-19 Antigen Test based on chromatographic Immunoassay.
- Qualitative detection of specific Antigen to SARS-CoV-2.
- Specimen : Human Nasal/Oropharyngeal swab samples.
- Fast results within 15-30 mins.
- All necessary reagents provided & no equipment needed.
- COVID antigen test device, buffer, swabs and dropper provided.
- Quick, Economic, reliable & Easy to use with 25 Test pack.

Marketed By

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Complete Medical Solution

R & D

Sperogenx Biosciences Pvt. Ltd.

Co-developed with

RGCB
DBT-Rajiv Gandhi Centre for Biotechnology, Govt. of India.

Q-line® Rapid Coronavirus (COVID-19) Antigen Test

Reference / Pack Sizes
COVIAG25PS 1 x 25 Test

Kit Composition
Test Cassettes
Lysis Buffer, Swabs
Droppers & IFU

INTENDED USE

Q-Line® *Rapid* Novel Coronavirus (COVID-19) Antigen Kit is a rapid, qualitative and convenient immunochromatographic in vitro assay for the detection of SARS COVID-19 Antigens in human nasal and oropharyngeal swab samples from patient with signs and symptoms of respiratory infection. The device is designed to aid in the rapid diagnosis of COVID-19 Virus infection.
This assay only provides a preliminary result. Negative results should be confirmed by Real- Time Reverse Transcriptase (RT)-PCR Diagnostic kit; they do not preclude COVID-19 Virus infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

SUMMARY AND PRINCIPLE OF THE ASSAY

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, birds and other mammals, that cause respiratory, enteric, hepatic, and neurologic diseases. Six coronavirus species are known to cause human disease. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.

Novel coronavirus pneumonia is short for NP, its pathogen is the novel coronavirus. WHO has officially named the disease as corona virus diseases 2019 (COVID-19).

The principle of Q-Line® Rapid Coronavirus (COVID-19) Antigen Test uses specific monoclonal antibody-coupled gold conjugate immobilized in the test line, which reacts with the antigens in the specimen to produce a faint to dark pink coloured band. Further, the sample migrates to the control region to bind with a control conjugate, thereby producing another faint to dark pink coloured band. If a sample contains SARS CoV-2 antigens, a visible line appears in both the test region (T) as well as the control region ©. To serve as an internal process control, a control line should always appear at Control region (C) when tested. Absence of a pink control line in the Control region is an indication of an invalid result.

KIT CONTENTS

- 25 Test Cassettes, Individually pouched
- Lysis Buffer - 500 µL x 25 Nos
- Sterile breakable swabs - 25 Nos.
- Dropper - 25 Nos
- Test instructions (IFU) - 1 No

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Gloves.
- Clock or timer.

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only. Do not reuse.
- Do not use if the product seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, regional or national regulations.
- Keep out of children's reach.

STORAGE & STABILITY

- The test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The bottle containing the lyse buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

SPECIMEN PREPARATION

- Naso-pharyngeal scrubbing is done according to the written guidelines of WHO.
- Once scrubbed / collected, the brush end has to be inserted into the lysing buffer vial, stirred to mix before broken and closed
- Collected specimen could be stored at room temperature for up to 4 days between 2-15°C or at -20°C for longer duration.

TEST PROCEDURE

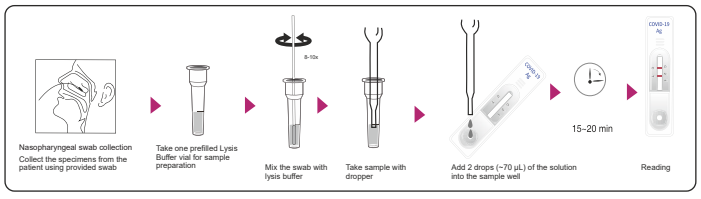
Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a flat, dry surface.

Add 2 drops (60-70µL) of sample on to the sample port and leave it for 15 minutes. Do not touch the membrane with the pipette tip

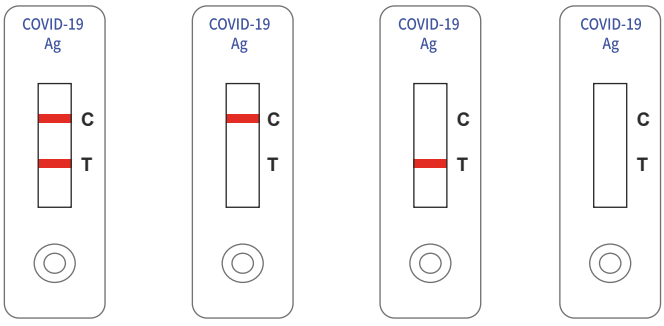
Vortex for a minute or keep the Swab inside the Lysis solution for 5 minutes. It is to disburse the specimens/Antigen sample from Swab to lysis solution.

Read the cassette visually or with a dedicated instrument within 15 ~ 30 minutes.

DO NOT INTERPRET RESULT AFTER 30 MINUTES.



RESULT INTERPRETATIONS.



Positive
Pink colored bands appear at the control region (C) and Test (T) region, indicating positive result for a possible COVID-19 infection

Negative
A pink colored band appears only at the control region (C), indicating a negative result for COVID-19 infection.

Invalid
No visible band at both control region (C) and Test (T) region or a line is visible at Test (T) only. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

LIMITATIONS

- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a 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.
- Although the test demonstrates superior accuracy in detecting antibodies against COVID-19 virus, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

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SYMBOLS:-

IVD	In vitro diagnostic medical device use		Single Use
	Manufacturer		Number of tests in the pack
	Date of Manufacturing		Do not use if pouch or kit damaged
	Expiry Date		This side Up
LOT	Lot Number		Read package insert before use
	Store at 2- 30°C		

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