



InnoScreen COVID-19 Rapid Antigen Test – Nasal Swab Self Tests (2 Pack)

INTENDED USE

The InnoScreen™ COVID-19 Rapid Antigen Test Device (Self-test) is a rapid lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens from individuals with or without symptoms suspecting a COVID-19 infection. This test is approved for home self use with self-collected direct anterior nasal swab samples from individuals aged 15 years or older or adult collected anterior nasal swab samples from individuals aged 2 years or older. Rapid Antigen testing is less reliable than PCR when testing an asymptomatic patient or testing patients after 7 days of symptom onset as it may produce false negative result. Do not use the test for child under 2 years old. For children 2-15 years old, the test should be performed by an adult.

If the test is being used for testing individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection, testing should be scheduled twice over two (or three) days with at least 24 hours (and no more than 36 hours) between tests.

This product cannot be shipped to WA or SA due to state government guidelines.

INTRODUCTION

COVID-19 is the disease associated with SARS-CoV-2, which was first identified in China at the end of 2019. The virus is transmitted mainly via respiratory droplets that people sneeze, cough, or exhale. The incubation period for COVID-19 is currently estimated at between 2 and 14 days. Common symptoms of COVID-19 infection include fever, cough and respiratory symptoms such as shortness of breath and breathing difficulties. More serious cases develop severe pneumonia, acute respiratory distress syndrome, sepsis and septic shock that can lead to the death of the patient. People with existing chronic conditions seem to be more vulnerable to severe illness.

PRINCIPLE

The InnoScreen™ COVID-19 Rapid Antigen Test Device is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect SARS-CoV-2 viral nucleoprotein antigens in nasal swabs.

PRECAUTIONS

- Read the Package Insert prior to use. Directions should be read and followed carefully.
- Children or teenagers aged 2 to 15 years old should have their samples collected and tested by an adult. Do not use the tests for anyone under 2 years of age.
- Do not use kit or components beyond the expiration date.
- All kit components are single use items. Do not use with multiple specimens. Do not reuse the used kit components.
- Do not touch swab tip when handling the swab sample.
- Perform the test immediately after collecting the sample.
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas of the nasal cavity when collecting specimens.
- Keep the test device on a flat surface during the testing.
- Do not interpret the test result before 15 minutes and after 20 minutes of starting the test.

STORAGE AND STABILITY

- Store the InnoScreen™ COVID-19 Rapid Antigen Test Device at 2-30°C.
- DO NOT FREEZE.
- Kit contents are stable until the expiration dates marked on their outer packaging and containers. Once opened the device should be used immediately.

SARS-CoV-2 VARIANTS

The following SARS-CoV-2 variants were tested on InnoScreen™ COVID-19 Antigen Rapid Test Device. All the variants can be detected at above mentioned limit of detection level.

SARS-CoV-2 Variants of Concern tested

- B.1.1.7 Alpha United Kingdom
- B.1.351 Beta South Africa
- B.1.427/B.1.429 Epsilon United States
- B.1.617.2 Delta India
- P.1 Gamma Japan/Brazil