

# Rapid COVID-19 Antigen Test

Catalog #: GCCOV-502a

CE

USFDA Emergency Use Authorization pending for POC; For use only by high complex laboratories

Availability of product is subject to various international regulatory requirements.

The Rapid COVID-19 Antigen Test is an *in vitro* immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal (NP) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. The Rapid COVID-19 Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2.

## Features

- Highly specific, and selective for SARS-CoV-2 nucleocapsid protein
- Simple, visual results within 15 minutes
- Specimen Type: Direct Nasopharyngeal Swab\*
- No Instrumentation Required
- Storage: 2-30°C
- Stability: 2 years from date of manufacture
- Controls availability separately

## Interim Test Performance

- Clinical POC study conducted at several sites in the US
- Positive Percent Agreement (PPA): 97.3%
- Negative Percent Agreement (NPA): 99.6%

\* Additional studies underway to support alternative specimen types.



## Components

- 20 Test Cassettes
- 20 Sterile Swabs
- 20 Extraction Tubes and Tips
- 2 Buffer Vials
- 1 Workstation
- 1 Instructions for Use