Rapid detection of SARS-CoV-2 will play a key role in the global spread of the virus.

Affordable and sensitive test that does not require an additional reader, with a processing time of 15-20 minutes.

For use under an Emergency Use Authorization (EUA) Only
For in vitro diagnostic use only
For professional use only

**Features**

- Detects SARS-CoV-2 nucleocapsid protein antigen
- Rapid results in 15-20 minutes
- Nasopharyngeal swab specimen collection
- Identifies acute infection with a 91.1% sensitivity and 100% specificity
- For use in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.

**Our Competitive Advantage**

- Large manufacturing capacity and immediately available for distribution
- Global sales and regulatory approval throughout Europe, Asia and South America
- Selected by NIH for the Rapid Acceleration of Diagnostics program, for the US production of the GenBody COVID-19 Ag test.
- Made in the USA (Q4 2021) and South Korea

The GenBody COVID-19 Ag is an immunochromatographic rapid diagnostic test (RDT) intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal swab (NP) specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.
Procedure

01
Add the Extraction solution to the Fill Line indicated on the Extraction Tube

02
Collect nasopharyngeal swab specimen.

03
Insert the collected specimen swab into the Extraction Solution. Mix by squeezing the tube and rotating the swab 8~10 times. Place the Dropper Tip

04
Add 4 drops of the solution to the sample well.

Result Interpretation

Read the results between 15-20 minutes

Start the timer

Positive
SARS-CoV-2 antigen present does not rule out co-infection with other pathogens. The color intensity in the test region will vary depending on the amount of SARS-CoV-2 antigen present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.

Negative
Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions. It is recommended that these results be confirmed by a molecular testing method, if necessary for patient management.

Invalid
Re-run the test one time using the remaining specimen in the extraction via if an invalid result is obtained during initial testing.

GenBody COVID-19 Ag Kit

Package Unit
25 tests / kit

Kit Component
- 25 Single Use Test Devices Individually Foil-Pouched
- 2 Bottles of Extraction Solution
- 25 Single Use Extraction Tubes
- 25 Single Use Dropper Tips
- 25 Sterilized Nasopharyngeal Swabs

Storage Temperature
Between 35.6 to 86 degrees Fahrenheit

Expiration date
12 months after the manufacture date
# GenBody COVID-19 Performance Comparison (Visually Read Tests)

<table>
<thead>
<tr>
<th>Company</th>
<th>Product Name</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Limit of Detection (TCID$_{50}$/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GenBody Inc</td>
<td>GenBody COVID-19 Ag</td>
<td>91.10%</td>
<td>100.00%</td>
<td>$1.11 \times 10^2$</td>
</tr>
<tr>
<td>Salofa Oy</td>
<td>Sienna-Clarity COVID-19 Antigen Rapid Test Cassette</td>
<td>87.50%</td>
<td>98.90%</td>
<td>$1.25 \times 10^3$</td>
</tr>
<tr>
<td>Celltrion USA Inc</td>
<td>DiaTrust COVID-19 Ag Rapid Test (Humasis product)</td>
<td>93.33%</td>
<td>99.03%</td>
<td>$3.2 \times 10^1$</td>
</tr>
<tr>
<td>Inbios International</td>
<td>SCoV-2 Ag Detect Rapid Test</td>
<td>86.67%</td>
<td>100.00%</td>
<td>$6.3 \times 10^3$</td>
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<tr>
<td>Access Bio Inc</td>
<td>CareStart COVID-19 Antigen test</td>
<td>87.18%</td>
<td>100.00%</td>
<td>$8 \times 10^2$</td>
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<tr>
<td>Quidel Corp</td>
<td>QuickVue SARS Antigen Test</td>
<td>96.60%</td>
<td>99.30%</td>
<td>$7.57 \times 10^3$</td>
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<tr>
<td>Abbott Diagnostics</td>
<td>BinaxNOW COVID-19 Ag Card</td>
<td>84.60%</td>
<td>98.50%</td>
<td>140.6</td>
</tr>
<tr>
<td>Orasure Technologies</td>
<td>InteliSwab COVID-19 Rapid Test Pro</td>
<td>84.40%</td>
<td>98.00%</td>
<td>$2.5 \times 10^2$</td>
</tr>
<tr>
<td>Phase Scientific</td>
<td>INDICAID COVID-19 Rapid Antigen Test</td>
<td>84.40%</td>
<td>96.80%</td>
<td>140 TCID$_{50}$/ per Swab</td>
</tr>
</tbody>
</table>