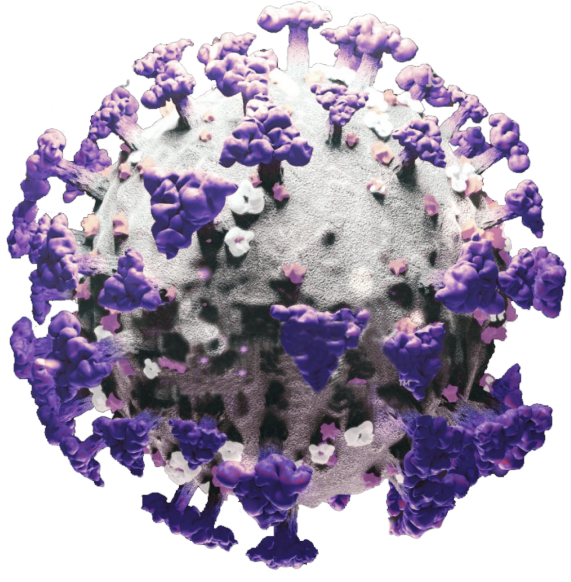
GenBody Inc.
CHANGE AND INNOVATION

GenBody COVID-19 Antigen Rapid Test Kit

For Point of Care

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

℞ Only

FDA EUA Authorized

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.

Manufactured by GenBody and exclusively distributed in the U.S. by Kwell Laboratories

3420 DeForest Circle
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GenBody.co.kr

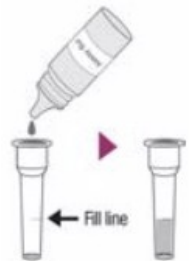
KWELL
www.kwelllabs.com

Refer to the GenBody COVID-19 Ag IFU or download detailed instructions at www.kwelllabs.com/IFU

Procedure

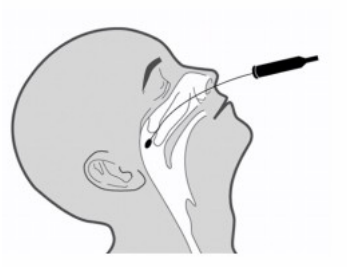
01

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



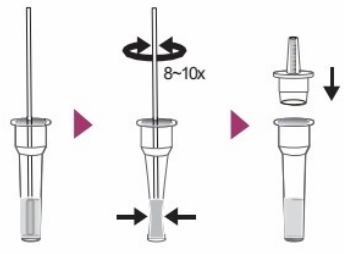
02

Collect nasopharyngeal swab specimen.



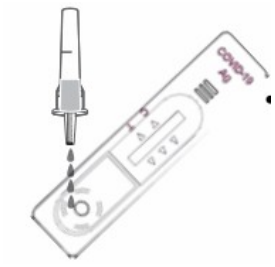
03

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



04

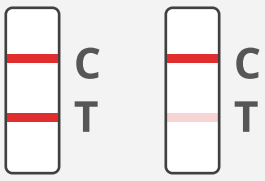
Add 4 drops of the solution to the sample well.



Result Interpretation

Read the results between 15-20 minutes

Positive

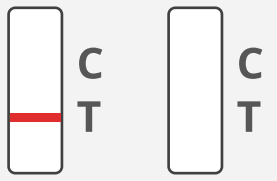


SARS-CoV-2 antigen present does not rule out co-infection with other pathogens. The color intensity in the test region will vary depending on the amount of SARS-CoV-2 antigen present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.

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 conrmed by a molecular testing method, if necessary for patientmanagement.

Invalid



Re-run the test one time using the remaining specimen in the extraction vial 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

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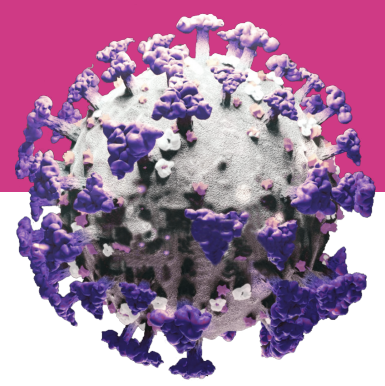
GenBody COVID-19 Performance Comparison
(Visually Read Tests)



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

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