GenBody America

MADE IN USA

GenBody COVID-19 Ag Packaging Information

Kit Box	Dimension	25 X 12.5 X 9 cm	9.84 X 4.92 X 3.54 in
	Weight	0.35 Kg / Kit	0.77 lbs / Kit
	Package	25 Tests / Kit	25 Tests / Kit
Carton Box	Dimension	57 X 39 X 52 cm	22.5 X 15.4 X 20.5 in
	Weight	15.9 Kg / Kit	35.05 lbs / Kit
	Package	36 Kits / Carton	36 Kits / Carton
Pallet	Dimension	122 X 102 X 173 cm	48 X 40 X 68 in
	Weight	190.8 Kg / Pallet	420.64 lbs / Pallet
	Package	12 Carton / Pallet	12 Carton / Pallet

Ordering Information

Cat No.	Product Name	Package	Kit Box Size (inch)	Carton Size (inch)
COVAG025-NU	GenBody COVID-19 Ag	25 Tests / Kit	9.84 X 4.92 X 3.54	22.44 X 15.35 X 20.47

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

3420 De Forest Circle
Jurupa Valley, CA 91752

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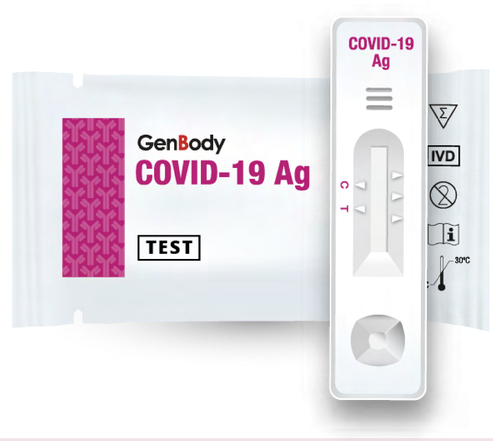
GenBody COVID-19 Antigen Rapid Test Kit

Anterior Nasal Swab

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

Features

- Detects SARS-CoV-2 nucleocapsid protein antigen
- Rapid results in 15-20 minutes
- Anterior nasal swab specimen collection
- Identifies acute infection with a 92.31% sensitivity and 99.04% specificity
- For use in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.
- The confirmed LoD for the GenBody COVID-19 Ag is 1.11 x 10 TCID50/mL.

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 test detects the Sars-CoV-2 variants.

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) or anterior nasal (AN) 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.

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

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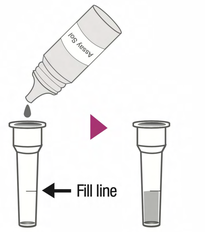
Procedure

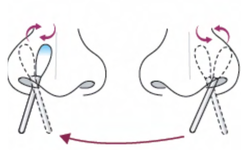
01

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



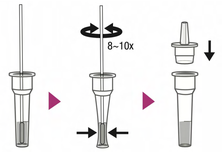
02

Collect anterior nasal swab specimen.



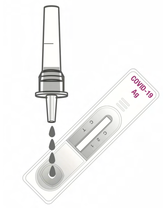
03

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



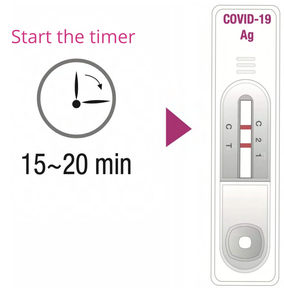
04

Place test device on a **level surface**. **Add 4 drops** of the solution to the sample well.

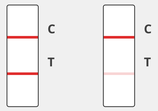


Result Interpretation

Read the results between **15-20 minutes.**
Do not read after 20 minutes.



Positive

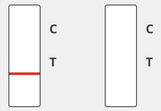


SARS-CoV-2 antigen present does not rule out co-infection with other pathogens. The color intensity in the test region will vary depending on the amount of SARS-CoV-2 antigen present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.

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



If the Control line does not appear within the designated incubation time (i.e., 15 - 20 minutes), the result is invalid and the test should be repeated with a new sample.

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 anterior nasal swabs
Storage Temperature	Between 35.6 to 86 degrees Fahrenheit
Expiration date	12 months from the date of manufacture
Catalog Number	COVAG025-NU

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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	92.31%	99.04%	1.11×10^2
Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette	87.50%	98.90%	1.25×10^3
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 $TCID_{50}$ per Swab
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

This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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