510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K251916

B Applicant

GenBody Inc.

C Proprietary and Established Names

GenBody COVID-19 Ag Home Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QYT	Class II	21 CFR 866.3984 - Over-The-Counter Test To Detect SARS-Cov-2 From Clinical Specimens	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain 510(k) clearance for the GenBody COVID-19 Ag Home Test.

B Measurand:

SARS-CoV-2 nucleocapsid antigens.

C Type of Test:

Qualitative Lateral Flow Immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The GenBody COVID-19 Ag Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment.

Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from March 2024 to January 2026, when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

The GenBody COVID-19 Ag Home Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of nucleocapsid protein antigen from directly in anterior nasal swab specimens from individuals who show symptoms of COVID-19 infection within the first five (5) days of symptom onset. The test cassette contains a test strip in a plastic housing. The test strip is a nitrocellulose membrane with two regions: a test region (T) and control region (C). The device is for in vitro diagnostic use only. The GenBody COVID-19 Ag Home Test is for over-the-counter (OTC) use.

The GenBody COVID-19 Ag Home Test is composed of the following components:

- Test cassette (individually packaged in a foil-pouch)
- Pre-filled extraction reagent tubes and dropper cap
- Tube holder
- Single-use nasal swabs (sterile)
- Quick Reference Instructions, QRI

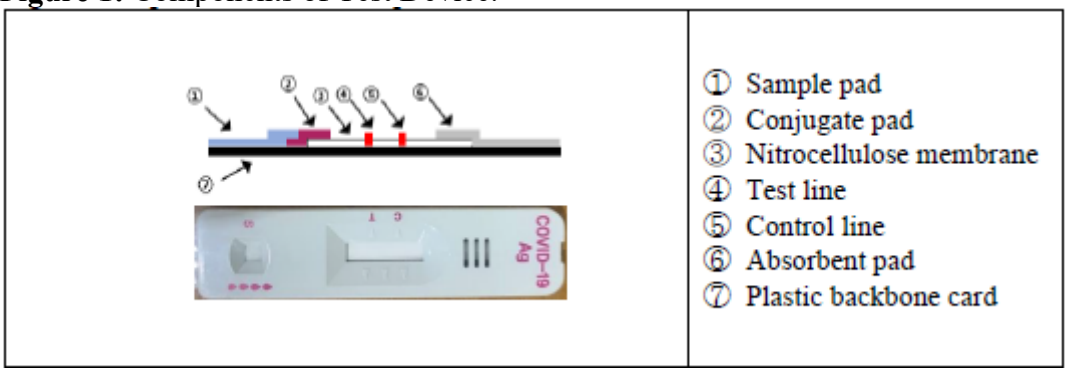
Materials required but not provided:

- Timer
- Face mask
- Gloves

B Principle of Operation:

The GenBody COVID-19 Ag Home Test device consists of a plastic cassette containing an assembled test strip. This strip includes a sample pad, conjugate pad, nitrocellulose membrane, and absorbent pad, all sequentially layered on a plastic backbone card (Fig 1). The gold pad contains colloidal gold particles conjugated with anti-SARS-CoV-2 nucleocapsid protein (NP) monoclonal antibodies for the Test Line or recombinant NusA protein for the Control Line. The membrane includes a test line coated with anti-SARS-CoV-2 NP monoclonal antibodies and a control line coated with anti-recombinant NusA protein antibodies.

Figure 1: Components of Test Device.



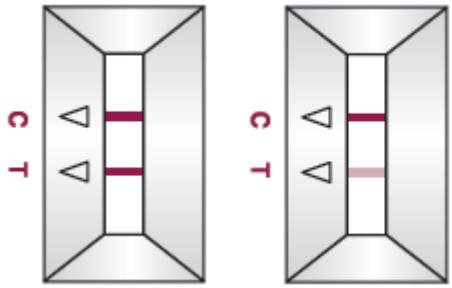
For sample processing, the swab is first inserted into the lysis buffer during which the buffer disrupts the virus particles in the specimen, exposing internal viral nucleocapsid antigens. Four (4) drops of the lysed specimen are added to the sample well on the test cassette, which migrate from the sample pad towards the absorbent pad via capillary action.

The test strip in each device contains mouse monoclonal antibodies to the NP of SARS-CoV-2. When the sample contains SARS-CoV-2 antigens, anti-SARS-CoV-2 monoclonal antibodies that are coupled with colloidal gold bind to SARS-CoV-2 antigens in the sample to form an antigen-antibody complex. This complex is then captured by anti-SARS-CoV-2 monoclonal antibodies immobilized on the Test line (T), and a visible line appears on the membrane, while unbound dye complexes continue to migrate beyond the test line area. Unbound protein-dye complexes are later captured at the Control line (C). Formation of the Control line serves as an internal control. 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 and a new test device. Absence of this colored band in the test region of test strip and only a visible control line suggests a negative result. This test does not use biotin-streptavidin/avidin chemistry in any of the steps for coupling reagents. The GenBody COVID-19 Ag Home Test is validated for use from direct specimens testing without transport media. This is a manually performed visually read lateral flow immunoassay without an instrument.

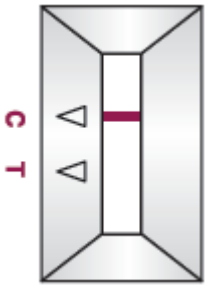
C Interpretation of Results:

1. Positive Result



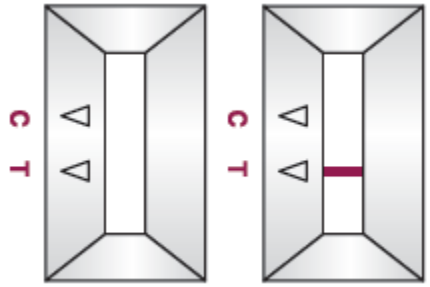
The Control line (C line) and Test line (T line) both appear in the window. Any faint visible reddish-purple test (T) line with the control line (C) should be read as positive. A positive test result is interpreted as protein antigen from the virus that causes COVID-19 was detected in the specimen. The individual is likely positive for COVID-19. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

2. Negative Result



If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours if the individual has symptoms on the first day of testing. A negative test means that antigen from the virus that causes COVID-19 is not detected in the sample. Negative results do not rule out SARS-CoV-2 infection. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. All negative results are considered presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed.

3. Invalid Result



If no line appears in the Control (C) area, the test result is invalid regardless of the presence or absence of a line in the Test (T) area. The test should be repeated with a new device and new swab.

V Substantial Equivalence Information:

A Predicate Device Name(s):

CorDx Tyfast COVID-19 Ag Rapid Test; CorDx COVID-19 Ag Test

B Predicate 510(k) Number(s):

K240728

C Comparison with Predicate(s):

Device & Predicate Device(s):	Candidate Device K251916	Predicate Device K240728
Device Trade Name	GenBody COVID-19 Ag Home Test	CorDx Tyfast COVID-19 Ag Rapid Test
Intended Use/ Indications For Use	The GenBody COVID- 19 Ag Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing	The CorDx Tyfast COVID- 19 Ag Rapid Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID19. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

Device & Predicate Device(s):	Candidate Device K251916	Predicate Device K240728
	individuals aged 2 years or older. All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider. The performance characteristics for SARS-CoV-2 were established from March 2024 to January 2026, when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.	The CorDx Tyfast COVID- 19 Ag Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2. All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider. The performance characteristics for SARS-CoV-2 were established from September 2023, to December 2023, when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
General Device Characteristic Similarities		
Intended Use Setting	OTC	Same
Analyte	Nucleocapsid protein antigen from SARS-CoV-2	Same

Device & Predicate Device(s):	Candidate Device K251916	Predicate Device K240728
Technology	Lateral flow immunoassay	Same
Sample Type	Anterior nasal specimen	Same
Assay Type	Qualitative	Same
Interpretation	Visually read	Same
Detection Period	Within 5 days of symptom onset	Same
General Device Characteristic Differences		
Development Time	15-20 min	10 min

VI Standards/Guidance Documents Referenced:

The following have been referenced for conformity:

Document number	Title	Publisher	Applicable Study
11135:2014/ A1:2018	Sterilization of health care products - Ethylene oxide - Requirements for development, validation, and routine control of a sterilization process for medical devices	ISO	Sterility
10993-7 2nd edition 2008-10-15	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals	ISO	Sterility
10993-10:2010 4th edition 2021-11	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	ISO	Biocompatibility
10993-5:2009/ (R)2014	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	ISO	Biocompatibility

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Multi-lot Precision:

The purpose of this study was to evaluate variability across days, operators, and device lots. The study used a single internal site using three (3) independently manufactured test kit lots of the GenBody COVID-19 Ag Home Test. Three (3) concentrations of heat-inactivated SARS-CoV-2; USA-WA1/2020, were spiked into pooled negative swab matrix (PNSM) as follows:

1) Negative sample (neat PNSM)
2) Low positive sample (1.5x LoD)

3) Positive sample (3x LoD)

The sample panel was tested in a blinded manner by two operators for 10 non-consecutive days. All three lots were tested by each operator on each testing day. Each sample level was tested in duplicate in each of two runs, morning and afternoon, per operator per day (i.e., 3 lots x 2 operators x 2 replicates/run x 2 runs x 10 days). A total of 240 test were run per panel member.

The results demonstrated 100% agreement with the expected outcomes across all kit lots, operators, and testing days. A summary of the results is presented in Table 1 below:

Table 1: Summary of Multi Lot Precision Study*

Analyte Concentration	Lot 1		Lot 2		Lot 3		Total Lot-to-Lot Precision		
	n/N	% Agmt	n/N	% Agmt	n/N	% Agmt	n/N	% Agmt	95% CI
Negative	80/80	100%	80/80	100%	80/80	100%	240/240	100%	95.5%-100%
1.5x LoD	80/80	100%	80/80	100%	80/80	100%	240/240	100%	95.5%-100%
3x LoD	80/80	100%	80/80	100%	80/80	100%	240/240	100%	95.5%-100%

*While the Low Positive sample used in this study at a 1.5 x LoD (1.6×10^3 TCID50/mL), generated **100% positivity**, the sequential dilution at 0.5x LoD (5.5×10^2 $TCID_{50}$/mL) of the same sample demonstrated **82% positivity**.

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

a. ***Cross Reactivity and Microbial Interference***

The analytical specificity of the Genbody COVID-19 Ag Home Test was evaluated by testing various microorganisms and viruses, for cross-reactivity (in the absence of SARS-CoV-2) and microbial interference (in the presence of SARS-CoV-2 at 3x LoD, or 3.3×10^3 $TCID_{50}$/mL). Respiratory viral pathogens were tested at a final concentration of ≥1 x 10^5 units/mL, or at the highest available concentrations. Common respiratory bacterial and yeast pathogens were tested at a final concentration of ≥1 x 10^6 units/mL, or at the highest available concentrations. Each organism was prepared in PNSM and assessed in replicates of three (3) for cross-reactivity by adding 50 µL directly to the test swab, and processing per the IFU. Microbial interference testing followed the same protocol, with samples co-spiked with heat-inactivated SARS-CoV-2 (USA-WA1/2020) at 3x LoD.

The summary of cross-reactivity and microbial interference results are shown in the table below. Neither cross-reactivity nor interference was observed for any of the organisms at the concentrations tested with the GenBody COVID-19 Ag Home Test device.

Table 2: Summary of Cross-Reactivity and Microbial Interference Results

Organism	Concentration Tested	Units	Results (Number of Positives/ Total Tested)	
			Interference	Cross Reactivity
SARS-CoV-1 (Gamma irradiated)	9.0×10^7	PFU/mL	3/3	0/3
NATtrol MERS-CoV	26.4	Ct	3/3	0/3

Organism	Concentration Tested	Units	Results (Number of Positives/ Total Tested)	
			Interference	Cross Reactivity
(Florida/USA-2 Saudi Arabia 2014)				
Coronavirus OC43	3.4×10^5	$TCID_{50}$/mL	3/3	0/3
Coronavirus 229E	1.3×10^5	$TCID_{50}$/mL	3/3	0/3
Coronavirus NL63	3.2×10^5	$TCID_{50}$/mL	3/3	0/3
Human coronavirus HKU1*	20.9	Ct	3/3	0/3
Adenovirus 3	1.8×10^9	PFU/mL	3/3	0/3
Adenovirus 1	1.3×10^8	PFU/mL	3/3	0/3
Adenovirus 7	3.6×10^8	PFU/mL	3/3	0/3
Adenovirus 4	3.6×10^8	PFU/mL	3/3	0/3
Adenovirus 5	3.6×10^8	PFU/mL	3/3	0/3
Adenovirus 9 (species D)	3.1×10^7	PFU/mL	3/3	0/3
Human Metapneumovirus (hMPV)	2.7×10^7	PFU/mL	3/3	0/3
Human Metapneumovirus (hMPV) Type A1	1.7×10^5	$TCID_{50}$/mL	3/3	0/3
Parainfluenza virus type 1	3.4×10^6	$TCID_{50}$/mL	3/3	0/3
Parainfluenza virus type 2	3.8×10^5	$TCID_{50}$/mL	3/3	0/3
Parainfluenza virus type 3	3.6×10^8	$TCID_{50}$/mL	3/3	0/3
Parainfluenza virus type 4A	5.3×10^7	$TCID_{50}$/mL	3/3	0/3
Parainfluenza virus type 4B	1.3×10^5	$TCID_{50}$/mL	3/3	0/3
Influenza A H3N2 (California/7/04)	1.5×10^5	$TCID_{50}$/mL	3/3	0/3
Influenza A H1N1 (Korea/2018/H1N1)	9.0×10^6	$TCID_{50}$/mL	3/3	0/3
Influenza B (Victoria/2/87)	9.5×10^5	$TCID_{50}$/mL	3/3	0/3
Enterovirus A71	1.1×10^9	PFU/mL	3/3	0/3
Enterovirus B111	4.1×10^6	$TCID_{50}$/mL	3/3	0/3
Respiratory syncytial virus A	1.1×10^6	$TCID_{50}$/mL	3/3	0/3
Respiratory syncytial virus B	9.5×10^5	$TCID_{50}$/mL	3/3	0/3
Rhinovirus A (8)	1.8×10^9	PFU/mL	3/3	0/3
Rhinovirus A (1B)	7.2×10^8	PFU/mL	3/3	0/3
Rhinovirus A (16)	1.4×10^9	PFU/mL	3/3	0/3
Rhinovirus B (42)	1.8×10^6	PFU/mL	3/3	0/3
Bordetella pertussis	1.5×10^{10}	CFU/mL	3/3	0/3
Candida albicans	3.3×10^7	CFU/mL	3/3	0/3
Chlamydophila pneumoniae	1.5×10^8	IFU/mL	3/3	0/3
Hemophilus influenzae	1.5×10^8	CFU/mL	3/3	0/3
Legionella pneumophila	5.0×10^8	CFU/mL	3/3	0/3
Mycoplasma pneumoniae	1.2×10^8	CCU/mL	3/3	0/3
Staphylococcus aureus	4.3×10^8	CFU/mL	3/3	0/3
Staphylococcus epidermidis	8.3×10^8	CFU/mL	3/3	0/3
Streptococcus pneumoniae	2.9×10^6	CFU/mL	3/3	0/3
Streptococcus pyogenes, Group A	2.1×10^9	CFU/mL	3/3	0/3
Streptococcus pyogenes, Type 1	8.6×10^8	CFU/mL	3/3	0/3
Pooled nasal fluid	N/A		3/3	0/3

*One human coronavirus HKU1 (HCoV-HKU1) clinical sample was tested.

b. Exogenous and Endogenous Interference

Thirty-one (31) potentially interfering substances were evaluated using the GenBody COVID-19 Ag Home Test. Each substance was prepared in PNSM and tested in triplicate, in either absence or presence of SARS-CoV-2, USA WA1/2020, at 3x LoD. 50 µL of sample was applied to the test swab and processed per the IFU. The results of this study are summarized in Table 3. All substances tested yielded expected results, indicating they do not impact the performance of the GenBody COVID-19 Ag Home Test at the concentrations specified.

Table 3: Interfering Substances Study Results

Interfering Substance	Test Concentration	SARS-CoV-2 Negative Sample (Number of Positives/Total Tested)	SARS-CoV-2 Positive Sample (Number of Positives/Total Tested)
Human Whole Blood (K2-EDTA)	2.5% v/v	0/3	3/3
Leukocytes	5.4 x 10^7 cells/mL	0/3	3/3
Benzocaine	3 mg/mL	0/3	3/3
Menthol	3 mg/mL	0/3	3/3
Mucin, bovine submaxillary glands	2.5 mg/mL	0/3	3/3
Zicam nasal spray	15% v/v	0/3	3/3
Phenylephrine	15% v/v	0/3	3/3
Oxymetazoline hydrochloride	15% v/v	0/3	3/3
Beclomethasone	15% v/v	0/3	3/3
Flunisolide	15% v/v	0/3	3/3
Budesonide	15% v/v	0/3	3/3
Mometasone furoate	15% v/v	0/3	3/3
Cromolyn sodium salt	15% v/v	0/3	3/3
Triamcinolone	15% v/v	0/3	3/3
Dexamethasone	15% v/v	0/3	3/3
Fluticasone propionate	15% v/v	0/3	3/3
Galphimia glauca	15% w/v	0/3	3/3
Luffa operculata	15% w/v	0/3	3/3
Histaminum hydrochloricum	15% w/v	0/3	3/3
Alkalol nasal wash	15% v/v	0/3	3/3
Phenol solution	5% v/v	0/3	3/3
Mupirocin	10 mg/mL	0/3	3/3
Molnupiravir (EIDD-2801)	5 mg/mL	0/3	3/3
Tamiflu-Oseltamivir	5 mg/mL	0/3	3/3
Zanamivir	5 mg/mL	0/3	3/3
Biotin	3500 ng/mL	0/3	3/3
Bilirubin	4% w/v	0/3	3/3
Hemoglobin	4% v/v	0/3	3/3
Hand Lotion	15% v/v	0/3	3/3
Hand Lotion	15% w/v	0/3	3/3

Interfering Substance	Test Concentration	SARS-CoV-2 Negative Sample (Number of Positives/Total Tested)	SARS-CoV-2 Positive Sample (Number of Positives/Total Tested)
Hand Sanitizer (liquid, ethanol 70%)	15% w/v	0/3	3/3
Hand soap (liquid, lauric acid)	15% v/v	0/3	3/3

4. Assay Reportable Range:

Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

a. ***Internal controls:***

The GenBody COVID-19 Ag Home Test has built-in internal procedural control to indicate that the test is working (i.e., that sufficient flow and sufficient sample volume has occurred). A distinct reddish purple control line appearing at the "C" position means the test has been performed correctly. If the control line does not appear, the test result is invalid, and a new test should be performed.

The main component of "C" line consists of an anti-recombinant NusA protein antibody and the dye pad (conjugate pad) contains gold dye conjugated with recombinant NusA protein. Therefore, when the reagent system works appropriately, the gold dye with recombinant NusA protein will bind to the anti-recombinant NusA antibody resulting in a visible control line.

b. ***Stability:***

i. Real Time Stability:

The shelf-life of the GenBody COVID-19 Ag Home Test under the intended storage conditions (2-30 ℃) was assessed in a real-time stability study using three (3) lots of test kits stored at 2-8 ℃ and 30 ℃. The test kits were assessed with PNSM and contrived positive samples prepared at 3x LoD using heat-inactivated SARS-CoV-2 (USA-WA1/2020). Replicate samples were generated by spiking 50 µL of virus diluted in PNSM onto dry swabs. For each lot, five (5) replicates per time point per storage condition were tested. Data collected to date in this study (baseline, every 3 months up to 15 months) supports a test kit shelf-life of 14 months when stored at the intended storage temperature of 35.6 to 86 °F, 2- 30 °C.

ii. Transportation Stability:

In order to evaluate the stability of the test kit under different shipping conditions, kits were tested for:

a. Temperature fluctuations: Test kits were stored at cycling conditions: 45℃ → 30℃ → 2-8℃ → -20℃ → 2-8℃ → 30℃ → 45℃ →room temperature (RT) for 8 days, 1 day at each temperature condition. Samples were tested after the test kits completed the temperature cycling process.

b. Harsh temperatures: Test kits were stored at RT, 45℃ (incubator) and -20℃ (freezer) for a total of 8 days. Sample were tested at 4-day intervals from the initial test (t=0).

c. Freeze/thaw cycles: Test kits were store at -20℃ for 24 hours, then transferred to RT for 24 hours. Four (4) freeze/thaw cycles were completed. Sample were tested after each cycle.

d. Low atmospheric condition: Test kits were tested after being stored in vacuum chamber set at 0.2 atm for 4 days.

All tests were performed in five (5) replicates, through the entire test system including the sample application and processing step. All negative samples tested negative; all positive samples (3x LoD) tested positive in all testing conditions.

iii. Sample Stability

Samples in the OTC environment will not undergo storage as the IFU instructs the user to immediately proceed from sample collection to the testing steps

6. Detection Limit:

a. Limit of Detection (LoD)

The Limit of Detection (LoD) of the GenBody COVID-19 Ag Home Test was determined by evaluating different dilutions of heat-inactivated SARS-CoV-2 (isolate USA-WA1/2020) in PNSM. The LoD was determined as the lowest virus concentration that was detected >95% of the time (e.g., concentration at which at least 19 out of 20 replicates tested positive). The limit of detection was established in two phases.

i. Preliminary LoD Study:

The preliminary LoD was determined by first testing serial ten-fold dilutions of heat inactivated SARS-CoV-2 virus stocks diluted into PNSM in replicates of three (3) per dilution and lot. Once the ten-fold LoD range was established, additional two-fold dilutions of the lowest positive ten-fold dilution were tested in replicates of five (5) to determine the preliminary LoD. Virus dilutions (50 µL/swab) were each spiked onto dry sterile swabs and tested per the QRI. Total of three (3) test kit lots have been tested to demonstrate LOD consistency across different device lots. The preliminary LoD results for each individual virus strain is shown in the table below.

Table 4: Preliminary LoD Study Results

Isolate/Lineage	SARS-CoV-2 ($TCID_{50}$/mL)	SARS-CoV-2 ($TCID_{50}$/Swab)	# of Positive/# Total Tested (All lots combined)
SARS-CoV-2 USA-WA1-2020 (heat inactivated)	2.19×10^5	1.10×10^4	9/9
	2.19×10^4	1.10×10^3	9/9
	2.19×10^3	1.10×10^2	9/9
	2.19×10^2	1.10×10^1	1/9
	2.19×10^3	1.10×10^2	15/15
	1.10×10^3	5.50×10^1	15/15
	5.48×10^2	2.74×10^1	12/15

ii. Confirmatory LoD Study:

To confirm LoD, 15 additional replicates were tested at each device lot at the preliminary LoD concentration, as determined above (n=20 per lot, including data in table 4). The LoD was confirmed if at least 95% (≥19/20) of the replicates yielded positive results. Results of the LoD confirmation testing are summarized in the table below.

Table 5: Confirmatory LoD Study Results

Isolate/Lineage	LoD Concentration ($TCID_{50}$/mL)	LoD Concentration ($TCID_{50}$/swab)	# of Positive/# Total Tested (All Lots combined)
SARS-CoV-2 USA-WA1/2020 (heat inactivated)	2.19×10^3	1.10×10^2	45/45
	1.10×10^3	5.50×10^1	45/45
	5.48×10^2	2.74×10^1	37/45

The limit of detection for the Genbody COVID-19 Ag Home Test was determined to be 1.10×10^3 $TCID_{50}$/mL of sample and was achieved by all tested lots. This is equivalent to 5.5×10^1 $TCID_{50}$/swab.

b. International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368)

The LoD of the Genbody COVID-19 Ag Home Test was determined by evaluating different dilutions of SARS-CoV-2 antigen (NIBSC code: 21/368) in PNSM. The preliminary LoD was determined by testing serial two -fold dilutions of SARS-CoV-2 antigen in PNSM in replicates of three (3) per dilution and lot. For each sample, 50 µL/swab was applied onto dry sterile swabs and tested per the IFU. The confirmatory LoD study included an additional 17 replicates per dilution level, bringing total to 20 replicates per lot (including preliminary LoD).

The LoD of GenBody COVID-19 Ag Home Test using the 1st International Standard for SARS-CoV-2 antigen (NIBSC 21/368) was confirmed to be 625 IU/mL (31.3 IU/swab).

Table 6: LoD Study Results for SARS-CoV-2 Antigen (NIBSC code: 21/368)

Preliminary LoD			Confirmatory LoD		
Concentration (IU/ml)	IU/swab	#Positive/ # Total (All lots combined)	Concentration (IU/ml)	IU/swab	# of Positive/ # Total Tested (All lots combined)
5×10^3	250	9/9			
2.5×10^3	125	9/9			
1.25×10^3	62.5	9/9	1.25×10^3	62.5	51/51
6.25×10^2	31.3	9/9	6.25×10^2	31.3	49/51
3.13×10^2	15.7	4/9	3.13×10^2	15.7	27/51

7. High-Dose Hook Effect Study:

No high-dose hook effect was observed with a concentration of 2.19×10^6 $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus (isolate USA-WA1/2020) tested with the GenBody COVID-19 Ag Home Test.

8. Inclusivity Study:

Analytical reactivity testing was performed for the GenBody COVID-19 Ag Home Test to determine if the device can detect the target analytes across a variety of strains. A selection of temporally, geographically, and genetically diverse SARS-CoV-2 strains were tested for inclusivity. A series of three (3) ten-fold dilutions of each virus was spiked into PNSM and tested. Once the ten-fold LoD range was established for each strain, an additional series of three (3) two-fold dilutions of the lowest positive ten-fold dilution for each virus was tested in replicates of five (5) to demonstrate inclusivity. The minimum detectable level of each variant (lowest concentration at which all replicates tested positive) is summarized in the table below.

Table 7: Minimal Detectable Concentrations of SARS-CoV-2 Variants

SARS-CoV-2 Variant	Subtype/lineage	Concentration ($TCID_{50}$/mL)
Alpha	B.1.17	1.2×10^3
Beta	B.1.351	3.8×10^2
Gamma	P.1	8.5×10^3
Delta	B.1.617.2	5.0×10^2
Omicron	BA 5.5	1.6×10^2
	BQ.1	1.4×10^3
	XBB	6.6×10^3
	BQ 1.1	3.3×10^2
	BA 2.75.5	1.7×10^2
	BA 2.12.1	1.3×10^3
	JN 1.4	4.2×10^2
	B.1.1.529	1.4×10^1
	BA.2.3	1.2×10^2

9. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable. See Section C. Clinical Studies.

2. Matrix Comparison:

The GenBody COVID-19 Ag Home Test is only intended for use with direct anterior nasal swab specimens. As no other specimen or sample type is claimed for this device, a matrix comparison study is not applicable.

C Clinical Studies:

1. Clinical Performance Assessment:

A prospective, multi-center clinical study was conducted across eleven (11) clinical U.S. sites between March 2024 to January 2026 to evaluate the clinical performance of the

GenBody COVID-19 Ag Home Test in detecting nucleoprotein antigen in anterior nasal swab specimens. The lay user study was conducted in a simulated home-use setting with symptomatic subjects aged 2 years or older who presented two or more symptoms of respiratory infection consistent with COVID-19. Two anterior nasal swab samples were collected from each subject: one for the candidate test and one for the comparator test. Healthcare professionals at the clinical study sites collected the comparator test samples first, which were inserted into viral transport media and transported to a central laboratory for testing with a highly sensitive RT PCR test. Samples for the GenBody COVID-19 Ag Home Test were collected per the test's quick reference instructions (QRI) and were either self-collected by a lay user aged ≥14 years or collected by an adult (parent/guardian) from individuals aged 2 to <14 years. 1096 samples were deemed evaluable. 43 results were excluded from the clinical study analysis due to enrollment past 5 days post symptom onset (DPSO), not meeting enrollment criteria, protocol deviations, and comparator invalid results.

Detailed study subject demographics are listed below:

Table 8: Summary of Overall Demographics

Age	**Mean**	**Median**
	38.5 (20.0)	36 [2, 89]
	N	**%**
≥2 and <14 years of age	121	11.1
14-21 years of age	116	10.6
>22-64 years of age	712	65.0
≥65 years of age	146	13.3
Sex	**N**	**%**
Female	654	59.7
Male	442	40.3
Race	**N**	**%**
American Indian/Alaskan Native	6	0.5%
Asian	263	24.0%
Black/African American	206	18.8%
Native Hawaiian or Pacific Islander	11	1.0 %
White	517	47.2%
Afro-Indigenous	1	0.1%
Columbian	4	0.4%
Hispanic	3	0.3%
Mexican	5	0.5%
Middle Eastern	2	0.2%
Mixed	12	1.1%
Unknown/Prefer not to answer	35	3.2%
Other	4	0.4%
Ethnicity	**N**	**%**
Hispanic/Latino	155	14.1%
Not Hispanic/Latino	770	70.3%
Not Provided/Unknown	171	15.6%

Results obtained with the GenBody COVID-19 Ag Home Test were compared to the results obtained with highly sensitive RT-PCR comparator tests giving rise to the following performance estimates:

Table 9: Clinical Performance for Detection of SARS-CoV-2

SARS-CoV-2	Comparator Positives	Comparator Negatives	Total
Candidate Positives	131	0	131
Candidate Negatives	21	944	965
Total	152	944	1096

Positive Percent Agreement = (131/152) = 86.2% (95% CI: 79.8% - 90.8%)
Negative Percent Agreement = (944/944) = 100.0% (95% CI: 99.6% - 100.0%)

Results for SARS-CoV-2 were also analyzed stratified by the number of days post symptom onset (DPSO) and are presented below.

Table 10: Clinical Performance for Detection of SARS-CoV-2 stratified by DPSO

DPSO*	Number of Subject samples tested	Investigational Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA (95% CI)
0	73	9	11	81.8%	52.3% - 94.9%
1	286	37	42	88.1%	75.0% - 94.8%
2	336	38	43	88.4%	75.5% - 94.9%
3	233	29	33	87.9%	72.7% - 95.2%
4	124	13	18	72.2%	49.1% - 87.5%
5	44	5	5	100.0%	56.6% - 100.0%
Total	1096	131	152	86.2%	79.8% - 90.8%

* DPSO: Days Post Symptom Onset

2. Usability Study:

A human factors usability study was conducted from March 24, 2025, to May 16, 2025, to evaluate whether lay users could correctly perform the GenBody COVID-19 Ag Home Test using only the Quick Reference Instructions (QRI). A total of 70 participants, across two (2) clinical sites, were enrolled, including 45 individuals who self-collected and tested their own samples and 25 adult lay users who collected and tested samples from another individual (child or adult), in a simulated home-use environment without professional assistance.

Participants were observed performing each step of the test procedure. Tasks were categorized as either critical (C) or non-critical (NC) based on potential use-related risk. The predefined acceptance criteria were ≥90% correct performance for critical tasks and ≥80% for non-critical tasks. Overall, 97.9% of critical tasks (617/630) and 95.0% of non-critical tasks (532/560) were performed correctly, meeting all usability performance thresholds. No unplanned deviations from the protocol were reported. A summary of the usability study is listed in the table below:

Table 11: Age Distribution of the Usability Study Cohort

Age Group	Lay-user collection and testing (Tester, N=25)	Self-collecting and testing (Subject, N=45)	Overall (N=70)
≥2 - <14 years of age	15 (60.0%)	0 (0.0%)	15 (21.4%)
14-24 years of age	0 (0.0%)	13 (28.9%)	13 (18.6%)
>24-64 years of age	10 (40.0%)	31 (68.9%)	41 (58.6%)
≥65 years of age	0 (0.0%)	1 (2.2%)	1 (1.4%)

Table 12: Usability Study Results

Steps	Tasks performed correctly	Total number of tasks	Percentage of tasks performed correctly
Critical	617	630	97.9%
Non-Critical	532	560	95.0%
Total	**1149**	**1190**	**96.6%**

3. Lay User Readability Study

The purpose of this study was to determine whether lay users could interpret test results correctly, especially with mock low positive samples from GenBody COVID-19 Ag Home Test. All 70 subjects who participated in the human factors assessment also completed a labeling comprehension and readability assessment by interpreting a blinded and randomized panel of mock investigational tests, which included results reflecting test concentrations at approximately 1.9x and 5x LoD, as well as negative and invalid results. Each subject interpreted a total of five mock results, yielding 350 total interpretations across the study. Each panel contained one negative, one invalid, one low positive (1.9x LoD), one positive (5x LoD) and a test result that was either low positive or negative (randomized by each panel).

A total of 16 subjects (22.9%) reported having vision impairments, including near sightedness, far-sightedness, or diabetic retinopathy. No subjects with macular degeneration, color blindness, cataracts, or amblyopia/strabismus were enrolled in the study. The overall interpretation accuracy across all participants was 95.7% (335/350), with a 95% CI of 93.0% to 97.4%. Interpretation performance was consistent regardless of the presence or absence of visual impairment.

Table 13: Vision Impairment of Readability Study

Type of Vision Impairment	# of Subjects	Percentage of Total Human Factors Subjects with Vision Impairment (N=70)
Near sightedness only (with lens prescription)	6	8.6%
Far sightedness only (with lens prescription)	5	7.1%
Astigmatism	0	0.0%
Diabetic retinopathy	1	1.4%
More than one visual impairment condition	4	5.7%
Total subjects/testers with vision impairment	16	22.9%

Table 14: Lay User Readability Study Results

Mock Device Type	Percent Accuracy of Mock Test Interpretation

	Subjects without Visual Impairment (N= 54)	Subjects with Visual Impairment (N=16)
1.9x LoD	90.8%	91.7%
5x LoD	100.0%	100.0%
Invalid	90.7%	100.0%
Negative	100.0%	95.8%
Total	95.6%	96.3%

Out of 350 mock device readings, one low positive mock device was interpreted as invalid, and eight low-positive mock devices (1.9x LoD) were incorrectly read as negative. One negative mock device was interpreted as positive; four invalid mock devices were interpreted as positive (n=2) and negative (n=2). All moderate positive mock devices (5x LoD) were interpreted correctly. Of the 16 incorrectly interpreted devices, 43% were read by study participants with vision impairment. Therefore, it is recommended that users with conditions affecting their vision ensure help in interpretation of their test results. A related warning statement is included in the labelling documents.

4. Clinical Sensitivity:

   Please refer to Section VII.C (Clinical Studies) above for the clinical validation.

5. Clinical Specificity:

   Please refer to Section VII.C (Clinical Studies) above for the clinical validation.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable. A patient is expected to be negative for SARS CoV-2.

F Other Supportive Performance Characteristics Data:

1. **Flex Studies:**

   To assess the robustness of the GenBody COVID-19 Ag Home Test, flex studies were conducted that assessed all major aspects of the test procedure (e.g., sample volume, reading time, extraction buffer volume, swab elution time, and procedure), variability of environmental test conditions that the test may be subjected to when in use (e.g., device orientation, lighting, various temperature, and humidity stress conditions) and specimen stability before and after extraction. Testing was performed with contrived positive nasal swabs generated by diluting heat inactivated SARS-CoV-2 virus into PNSM at 1.5x LoD. The studies support that the test is robust in the intended use condition with an insignificant risk of erroneous result.

2. **Serial Testing:**

As a mitigation for the low performance of antigen tests very early and at the tail end of infection, the Intended Use for this test device (and associated Instructions for Use) states that negative results are presumptive, and it includes the need for repeat testing (i.e., test at least twice over three days with at least 48 hours between tests). Although the data, when stratified by symptom onset have performance estimates with insufficient statistical confidence, the clinical study data set of this and similar studies for test devices of a similar principle and design, indicate that such mitigation is needed.

This mitigation is supported by data generated by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School (in collaboration with the FDA) demonstrating that repeat testing over multiple days improves test performance and increases the likelihood that a COVID-19 antigen test will accurately detect an infection. These results have informed the FDA's general understanding that repeat testing after a negative result from a COVID-19 antigen test reduces the risk of a false negative result. Please refer to the following studies for additional details:

- Finding a Needle in the Haystack: Design and Implementation of a Digital Site-less Clinical Study of Serial Rapid Antigen Testing to Identify Asymptomatic SARS-CoV-2 Infection –

  https://www.medrxiv.org/content/10.1101/2022.08.04.22278274v1

- Performance of Screening for SARS-CoV-2 using Rapid Antigen Tests to Detect Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infection: findings from the Test Us at Home prospective cohort study – https://www.medrxiv.org/content/10.1101/2022.08.05.22278466v1

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.