March 13, 2026

GenBody Inc.
Han-Bum Park
RA Manager
3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si
Chungcheongnam-do
Cheonan-si, 31077
Korea, South

Re: K251916
Trade/Device Name: GenBody COVID-19 Ag Home Test
Regulation Number: 21 CFR 866.3984
Regulation Name: Over-The-Counter Test To Detect SARS-Cov-2 From Clinical Specimens
Regulatory Class: Class II
Product Code: QYT
Dated: February 13, 2026
Received: February 13, 2026

Dear Han-Bum Park:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH BRIGGS -S

Joesph Briggs, Ph.D.
Deputy Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251916

Device Name
GenBody COVID-19 Ag Home Test

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

I. Background Information:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

A. 510(k) Number

K251916

B. Applicant

GenBody Inc.
Address: 3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea (Zip code: 31077)
Phone number: +82-10-9522-4244
Contact: Han-bum, Park (Mr.)
Contact email: hbpark@genbody.co.kr
Date: June 23, 2025

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	MI-Microbiology

II. Submission/Device Overview:

A. Purpose for Submission:

To obtain 510(k) clearance for the GenBody COVID-19 Ag Home Test. The identical test kit is currently marketed as *GenBody COVID-19 Ag Home Test* under Emergency Use Authorization, EUA210676.

B. Measurand

Nucleocapsid protein antigen from SARS-Coronavirus 2 (SARS-CoV-2)

C. Type of Test

Qualitative lateral flow immunoassay

III. Intended Use/Indications for Use:

A. Intended Use(s):

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.

B. Indications(s) for Use:

See Intended Use above

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 manually performed and 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 when tested at least twice over three (3) days with at least 48 hours between tests. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged two (2) years or older.

B. Principle of Operation.

The test strip in each device contains mouse monoclonal antibodies to the nucleocapsid protein (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, 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. Formation of the Control line serves as 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.

V. Substantial Equivalence Information:

A. Predicate Device Name(s):

CorDx Tyfast COVID-19 Ag Rapid 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	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 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	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. 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.

	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 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
Regulation Number	21 CFR 866.3984	Same
Classification Regulation	Class II	Same
Product Code	QYT	Same
Analyte	Nucleocapsid protein antigen from SARS-CoV-2	Same
Principle of the Technology	Qualitative lateral flow immunoassay	Same
Sample Type	Anterior nasal swab specimen	Same
Detection Format	Test cassette, visually read without an instrument,	Same
Assay Result	Qualitative (positive, negative, invalid)	Same
Reagent Storage	Store at 35.6-86°F/2-30°C	Same
Method to Obtain Result	Visually read by user	Same
Detection Period	Within 5 days of symptom onset	Same
General Device Characteristic Differences		
Development time	15-20 minutes	10 minutes

The differences between the GenBody COVID-19 Ag Home Test (proposed device) and the CorDx Tyfast COVID-19 Ag Rapid Test (predicate device, K240728) are limited to the development time of the lateral flow component. This difference does not impact the overall

substantial equivalence of the proposed device to the predicate device with respect to technological characteristics, intended use, safety, and effectiveness.

VI. Standards/Guidance Documents Referenced:

Document Title	Title	Publisher
Nonbinding recommendations September 6, 2023	Premarket validation recommendations for developers of in vitro diagnostic tests for SARS-CoV-2 antigen	FDA/CDRH /OHT7/DMD
EP17-A2	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures	CLSI
EP07-Ed3	Interference Testing in Clinical Chemistry	CLSI
EP34	Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking	CLSI
EP12-A2	User Protocol for Evaluation of Qualitative Test Performance	CLSI
EP05-A3	Evaluation of Precision of Quantitative Measurement Procedures	CLSI
ISO11135:2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices	ISO
ISO 10993-7	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals	ISO
ISO 10993-1	Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process	ISO
ISO 10993-5	Biological Evaluation of Medical Devices Tests for In vitro cytotoxicity	ISO
ISO 10993-10	Biological Evaluation of Medical Devices Tests for irritation and skin sensitization – Part 10: Tests for irritation and skin sensitization	ISO

VII. Performance Characteristics

A. Analytical Performance

1. Multi-lot Precision:
   The purpose of this study was to evaluate multi-lot precision (lot-to-lot variability) of the GenBody COVID-19 Ag Home Test using three (3) independently manufactured kit lots. Samples with three concentrations of heat-inactivated SARS-CoV-2 (Isolate: USA-WA1/2020) were generated by spiking the virus material into pooled negative swab matrix (PNSM) as follows:

1) Negative sample
2) Low positive sample at 1.5x LoD
3) Positive sample at 3x LoD

Each operator applied 50 µL of the coded sample to each dry nasal swab and processed the sample per the QRI of the GenBody COVID-19 Ag Home Test. The sample panel was tested in a blinded manner by two operators for 10 non-consecutive days. Each operator performed 2 replicates for each sample concentration during both morning and afternoon runs for all three test kit lots (3 Lots × 2 Runs × 2 Replicates × 2 Operators × 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 0.5x LoD (5.5×10^2 $TCID_{50}$/mL) of the same sample demonstrated 82% positivity.

2. Linearity:

Not applicable, the device is a qualitative visually read assay.

3. Analytical Specificity/Interference:

a. Cross-Reactivity and Microbial Interference

Cross-reactivity and microbial interference studies were performed to demonstrate that the GenBody COVID-19 Ag Home Test does not react and/or is not interfered with related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen of the nasal cavity.

Each microorganism and virus were tested in triplicate, both in the absence and presence of heat-inactivated SARS-CoV-2; USA-WA1/2020 at the 3x LoD concentration (3.3 x 10^3 $TCID_{50}$/mL). The tested concentrations were prepared to exceed 10^6 CFU/mL for bacteria and fungi, and 10^5 PFU/mL or $TCID_{50}$/mL for

viruses. All samples were randomized, coded, and distributed in a blinded manner to the operator for testing.

All tests were conducted by applying 50 μL of the sample to a nasal swab and then testing with the GenBody COVID-19 Ag Home Test according to the test procedure. No cross reactivity or interference was observed at the concentrations tested as shown in the table below.

Table 2. Summary of Cross-reactivity/Microbial Interference Study

No. Microorganisms		Final Testing Concentration	Unit	(Number of Positives/Total Tested)	
				Interference	Cross Reactivity
1	Coronavirus 229E	1.3E+05	$TCID_{50}$/mL	3/3	0/3
2	Coronavirus OC43	3.4E+05	$TCID_{50}$/mL	3/3	0/3
3	Coronavirus NL63	3.2E+05	$TCID_{50}$/mL	3/3	0/3
4	NATtrol MERS-CoV (Florida/USA-2 Saudi Arabia 2014)	26.4	Ct	3/3	0/3
5	SARS-CoV (Gamma-Irradiated) in PBS	9.0E+07	PFU/mL	3/3	0/3
6	Adenovirus 3	1.8E+09	PFU/mL	3/3	0/3
7	Adenovirus 7	3.6E+08	PFU/mL	3/3	0/3
8	Adenovirus 4	3.6E+08	PFU/mL	3/3	0/3
9	Adenovirus 1	1.3E+08	PFU/mL	3/3	0/3
10	Adenovirus 5	3.60.E+08	PFU/mL	3/3	0/3
11	Adenovirus 9 (Species D)	3.1E+07	$TCID_{50}$/mL	3/3	0/3
12	Human Metapneumovirus (hMPV)	2.7E+07	PFU/mL	3/3	0/3
13	Human Metapneumovirus (hMPV) Type A1	1.7E+05	$TCID_{50}$/mL	3/3	0/3
14	Parainfluenza Virus Type 1	3.4E+06	$TCID_{50}$/mL	3/3	0/3
15	Parainfluenza Virus Type 2	3.8E+05	$TCID_{50}$/mL	3/3	0/3
16	Parainfluenza Virus Type 3	3.6E+08	$TCID_{50}$/mL	3/3	0/3
17	Parainfluenza Virus Type 4A	5.3E+07	$TCID_{50}$/mL	3/3	0/3
18	Parainfluenza Virus Type 4B	1.3E+05	$TCID_{50}$/mL	3/3	0/3
19	Influenza A H3N2 (California/7/04)	1.5E+05	$TCID_{50}$/mL	3/3	0/3
20	Influenza B (Victoria/2/87)	9.5E+05	$TCID_{50}$/mL	3/3	0/3

21	Influenza A H1N1 (Korea/2018/H1N1)	9.0E+06	PFU/mL	3/3	0/3
22	Enterovirus B111	4.1E+06	$TCID_{50}$/mL	3/3	0/3
23	Enterovirus A71	1.1E+09	PFU/mL	3/3	0/3
24	Respiratory Syncytial Virus Type A (RSV-A)	1.1E+06	$TCID_{50}$/mL	3/3	0/3
25	Respiratory Syncytial Virus Type B (RSV-B)	9.5E+05	$TCID_{50}$/mL	3/3	0/3
26	Rhinovirus A (8)	1.8E+09	PFU/mL	3/3	0/3
27	Rhinovirus B (42)	1.8E+06	PFU/mL	3/3	0/3
28	Rhinovirus A (1B)	7.2E+08	PFU/mL	3/3	0/3
29	Rhinovirus A (16)	1.4E+09	PFU/mL	3/3	0/3
30	*Haemophilus influenzae*	1.5E+08	CFU/mL	3/3	0/3
31	*Streptococcus pneumoniae*	2.9E+06	CFU/mL	3/3	0/3
32	*Streptococcus pyogenes* (Group A)	2.1E+09	CFU/mL	3/3	0/3
33	*Streptococcus pyogenes* (Type 1)	8.6E+08	CFU/mL	3/3	0/3
34	*Candida albicans*	3.3E+07	CFU/mL	3/3	0/3
35	*Bordetella pertussis*	1.5E+10	CFU/mL	3/3	0/3
36	*Mycoplasma pneumoniae*	1.2E+08	CCU/mL	3/3	0/3
37	*Chlamydophila pneumoniae* (*Chlamydia pneumoniae*)	1.5E+08	IFU/mL	3/3	0/3
38	*Legionella pneumophila*	5.0E+08	CFU/mL	3/3	0/3
39	*Staphylococcus aureus*	4.3E+08	CFU/mL	3/3	0/3
40	*Staphylococcus epidermidis*	8.1E+08	CFU/mL	3/3	0/3
41	Pooled human nasal fluid	N/A		3/3	0/3
42	Human coronavirus HKU1*	20.9	Ct	3/3	0/3

*One clinical sample was tested.

b. Endogenous / Exogenous Interference Substances Study

A total of thirty-one (31) potentially interfering substances including endogenous and exogenous substances that may be found in upper respiratory tract, as well as household items such as soaps, were evaluated for their potential impact on the test performance.

Each substance was tested in triplicate, both in the presence and absence of heat-inactivated SARS-CoV-2;USA-WA1/2020 at 3x LoD concentration (3.3×10^3 $TCID_{50}$/mL). All samples were randomized, coded and distributed in a blinded manner to the operator for testing.

All tests were conducted by applying 50 µL of the sample to a nasal swab and then testing with the GenBody COVID-19 Ag Home Test according to the test procedure. The performance of GenBody COVID-19 Ag Home Test was not affected by any of the potentially interfering substances listed in the table below at the concentrations tested.

Table 3. Summary of Interfering Substances Study

No.	Interfering Substances	Tested Concentration	With SARS-CoV-2 (Number of Positives/Total Tested)	Without SARS-CoV-2 (Number of Positives/Total Tested)
1	Benzocaine	3 mg/mL	3/3	0/3
2	Menthol	3 mg/mL	3/3	0/3
3	Phenol solution	5% (v/v)	3/3	0/3
4	Phenylephrine	15% (v/v)	3/3	0/3
5	Cromolyn sodium salt	15% (v/v)	3/3	0/3
6	Oxymetazoline hydrochloride	15% (v/v)	3/3	0/3
7	Beclomethasone	15% (v/v)	3/3	0/3
8	Dexamethasone	15% (v/v)	3/3	0/3
9	Flunisolide	15% (v/v)	3/3	0/3
10	Triamcinolone	15% (v/v)	3/3	0/3
11	Budesonide	15% (v/v)	3/3	0/3
12	Mometasone furoate	15% (v/v)	3/3	0/3
13	Fluticasone propionate	15% (v/v)	3/3	0/3
14	Tamiflu (Oseltamivir)	5 mg/mL	3/3	0/3
15	Molnupiravir (EIDD-2801)	5 mg/mL	3/3	0/3
16	Zanamivir	5 mg/ mL	3/3	0/3
17	Mupirocin	10 mg/mL	3/3	0/3
18	Mucin, bovine submaxillary glands	2.5 mg/mL	3/3	0/3
19	Bilirubin	4% (w/v)	3/3	0/3
20	Biotin	3500 ng/mL	3/3	0/3
21	Hemoglobin	4% (v/v)	3/3	0/3
22	Leukocytes	5.4×10^7 Cells/mL	3/3	0/3
23	Luffa Operculata	15% (w/v)	3/3	0/3
24	Galphimia glauca	15% (w/v)	3/3	0/3
25	Histaminum hydrochloricum	15% (w/v)	3/3	0/3
26	Alkalol (nasal wash)	15% (v/v)	3/3	0/3
27	Zicam nasal spray	15% (v/v)	3/3	0/3
28	Hand lotion	15% (v/v)	3/3	0/3
29	Hand sanitizer (liquid, Ethanol 70%)	15% (v/v)	3/3	0/3

30	Hand soap (liquid, Lauric acid)	15% (v/v)	3/3	0/3
31	Whole Blood (K2 EDTA)	2.5% (v/v)	3/3	0/3

4. Assay Reportable Range:

   Not applicable, the device is a binary qualitative assay that is visually read.

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

   a. Controls

   Internal Control:
   GenBody COVID-19 Ag Home Test has a built-in control; Control (C) line. A distinct reddish purple Control line should always appear if 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.

   b. Device Stability

   Real Time Stability (Shelf Life):

   The Real-Time stability study has been performed using three lots of unopened GenBody COVID-19 Ag Home Test kits. Three independently manufactured kit lots within 1 month from manufacturing were introduced in this study. The unopened test devices were stored at 2-8°C and 30°C. Two test samples, corresponding to 3x LoD and neat PNSM were tested at each test time point (every 3 months from t=0) in 5 replicates for each lot.
   All tests at each dilution were performed by adding 50 µL sample to a swab and then testing with the GenBody COVID-19 Ag Home Test according to the test procedure. Data collected to date in this study (baseline, every 3 months up to 18 months) supports a test kit shelf-life of 16 months when store at the intended storage temperature of 35.6 to 86℉, 2 to 30℃, at the time of clearance.

   Shipping Stability:

   A simulated shipping stability study was conducted to evaluate the robustness of the GenBody COVID-19 Ag Home Test under extreme transport conditions. Kits were subjected to:
   1) Severe temperature fluctuations (8 days, ranging from –20°C to 45°C),
   2) Prolonged high/low temperature storage (8 days at –20°C or 45°C),
   3) Freeze/thaw cycling (4 full cycles at –20°C to room temperature), and
   4) Low atmospheric pressure (0.2 atm for 4 days).

   At each stress condition, test performance was evaluated using contrived positive samples at 3x LoD (3.3×10^3 $TCID_{50}$/mL, USA-WA1/2020 strain) and SARS-CoV-2 negative pooled nasal swab matrix (PNSM). Each condition included 5 replicate tests per sample type. All tests were conducted according to the IFU procedures.

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.

6. Detection Limits:

a. Limit of Detection (LoD)

The LoD of the GenBody COVID-19 Ag Home Test was determined by limiting dilution studies using the heat-inactivated SARS-CoV-2 (isolate USA-WA1/2020; ZeptoMetrix, Cat No. 0810587CFHI). The concentration of virus provided by the manufacturer, ZeptoMetrix, was 2.19 x 10^6 $TCID_{50}$/mL. The strain was spiked into the pooled nasal swab matrix (PNSM) to prepare positive samples. All tests at each dilution were performed by adding 50 µL sample to a swab and then testing with the GenBody COVID-19 Ag Home Test according to the test procedure.

In order to approximate the LoD concentration, 10-fold serial dilutions of the heat-inactivated SARS-CoV-2 were tested in triplicates from each of the three lots. The lowest concentration at which all 9 replicates produced a positive result, 2.19 x 10^3 $TCID_{50}$/mL, was chosen for preliminary LoD study.

Table 4. Test Results of Initial Range Finding LoD

Tested Concentration ($TCID_{50}$/mL)	Tested Concentration ($TCID_{50}$/Swab)	Test Results (Positive/Tested)			Total Agreements Positive/Tested
		Lot #1	Lot #2	Lot #3	
2.19 x 10^5	1.10 x 10^4	3/3	3/3	3/3	9/9
2.19 x 10^4	1.10 x 10^3	3/3	3/3	3/3	9/9
2.19 x 10^3	**1.10 x 10^2**	**3/3**	**3/3**	**3/3**	**9/9**
2.19 x 10^2	1.10 x 10^1	0/3	1/3	0/3	1/9

Once the ten-fold LoD range was established, additional two-fold dilutions of the lowest positive ten-fold dilution were tested in 5 replicates per test kit lot to determine the preliminary LoD of each virus. The lowest concentration producing all 15 positive results was 1.10 x 10^3 $TCID_{50}$/mL (Table 5).

Table 5. Test Results of Preliminary LoD Determination

Tested Concentration ($TCID_{50}$/mL)	Tested Concentration ($TCID_{50}$/Swab)	Test Results (Positive/Tested)			Total Agreements Positive/Tested
		Lot #1	Lot #2	Lot #3	
2.19 x 10^3	1.10 x 10^2	5/5	5/5	5/5	15/15
1.10 x 10^3	**5.5 x 10^1**	**5/5**	**5/5**	**5/5**	**15/15**
5.48 x10^2	2.74 x 10^1	3/5	5/5	4/5	12/15

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. Tests were conducted over three consecutive days, with a

different test kit lot each day. The confirmatory LoD results are shown below (Table 6).

Table 6. Test Results of LoD Confirmation

Tested Concentration ($TCID_{50}$/mL)	Tested Concentration ($TCID_{50}$/Swab)	Test Results (Positive/Tested)			Total Agreements Positive/Tested
		Lot #1	Lot #2	Lot #3	
2.19×10^3	1.10×10^2	15/15	15/15	15/15	45/45
1.10×10^3	**5.5×10^1**	**15/15**	**15/15**	**15/15**	**45/45**
5.48×10^2	2.74×10^1	12/15	12/15	13/15	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. NIBSC code: 21/368 – WHO International Standard

For the LoD testing of the GenBody COVID-19 Ag Home Test, the SARS-CoV-2 Antigen 1st WHO International Standard (NIBSC code: 21/368) was reconstituted following the IFU provided by NIBSC (i.e., in 0.25 mL of ultra-pure water), resulting in a concentration of 20,000 IU/mL. All tests were performed by adding 50 µL sample to a swab and then testing with the GenBody COVID-19 Ag Home Test according to the test procedure.

In order to approximate the LoD concentration, two (2) ampoules of NIBSC 21/368 were reconstituted and pooled prior to the start of the study. The initial test concentration was prepared as 5,000 IU/mL by diluting the reconstituted solution 4-fold with pooled negative swab matrix (PNSM), and then serially diluted 2-fold.

The preliminary LoD was determined by testing serial two-fold dilutions of SARS-CoV-2 antigen in PNSM in 3 replicates per dilution and lot. The lowest concentration at which all 9 replicates (3 replicates per lot) produced a positive result was selected as the Preliminary LoD, 625 IU/mL (Table 7).

Table 7. Test Results of Preliminary LoD Determination

Tested Concentration (IU/mL)	Tested Concentration (IU/Swab)	Test Results (Number of Positives/Total Tested)			Results (Number of Positives/Total Tested)
		Lot #1	Lot #2	Lot #3	
5,000	250.0	3/3	3/3	3/3	9/9
2,500	125.0	3/3	3/3	3/3	9/9
1,250	62.5	3/3	3/3	3/3	9/9
625	**31.3**	**3/3**	**3/3**	**3/3**	**9/9**
313	15.7	1/3	1/3	2/3	4/9

The confirmatory LoD study included an additional 17 replicates per dilution level, bringing total to 20 replicates per lot (including preliminary LoD). The confirmatory LoD results are shown below (Table 8).

Table 8. Test Results of LoD Confirmation

Tested Concentration (IU/mL)	Tested Concentration (IU/Swab)	Test Results (Number of Positives /Total Tested)			Results (Number of Positives /Total Tested)
		Lot #1	Lot #2	Lot #3	
1,250	62.5	17/17	17/17	17/17	51/51
625	**31.3**	**16/17**	**17/17**	**16/17**	**49/51**
313	15.7	9/17	8/17	10/17	27/51

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).

7. Inclusivity

To evaluate the inclusivity (analytical reactivity) of the GenBody COVID-19 Ag Home Test, major SARS-CoV-2 variants across multiple lineages were tested. Each variant was serially diluted in pooled negative clinical matrix for testing.
A series of 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-fold dilutions of the lowest positive ten-fold dilution for each virus was tested in 5 replicates. In this study, 50 µL each SARS-CoV-2 strain sample was spiked onto sterile swab and tested in 5 replicates. The samples were randomized and blinded during testing. The summary of test results is presented below (Table 9).

Table 9. Inclusivity (Analytical Reactivity)

SARS-CoV-2 variant	Subtype / Lineage	Lowest Test Concentration with 100% detection [$TCID_{50}$/mL]	Result (Number of Positives/Total Tested)
Alpha	B.1.1.7	1.2×10^3	5/5
Beta	B.1.351	3.8×10^2	5/5
Gamma	P.1	8.5×10^3	5/5
Delta	B.1.617.2	5.0×10^2	5/5
Omicron	BA 5.5	1.6×10^2	5/5
	BQ.1	1.4×10^3	5/5
	XBB	6.6×10^3	5/5
	BQ 1.1	3.3×10^2	5/5
	BA 2.75.5	1.7×10^2	5/5
	BA 2.12.1	1.3×10^3	5/5
	JN 1.4	4.2×10^2	5/5
	B.1.1.529	1.4×10^1	5/5
	BA.2.3	1.2×10^2	5/5

8. High Dose Hook Effect

The hook effect study was conducted to evaluate if high levels of antigen present in the sample could result in a false negative test result. In this study, 50 µL of the highest concentration possible for heat inactivated SARS-CoV-2 virus stock was spiked onto sterile swab and each sample was tested in triplicate per QRI of the GenBody COVID-19 Ag Home Test. Testing showed no hook effect for SARS-CoV-2 at the concentrations listed in the table 10 below.

Table 10. Summary of High Dose Hook Effect Results

Virus	Strain	Virus Concentration [$TCID_{50}$/mL]	Virus Concentration [$TCID_{50}$/swab]	Result (Number of Positives/Total Tested)
SARS-CoV-2	USA-WA1/2020	2.19×10^3	1.10×10^2	3/3
		2.19×10^4	1.10×10^3	3/3
		2.19×10^5	1.10×10^4	3/3
		2.19×10^6	1.10×10^5	3/3

B. Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable, See "C. Clinical Studies" for clinical performance comparison with a clinical comparator.

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 used with this device, a matrix comparison study to support other sample types for clinical testing with this device was not performed.

C. Clinical Studies

1. Clinical Sensitivity and Specificity

A prospective, multi-center clinical study was conducted with lay users to evaluate the clinical performance of the GenBody COVID-19 Ag Home Test in detecting nucleoprotein antigens extracted from COVID-19 in self-collected and self-tested anterior nasal swab samples at simulated home-use setting. The study only enrolled subjects aged 2 years and older with two or more symptoms of respiratory infection consistent with COVID-19. Eleven (11) sites across the U.S. conducted the study from March 2024 to January 2026. Both the comparator and the candidate test used anterior nasal swab samples. Comparator test samples were collected first by health care professionals at the clinical study sites. Samples were then sent to a reference laboratory for testing with highly sensitive RT-PCR tests detecting SARS-CoV-2. 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. Detailed study subject demographics are summarized below:

Table 11. Summary of Overall Demographics

Categories	Factor	
Age Distribution*	Mean (SD)	38.5 (20.0)
	Median [Min, Max]	36 [2, 89]
Sex	Female	654 (59.7%)
	Male	442 (40.3%)
	Total	**1,096 (100.0%)**
Age Group*	**Total**	**%**
≥2 - <14 years of age	121	11.1%
14-24 years of age	116	10.6%
>24-64 years of age	712	65.0%
≥65 years of age	146	13.3%
Total	**1,095**	**100.0%**

*One participant ('self-tester') declined to provide age information

Education Level for Self-testers or Testers testing on another	Total	%
Less than High School Diploma	165	17.7%
High School Diploma	269	28.9%
Some college, no degree	217	23.3%
Associates Degree	72	7.7%
Bachelor's Degree	247	26.5%
Master's Degree	86	9.2%
Doctorate (e.g. PhD, EdD)	14	1.5%
Professional Degree (e.g. MD, DDS, JD)	19	2.0%
Other	5	0.5%
Not Provided/Unknown	2	0.2%
Total	**1,096**	**100.0%**

A total of 1,096 evaluable subjects were included in the final analysis, including 152 RT-PCR positive (13.9%) and 944 RT-PCR-negative cases (86.1%). When compared to the comparator assay, the GenBody COVID-19 Ag Home Test demonstrated a Positive Percent Agreement (PPA) of 86.2% (95% CI: 79.8% to 90.8%) and a Negative Percent Agreement (NPA) of 100.0% (95% CI: 99.6% to 100%). Results are listed in the table below:

Table 12. Clinical Performance Estimates

Investigational Test	Comparator Test		Total
	Positive	Negative	
Positive	131	0	**131**
Negative	21	944	**965**
Total	**152**	**944**	**1,096**
Positive Percent Agreement (PPA)		**86.2% (95% CI: 79.8% - 90.8%)**	
Negative Percent Agreement (NPA)		**100% (95% CI: 99.6% - 100.0%)**	

Clinical performance was assessed in subjects tested within 0 to 5 days of symptom onset (DPSO). The clinical performance of GenBody COVID-19 Ag Home Test stratified by DPSO is summarized in the table below:

Table 13. Clinical Performance Stratified by DPSO

DPSO	Total	Investigational Positive	Comparator Positives	PPA (%)	95% CI
Day 0	73	9	11	81.8%	52.3%-94.9%
Day 1	286	37	42	88.1%	75.0%-94.8%
Day 2	336	38	43	88.4%	75.5%-94.9%
Day 3	233	29	33	87.9%	72.7%-95.2%
Day 4	124	13	18	72.2%	49.1%-87.5%
Day 5	44	5	5	100.0%	56.6%-100.0%
Total	**1,096**	**131**	**152**	**86.2%**	**79.8%-90.8%**

Approximately 10.5% of RT-PCR positive samples were classified as low positive based on the comparator's Ct values.

Table 14. Clinical Performance Stratified by Age

Subject Age*	Total	Investigational Positive	Comparator Positives	% Positivity Rate (by Comparator)
≥2 and <14 years of age	121	6	6	5.0%
14-21 years of age	116	11	14	12.1%
>22-64 years of age	712	85	102	14.3%
≥65 years of age	146	29	30	20.5%
Total	**1,095**	**131**	**152**	**13.9%**

*One participant ('self-tester') declined to provide age information

2. Usability

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 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 15. Age Distribution of the Usability Study Cohort

Factor	Lay-user collection and testing (Tester, N=25)	Self-collecting and testing (Subject, N=45)	Overall (N=70)
Age			
Mean (SD)	19.1 (15.3)	35.6 (14.8)	29.7 (16.9)
Median [Min, Max]	11.0 [2.0, 49.0]	38.0 [14.0, 70.0]	28.0 [2.0, 70.0]
Age Group			
≥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 16. 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. Readability and Comprehension

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.
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 17. 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 18. 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%**

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. OTC Flex Studies

To evaluate the robustness of the GenBody COVID-19 Ag Home Test, a series of flex studies were conducted under various stress conditions based on risk analysis of potential user-related errors and environmental factors. The following conditions were assessed: swab sample stability before and after extraction, reagent stability after opening, sample input volume (number of drops), extraction buffer volume, swab extraction method (e.g., varying the rotations and tube squeezing), device positioning (non-level surfaces), environmental disturbances during use, variation in light sources, and deviations in result reading time. Testing was performed with contrived positive nasal swabs generated by diluting SARS-CoV-2 virus into negative PNSM at 1.5x LoD. Across all tested conditions, the assay demonstrated consistent performance within predefined acceptance criteria. No significant impact on test accuracy was observed across the evaluated stress scenarios. These findings confirm the assay's robustness to minor deviations from the Instructions for Use (IFU) and support its reliability in varied home-use environments.

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. Conclusion

The information provided in this Premarket Notification demonstrates that the performance of the GenBody COVID-19 Ag Home Test is substantially equivalent in intended use, technological characteristics and performance to the predicate device.