



September 5, 2025

Genabio Diagnostics Inc
Han Si
Regulatory and Quality Manager
19 Crosby Dr
Suite 220
Bedford, Massachusetts 01730

Re: K251753

Trade/Device Name: GenaCheck COVID-19 Rapid Self-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: June 6, 2025
Received: June 9, 2025

Dear Han Si:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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

Joseph 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

Indications for Use

510(k) Number (if known)
K251753

Device Name
Genacheck COVID-19 Rapid Self-Test

Indications for Use (Describe)

The GenaCheck COVID-19 Rapid Self-Test is a visually read lateral flow immunoassay test 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 either 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 October 2024 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 suspect.

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.

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510(k) Summary

1. Submitter

Genabio Diagnostics Inc.

Address: 19 Crosby Drive, Suite 220, Bedford, MA 01730, USA

Phone number: 1-800-614-3365

Contact: Han Si

Contact email: han.si@genabio.com

Date Prepared: September 4th, 2025

2. Device Classification

Device trade name: GenaCheck® COVID-19 Rapid Self-Test

Device common name: Coronavirus Antigen Detection Test

Product code: QYT

Classification Regulation: 21 CFR 866.3984 - Over-The-Counter Covid-19 Antigen Test

Classification: Class II

Review panel: Microbiology

Predicate device ACON - Flowflex Plus COVID-19 Home Test (K233373)

3. Device Description

The GenaCheck® COVID-19 Rapid Self-Test is a rapid, qualitative latex particles based immunochromatography test. The test is designed to detect nucleocapsid protein antigen in anterior nasal swab specimens from individuals who show symptoms of COVID-19 infection within the first five (5) days of symptom onset. The GenaCheck® COVID-19 Rapid Self-Test is validated for use from direct specimens testing without transport media.

The test package is composed of the following components:

- Test Cassette within a Foil Pouch
- Lysis Buffer
- Anterior Nasal Swab
- Quick Reference Instructions

The test cassette contains a test strip (binding pad) in a plastic housing. The binding pad is a nitrocellulose membrane with two regions: test region (T) and control region (C).

3.1 Principle of Operation

To perform the test, an anterior nasal swab specimen is obtained by a lay user. Swabs can be self-collected by the user (age ≥ 14 years) or collected by an adult from another individual (age ≥ 2 years). For sample processing, the swab is inserted into the lysis buffer which disrupts the virus particles in the specimen, exposing internal viral nucleocapsid antigens. Three (3) drops of the lysed specimen are added to the sample well on the test cassette, the specimen migrates via capillary action from the sample well over the binding pad.

The binding pad is coated with anti-SARS-CoV-2 antibodies which are labeled with a latex bead marker. The test region is coated with monoclonal anti SARS-CoV-2 antibodies. The control region is coated with goat anti-mouse IgG antibodies. During testing, the anti-SARS-CoV-2 antibodies labeled with the latex bead marker, form immune complexes with the antigen protein of the virus in the specimen. The immune complexes move along the membrane via capillary action and are captured by the anti-SARS-CoV-2 monoclonal antibodies coated in the test region (T) to form a visible pink colored line. The anti-SARS-CoV-2 antibodies or immune complexes continue to move forward and specifically bind to the goat anti-mouse antibody coated in the control region (C) to form a visible pink line.

The results of the test are interpreted between 10 and 30 minutes after adding the lysed specimen solution into the sample well. A false negative or false positive result may occur if the test result is read before 10 minutes or after 30 minutes.

The formation of pink colored lines in the T region and the C region at the same time indicates that the sample is positive for the presence of the viral nucleocapsid protein antigen; the appearance of a pink colored line in the C region, but not T region, indicates that the sample is negative for the presence of nucleocapsid protein antigen. If no visible signal (i.e., pink colored line of any shade or intensity) appears in the C region the test result is invalid, and this sample should be tested again with another test cassette.

4. Intended Use

The GenaCheck® COVID-19 Rapid Self-Test is a visually read lateral flow immunoassay test 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 either 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 October 2024 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.

5. Comparison with Predicate Device

Characteristics	Subject Device	Predicate Device (K233373)
Product Name	GenaCheck® COVID-19 Rapid Self-Test	Flowflex Plus COVID-19 Home Test
Intended Use	<p>The GenaCheck® COVID-19 Rapid Self-Test is a visually read lateral flow immunoassay test 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.</p> <p>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.</p> <p>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 either 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.</p> <p>Positive results do not rule out co-infection with other respiratory pathogens.</p> <p>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,</p>	<p>The Flowflex Plus COVID-19 Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of</p> <p>SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal (nares) swab specimens from individuals with signs and symptoms of COVID-19 within the first 6 days from symptom onset.</p> <p>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.</p> <p>The Flowflex Plus COVID-19 Home Test does not differentiate between SARS-CoV and SARS-CoV-2.</p> <p>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 either 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.</p> <p>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</p>

	<p>such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.</p> <p>The performance characteristics for SARS-CoV-2 were established from March 2024 to October 2024 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 suspect.</p>	<p>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.</p> <p>The performance characteristics for SARS-CoV-2 were established from June 2022 to April 2023 when the COVID-19 variant 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.</p>
Product Code	QYT	QYT
Regulation Number	21 CFR 866.3984	21 CFR 866.3984
Target	SARS-CoV-2 virus nucleocapsid protein antigen	SARS-CoV-2 virus nucleocapsid protein antigen
Intended Use Population	Individuals with symptoms of COVID-19 within the first 5 days of symptom onset	Individuals with symptoms of COVID-19 within the first 6 days of symptom onset
Intended Use Setting	Over the counter use/self-testing	Over the counter use/self-testing
Usage Type	Single use test	Single use test
Test Result Type	Qualitative	Qualitative
Specimen Type	Anterior nasal swab specimens	Anterior nasal swab specimens
Analyte	SARS-CoV-2 nucleocapsid protein antigen	SARS-CoV-2 nucleocapsid protein antigen
Test Principle	Lateral flow immunoassay	Lateral flow immunoassay
Instrument Needed	No	No
Time to Result	10-30 min	15-30 min
Result Interpretation	Visually read	Visually read
Storage Condition	2-30 °C	2-30 °C

6. Analytical Performance Summary

6.1 Limit of Detection (LoD)

6.1.1 LoD using SARS-CoV-2 virus (USA-WA1/2020)

The Limit of Detection (LoD) was determined through two studies: Preliminary Testing and Confirmation Testing. One lot of the GenaCheck® COVID-19 Rapid Self-Test was used for preliminary LoD testing, while three separate lots were used for confirmation LoD testing.

The preliminary LoD of the GenaCheck® COVID-19 Rapid Self-Test was established by performing serial dilutions of UV-inactivated SARS-CoV-2 (USA-WA1/2020) in a negative clinical matrix (NCM) prepared as described in section 6.2, with each dilution tested in triplicate. The lowest concentration yielding positive results in all three replicates (3/3) was considered the preliminary LoD, which was determined to be 4.57×10^3 TCID₅₀/mL.

For confirmation, the preliminary LoD concentration and a series of 3-fold dilutions above and below this concentration were tested on each of the three lots, with 20 randomized replicates per concentration. The confirmed LoD concentration was defined as the concentration at which >95% of replicates tested positive. The final confirmed LoD of the GenaCheck® COVID-19 Rapid Self-Test was established at 1.52×10^3 TCID₅₀/mL.

Table 1. Preliminary LoD Determination and High Dose Hook Effect Study

Concentration (TCID ₅₀ /mL)	Number of Positive Results / Number of Repeat Tests
4.57E+06	3/3
4.57E+05	3/3
4.57E+04	3/3
4.57E+03 (Preliminary LoD)	3/3
4.57E+02	0/3

Table 2. LoD Confirmation

Concentration (TCID ₅₀ /mL)	Number of Positive Results / Number of Repeat Tests		
	Lot 1	Lot 2	Lot 3
4.57E+03	20/20	20/20	20/20
1.52E+03	20/20	20/20	20/20
5.08E+02	0/20	2/20	0/20

6.1.2 LoD using WHO International Standard (NIBSC 21/368)

Analytical sensitivity of the GenaCheck® COVID-19 Rapid Self-Test was also evaluated using the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368). A preliminary LoD with the WHO standard was determined to be 250 IU/mL through testing a series of 2-fold dilutions of the antigen spiked into negative clinical matrix (NCM), with each dilution tested in triplicate.

The LoD was then confirmed by testing an additional twenty (20) replicates at the concentrations 3-fold above and below the preliminary LoD. The results in Table 3 and Table 4 below confirmed the LoD for the WHO International Standard to be 250 IU/mL.

Table 3. Preliminary LoD with WHO Standard

Concentration of the WHO Standard (IU/mL)	Number of Positive Results / Number of Repeat Tests
20,000	3/3
4,000	3/3
2,000	3/3
1,000	3/3
500	3/3
250	3/3
125	0/3
62.5	0/3

Table 4. LoD Confirmation with WHO Standard

Concentration of the WHO Standard (IU/mL)	Number of Positive Results / Number of Repeat Tests
750	20/20
250	20/20
83.3	0/20

6.2 Multi-lot Precision

6.2.1 Initial Multi-Lot Precision Study

A precision study was conducted to evaluate variability across days, operators, and device lots. The study used a single internal site with two trained operators and three lots of test kits. Each day, three sample levels (Negative, 1.5× LoD, and 3× LoD) were tested with two replicates per run, per operator, and per kit lot. Two runs were conducted each day (at least four hours apart, typically morning and afternoon) by each operator with each lot. This exact testing scheme was followed for 12 days, with the same three sample levels tested across the same three lots by the same two operators in two runs per day, yielding a total of 864 tests.

Samples with three concentrations of UV-inactivated SARS-CoV-2 virus material (USA-WA1/2020) were prepared by spiking the virus material into a negative clinical matrix (NCM), resulting in the following sample types:

- Negative Sample
- Low Positive Sample at 1.5× LoD
- Positive Sample at 3× LoD

The NCM was prepared by diluting raw pooled nasal fluid in 0.9% saline solution at a 1:8 ratio due to high viscosity of nasal fluid samples. For the test, a 50µL volume of each sample was applied to dry nasal swabs. After blinding and randomization, samples were processed according to the Quick Reference Instructions for the candidate device.

All results matched the expected outcomes for the virus concentrations in the samples (Table 5). All negative samples (288/288) tested negative, yielding a 100% agreement (95% CI: 98.68–100). For both the 1.5×LoD and 3×LoD concentrations, all samples (288/288) tested positive, demonstrating 100% agreement (95% CI: 98.68–100%). No variability was observed across different conditions, including kit lots, operators, or days.

Table 5. Precision Study Summary Results

Sample Type	Kit Lot 1	Kit Lot 2	Kit Lot 3	Operator 1	Operator 2	Total Result	% Agreement (95% CI)
Negative	96/96	96/96	96/96	144/144	144/144	288/288	100% (98.68-100%)
Low Positive 1.5×LoD	96/96	96/96	96/96	144/144	144/144	288/288	100% (98.68-100%)
Moderate Positive 3×LoD	96/96	96/96	96/96	144/144	144/144	288/288	100% (98.68-100%)

6.2.2 Supplemental Precision Study

This study was specifically conducted to further evaluate potential differences between distinct lots, because the initial precision study resulted in 100% agreement across all sources of variation and did not allow a conclusive assessment of lot-to-lot variability of the test. The study was performed using a negative sample, one low positive sample at 0.8 X LoD (i.e., below the concentration tested in the initial study, and near the analyte's C95 concentration) and one positive sample at 3 X LoD.

Testing was conducted using the same protocol as the preliminary study, with the exception that the negative and 3 X LoD samples were only tested with one replicate per run, whereas the 0.8 X LoD samples were tested twice per run. For the negative and the 3 X LoD, samples the results were in 100% agreement with the expected result. Consistent with the analyte concentration of the low positive sample, the 0.8X LoD sample resulted in percent agreements less than 95%, with similar results for all lots. The results are summarized below in Table 6.

Table 6. Supplemental Precision Study Summary Results

Sample Type	Kit Lot 1	Kit Lot 2	Kit Lot 3	Operator 1	Operator 2	Total Result	% Agreement (95% CI)
Negative	48/48	48/48	48/48	72/72	72/72	144/144	100% (97.4-100%)
Low Positive <i>0.8xLoD</i>	77/96	80/96	81/96	128/144	110/144	238/288	82.64% (77.8-86.6%)
Moderate Positive <i>3xLoD</i>	48/48	48/48	48/48	72/72	72/72	288/288	100% (97.4-100%)

6.3 Cross-Reactivity/Microbial Interference

The analytical specificity of the GenaCheck® COVID-19 Rapid Self-Test was evaluated by testing various microorganisms, viruses, and negative clinical matrices for cross-reactivity (in the absence of SARS-CoV-2) and microbial interference (in the presence of SARS-CoV-2 at 3x LoD, or 4.57 x 10³ TCID₅₀/mL). Respiratory viral pathogens were tested at a final concentration of ≥1 x 10⁵ units/mL, or at the highest available concentrations. Common respiratory bacterial and yeast pathogens were tested at a final concentration of ≥1 x 10⁶ units/mL, or at the highest available concentrations. Each organism was assessed for potential cross-reactivity with the test antibodies by adding 50 µL of each sample directly to the test swab, followed by processing in accordance with the test's Quick Reference Instructions (QRI). Three replicates per microorganism were tested in this study.

Microbial interference testing was conducted similarly, with SARS-CoV-2 (USA-WA1/2020) co-spiked into the samples at 3x LoD.

Neither cross-reactivity nor microbial interference was observed for any of the tested microorganisms at the concentration used in the study.

Table 7. Cross-reactivity and Microbial Interference Study Results

Pathogens Added	Concentration Tested	Cross-reactivity Results (Positive/Tested)	Microbial Interference Results (Positive/Tested)
Adenovirus Type 1	2.23E+05 TCID ₅₀ /mL	0/3	3/3
Adenovirus Type 2	2.13E+06 TCID ₅₀ /mL	0/3	3/3
Adenovirus Type 7A	1.58E+05 TCID ₅₀ /mL	0/3	3/3
<i>Bordetella pertussis</i>	2.90E+08 CFU/mL	0/3	3/3
<i>Candida albicans</i>	1.21E+07 CFU/mL	0/3	3/3
<i>Chlamydia pneumoniae</i>	4.33E+06 IFU/mL	0/3	3/3
Enterovirus Type 68	2.23E+05 TCID ₅₀ /mL	0/3	3/3
<i>Hemophilus influenzae</i>	9.68E+06 CFU/mL	0/3	3/3
Human coronavirus 229E	1.58E+05 TCID ₅₀ /mL	0/3	3/3
Human coronavirus NL63	8.00E+04 TCID ₅₀ /mL	0/3	3/3
Human coronavirus OC43	7.00E+05 TCID ₅₀ /mL	0/3	3/3
Human Metapneumovirus	1.40E+05 TCID ₅₀ /mL	0/3	3/3
Influenza A H1N1	1.85E+08 CEID ₅₀ /mL	0/3	3/3
Influenza A H3N2	6.50E+06 FFU/mL	0/3	3/3
Influenza B Victoria	1.58E+05 TCID ₅₀ /mL	0/3	3/3
Influenza B Yamagata	1.90E+06 TCID ₅₀ /mL	0/3	3/3
<i>Legionella pneumophila</i>	6.50E+06 CFU/mL	0/3	3/3
MERS-coronavirus	1.40E+05 TCID ₅₀ /mL	0/3	3/3
<i>Mycobacterium tuberculosis avirulent</i>	3.03E+06 CFU/mL	0/3	3/3
<i>Mycoplasma pneumoniae</i>	2.50E+07 CFU/mL	0/3	3/3
Parainfluenza virus 1	2.00E+05 TCID ₅₀ /mL	0/3	3/3
Parainfluenza virus 2	1.40E+05 TCID ₅₀ /mL	0/3	3/3
Parainfluenza virus 3	7.00E+05 TCID ₅₀ /mL	0/3	3/3
Parainfluenza virus 4	2.39E+05 TCID ₅₀ /mL	0/3	3/3
Pooled Nasal Wash	N/A	0/3	3/3
Respiratory syncytial virus Type A	3.50E+05 TCID ₅₀ /mL	0/3	3/3
Respiratory syncytial virus Type B	2.29E+05 TCID ₅₀ /mL	0/3	3/3
Rhinovirus 1A	7.05E+04 TCID ₅₀ /mL	0/3	3/3
Rhinovirus B14	1.31E+05 TCID ₅₀ /mL	0/3	3/3
SARS-CoV-1	1.25E+05 PFU/mL	0/3	3/3
<i>Staphylococcus aureus</i>	2.60E+08 CFU/mL	0/3	3/3
<i>Staphylococcus epidermidis</i>	9.00E+07 CFU/mL	0/3	3/3
<i>Streptococcus pneumoniae</i>	1.81E+07 CFU/mL	0/3	3/3
<i>Streptococcus pyogenes</i>	7.50E+07 CFU/mL	0/3	3/3
HKU1 clinical sample 1	Ct value: 31.8	0/3	3/3
HKU1 clinical sample 2	Ct value: 27.4	0/3	3/3
HKU1 clinical sample 3	Ct value: 23.1	0/3	3/3

6.4 Interfering Substances Study

Thirty (30) potentially interfering substances were evaluated using the GenaCheck® COVID-19 Rapid Self-Test. Each substance was tested in triplicate, both in the absence and presence of SARS-CoV-2 at 3x LoD (4.57×10^3 TCID₅₀/mL).

Among all substances tested, hand sanitizer cream lotion was the only one to cause a false-positive result when tested at concentrations of 5% w/v or above. All other substances yielded expected results, indicating they do not impact the performance of the GenaCheck® COVID-19 Rapid Self-Test at the concentrations specified in the Table 8.

Table 8. Interfering Substances Study Results

Interfering Substances Tested	Test Concentration	SARS-CoV-2 Negative Sample (Positive/Tested)	SARS-CoV-2 Positive Sample (Positive/Tested)
Throat Lozenges (Benzocaine, Menthol)	3 mg/mL	0/3	3/3
Sore Throat Spray (Phenol)	5% v/v	0/3	3/3
Mucin (Purified mucin protein)	2.5 mg/mL	0/3	3/3
Whole Blood (Human)	2.5% v/v	0/3	3/3
Leukocytes	2×10^6 cells/mL	0/3	3/3
Throat Spray (Zinc)	15% v/v	0/3	3/3
Nasal Drops (Phenylephrine)	15% v/v	0/3	3/3
Nasal Spray (Cromolyn)	15% v/v	0/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	3/3
Nasal Spray (Saline)	15% v/v	0/3	3/3
Nasal corticosteroids (Beclomethasone)	15% v/v	0/3	3/3
Nasal corticosteroids (Dexamethasone)	15% v/v	0/3	3/3
Nasal corticosteroids (Flunisolide)	15% v/v	0/3	3/3
Nasal corticosteroids (Triamcinolone)	15% v/v	0/3	3/3
Nasal corticosteroids (Budesonide)	15% v/v	0/3	3/3
Nasal corticosteroids (Mometasone furoate)	15% v/v	0/3	3/3
Nasal corticosteroids (Fluticasone propionate)	15% v/v	0/3	3/3
Nasal Spray (Zicam, Luffa operculata, Galphimia glauca, Histaminum hydrochloricum)	15% v/v	0/3	3/3
Alkalol	15% v/v	0/3	3/3

Oseltamivir Phosphate (Tamiflu)	5 mg/mL	0/3	3/3
Remdesivir	10 mg/mL	0/3	3/3
Molnupiravir	10 mg/mL	0/3	3/3
Mupirocin	10 mg/mL	0/3	3/3
Nasal gel	5% v/v	0/3	3/3
Body Lotion (Dimethicone)	0.5% w/v	0/3	3/3
Hand Sanitizer (62% Ethyl alcohol)	5% v/v	0/3	3/3
Hand Sanitizer Cream Lotion* (Benzalkonium chloride)	5% w/v	3/3	3/3
Hand Sanitizer (80% Ethyl alcohol)	15% v/v	0/3	3/3
Hand Soap	10% w/v	0/3	3/3
Biotin	3,500 ng/mL	0/3	3/3

* Hand Sanitizer Cream Lotion was found to not interfere with testing at 1.67% w/v, giving negative results in 3 out of 3 replicates tested.

6.5 High Dose Hook Effect

This study evaluated the effect of a high concentration of SARS-CoV-2 antigen on the performance of GenaCheck® COVID-19 Rapid Self-Test. No high dose hook effect was observed for any of the UV-inactivated SARS-CoV-2 virus (USA-WA1/2020) dilutions from 4.57E+06 TCID₅₀/mL to 4.57E+03 TCID₅₀/mL tested.

6.6 Inclusivity (Analytical Reactivity)

The analytical reactivity of the GenaCheck® COVID-19 Rapid Self-Test was demonstrated in the inclusivity study testing additional 10 human SARS-CoV-2 variants listed in the table below. Each variant was serially diluted 3-fold in negative clinical matrix (NCM) and tested in triplicate. The minimum detectable level of each variant (lowest concentration at which all triplicates tested positive) is summarized in the table below.

Table 9. Inclusivity Study Results

SARS-CoV-2 Variant	Minimum Detectable Level (TCID ₅₀ /mL)
SARS-CoV-2 Lineage B.1.1.7; Alpha Variant	1.18E+04
SARS-CoV-2 Lineage B.1.351; Beta Variant	1.88E+03
SARS-CoV-2 Lineage P.1 Brazil; Gamma variant	1.56E+03
SARS-CoV-2 Lineage B.1.617.2; Delta Variant	1.30E+03
SARS-CoV-2 Lineage XBB; Omicron Variant	7.35E+03
SARS-CoV-2 Lineage BA.2.3; Omicron Variant	1.44E+02
SARS-CoV-2 Lineage BA.5; Omicron Variant	8.15E+02
SARS-CoV-2 Lineage B.1.1.529; Omicron Variant	4.80E+01
SARS-CoV-2; Hong Kong/VM20001061/2020	5.19E+02

SARS-CoV-2; Italy-INMI1	3.93E+03
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7. Clinical Testing Summary

7.1 Clinical Performance Study

The Clinical Performance Study was conducted from March 2024 to October 2024 as part of the clinical evaluation of the test device to demonstrate the performance characteristics of the GenaCheck® COVID-19 Rapid Self-Test to detect SARS-CoV-2 viral nucleoprotein antigen when used by lay users. The predominantly circulating variant was Omicron during the study period. This was a multi-center, prospective study performed at nine clinical sites in the U.S. One swab was first collected by the study staff and used for comparator testing at a central laboratory using a high-sensitivity RT-PCR test. The second swab was collected by a lay user and tested subsequently with the GenaCheck® COVID-19 Rapid Self-Test in a simulated home-use environment. A total of 666 specimens were either self-collected by lay users aged 14 or older or collected by a parent/guardian of the subjects between 2 and 13 years of age. Of those, 643 were evaluable based upon the inclusion and exclusion criteria for analysis. The GenaCheck® COVID-19 Rapid Self-Test results were compared to an FDA cleared highly sensitive molecular SARS-CoV-2 assay to determine the subject test performance.

The clinical study results presented in Tables 9-11 below demonstrate an acceptable performance of the GenaCheck® COVID-19 Rapid Self-Test.

Table 10. Subject Demographics

Demographic characteristic	n (%)
Age Group	
2-13 years	103 (16.0%)
14-21 years	52 (8.1%)
22-64 years	403 (62.7%)
≥65 years	85 (13.2%)
Gender	
Male	249 (38.7%)
Female	394 (61.3%)
Education Level (Lay User)	
Grade 12 or GED ^a	261 (40.6%)
Trade/tech/vocational	136 (21.1%)

Some college, no degree	105 (16.3%)
Bachelor’s degree	97 (15.1%)
Graduate or professional	37 (5.8%)
Not reported	7 (1.1%)
Race	
White or Caucasian	524 (81.5%)
Black or African	58 (9.0%)
Asian	47 (7.3%)
Native American	2 (0.3%)
Other ^b	12 (1.9%)

^a Includes subjects aged 14-18 who have not completed high school.

^b Includes subjects with two or more races.

Table 11. Clinical Performance of GenaCheck® COVID-19 Rapid Self-Test

GenaCheck® Self-Test	Comparator Method		
	Positive	Negative	Total
Positive	112	7	119
Negative	8	516	547
Total	120	523	643
Positive Percent Agreement (PPA)	93.3% (112/120) (95% CI: 87.4%-96.6%)		
Negative Percent Agreement (NPA)	98.7% (516/523) (95% CI: 97.3%-99.4%)		

Note: Out of the 7 false positive GenaCheck® results, 4 were tested to be positive with the high sensitivity RT-PCR test cobas® SARS-CoV-2 Qualitative for use on the cobas 5800/6800/8800 systems (K213804/K231306); out of the 8 false negative GenaCheck® results, 6 were tested to be positive with the cobas assay, 1 was presumptive positive, and 1 sample was not available for testing.

A total of 120 positive and 546 negative specimens were included in the performance data analysis, with an overall positive percent agreement (PPA) of 93.3% (112/120, 95% CI: 87.4%-96.6%) and negative percent agreement (NPA) of 98.7% (516/523, 95% CI: 97.3%-99.4%).

Table 12. Performance Stratified by Days Since Symptom Onset (DPSO)

DPSO	TN	FP	TP	FN	Total	PPA	NPA
1	28	2	4	0	34	100% (51.0-100%)	93.3% (78.7-98.2%)
2	147	3	39	3	192	92.9% (81.0-97.5%)	98.0% (94.3-99.3%)
3	161	1	40	4	206	90.9% (78.8-96.4%)	99.4% (96.6-99.9%)
4	114	1	18	1	134	94.7% (75.4-99.1%)	99.1% (95.2-99.8%)
5	66	0	11	0	77	100% (74.1-100%)	100% (94.5-100%)
Total	516	7	112	8	643	93.3% (87.4-96.6%)	98.7% (97.3%-99.4%)

TN: true negative; FP: false positive; TP: true positive; FN: false negative.

7.2 Usability Study

A total of 120 lay users participated in the usability study, including 106 who performed self-tests and 14 who tested children aged 2-13 years to provide feedback on the ease of the use of the GenaCheck® COVID-19 Rapid Self-Test. A questionnaire including 18 questions was given to the users and evaluated the following general topics:

- Ease of use of the test and test kit components
- Ability to follow the Quick Reference Instructions
- Ability to properly interpret results

Based on the study result, all 120 lay users successfully completed the test procedure independently, yielding either positive or negative results. Additionally, 89% of participants reported favorable responses (very easy and easy) and 11% reported neutral responses (OK) regarding their ability to understand and follow the Quick Reference Instructions.

7.3 Lay-User Readability Study

The purpose of this study was to determine whether lay users can interpret test results correctly, especially with mock low positive samples from the GenaCheck® COVID-19 Rapid Self-Test

A total of 69 lay users with diverse gender, ages and educational background participated in the Readability Study. Each lay user was asked to interpret one of the two sets of 4 mock test devices with three different concentrations. Set A devices are: Negative, 1.5xLoD, 1.5xLoD, 5xLoD; set B devices are: Negative, Negative, 1.5xLoD, 5xLoD.

Out of 276 mock device readings, one negative mock device was interpreted as invalid, and four low-positive mock devices (1.5x LoD) were incorrectly read as negative. All moderate positive mock devices (5x LoD) were interpreted correctly.

Table 13. Readability Study Stratified Results by Age and Overall

Age Group	Correct/Negative	Correct/Low positive (1.5xLoD)	Correct/Positive (5xLoD)	Correct/Total
14-19	3/3	3/3	2/2	8/8
20-30	26/26	25/25	17/17	68/68
31-50	53/53	49/49	34/34	136/136
51-54	6/6	6/6	4/4	16/16
55 above	16/17	15/19	12/12	43/48
Total	104/105	98/102	69/69	271/276
Correctness%	99.0%	96.1%	100.0%	98.2%

- Based on the randomized panels assigned to study participants, 105 negative devices, 102 low positive devices, and 69 positive devices were tested in the study.

8. Conclusion

These studies presented in this 510k premarket notification demonstrated equivalent performance of the GenaCheck® COVID-19 Rapid Self-Test to the predicate device ACON Flowflex Plus COVID-19 Home Test (K233373).