



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY**

I Background Information:

A 510(k) Number

K251595

B Applicant

InBios International, Inc.

C Proprietary and Established Names

COVID-19 Detect Rapid Self-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:

The purpose of this submission is to request premarket notification 510(k) clearance for the COVID-19 Detect Rapid Self-Test.

B Measurand:

Nucleoprotein 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):

See Indications for Use below.

B Indication(s) for Use:

The COVID-19 Detect Rapid Self-Test is a visually read lateral flow immunoassay intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal (nares) 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.

Performance characteristics for SARS-CoV-2 were established from October 2024 to March 2025 when SARS-CoV-2 Omicron variant 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 COVID-19 Detect Rapid Self-Test kit includes the foam swab that should be used to collect an anterior nasal swab sample. To begin the test, a self-collected anterior nasal swab sample (age ≥ 14 years) or a nasal swab sample collected from individuals 2 – 13 years by another lay user is inserted in the rapid test cassette. The sample port of the test cassette is designed to hold the kit-provided foam swab snugly.

Lysis buffer is added directly onto the swab head after insertion into the rapid test cassette. The lysis reagent disrupts the virus particles in the specimen, exposing internal viral nucleoprotein

antigens, and elutes the specimen from the swab onto the test strip inside the cassette. The eluted sample then migrates upward on the membrane to react with the test (T) and control (C) lines. The rapid test membrane is pre-coated with anti-SARS-CoV-2 nucleoprotein (NP) antibodies on the test line region and utilizes a separate control line to assure assay flow and performance.

If the eluted specimen contains SARS-CoV-2 viral NP antigens, a pink-to-red test line along with a pink-to-red procedural control line will appear in the reading window of the cassette indicating a positive result. If SARS-CoV-2 viral NP antigens are not present, or are present at very low levels, only the procedural control line will appear.

The cassette has a chemically built-in control feature to ensure that each test run is performed properly. This procedural control line (C) is the last line that the eluted specimen encounters before it enters the absorbent pad at the end of the test strip. The appearance of a procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test cassette was maintained. If the procedural control line is not developed at 15 minutes, then the test result is considered invalid.

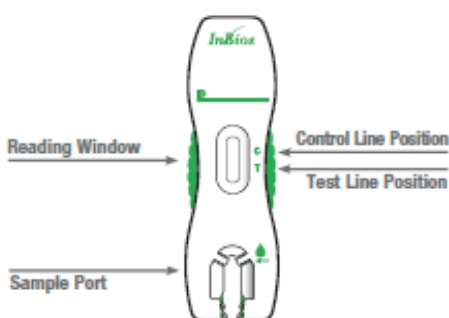


Figure 1. Schematic image of COVID-19 Detect Rapid Self-Test cassette. Control line and test line positions are marked with “C” and “T”, respectively.

The entire procedure takes 15-30 minutes. No instrumentation is required to perform or interpret this assay.

Kit Components

The kit is configured to contain two tests with the following components:

Table 1. Kit Components

Component	Quantity
Single-use test cassettes, individually pouched	2
Single-use dropper bottles of lysis buffer	2
Sterile nasal swabs, individually pouched	2
Quick Reference Instructions	1

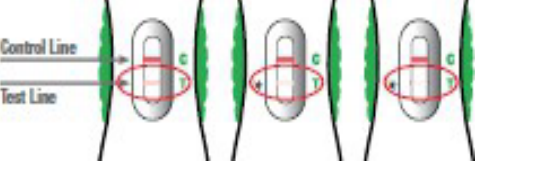
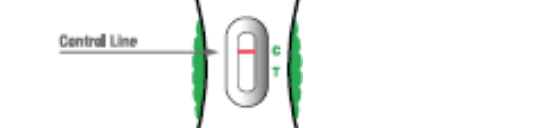
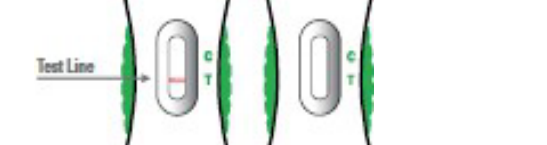
B Principle of Operation:

The rapid test membrane is pre-coated with anti-SARS-CoV-2 NP capture antibody on the test line region and anti-chicken IgY on the control line region. The rapid test conjugate pad contains a mixture of gold labeled with anti-SARS-CoV-2 NP detection antibody and gold labeled with chicken IgY.

The COVID-19 Detect Rapid Self-Test is housed in a cassette that enables insertion of the anterior nares swab specimen into the test cassette, facilitating direct application of test reagents to the cassette containing the swab. Lysis buffer solution is directly applied to the nasal swab specimen within the sample port and reacts with the gold labeled with anti-SARS-CoV-2 NP and chicken IgY. The eluted sample migrates upward on the membrane to react with the test and control lines. The viral antigens, if present, bind to the anti-SARS-CoV-2 NP antibody-labeled gold conjugates as the specimen flows upward. Gold conjugates bound to a viral antigen continue to travel upwards and are captured by the test line producing a pink-to-red color. The chicken-IgY-labeled gold is captured by the control line as eluted sample travels upward. The control line of the assay serves as an internal procedural control. If the control line is absent, then the test result is invalid.

C Interpretation of Results

The qualitative results of the COVID-19 Detect Rapid Self-Test kit are visually interpreted by the user.

	<p>Positive Result:</p> <p>If the control (C) line and the test (T) line are visible, the test is positive. Any faint visible pink test (T) line with the control line (C) should be read as positive.</p>
	<p>Negative Result:</p> <p>If the control (C) line is visible, but the test (T) line is not visible, the test is negative.</p>
	<p>Invalid results:</p> <p>If the control (C) line is not visible, the test is invalid. Re- test with a new swab and new test device.</p>

V Substantial Equivalence Information:

A Predicate Device Name(s):

Quidel QuickVue COVID-19 Test

B Predicate 510(k) Number(s):

K231795

C Comparison with Predicate(s):

Device & Predicate Device(s):	Quidel QuickVue COVID-19 Test, K231795	COVID-19 Detect Rapid Self-Test, K251595
	Predicate	Candidate device
General Device Characteristic Similarities		
Intended Use/Indications For Use	<p>The QuickVue COVID-19 Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of 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 5 days from symptom onset. 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 QuickVue COVID-19 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.</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.</p> <p>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 January 2021 to February 2024 when COVID-19 variants Alpha, Delta, and Omicron were dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with</p>	<p>The COVID-19 Detect Rapid Self-Test is a visually read lateral flow immunoassay intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal (nares) 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.</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.</p> <p>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>Performance characteristics for SARS-CoV-2 were established from October 2024 to March 2025 when SARS-CoV-2 Omicron variant 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>

	a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.	
Regulation	21 CFR 866.3984	Same
Product Code	QYT	Same
Qualitative	Yes	Same
Analyte	SARS-CoV-2 nucleoprotein antigen	Same
Intended Matrix	Anterior nasal (nares) swab	Same
Intended Population	Symptomatic	Same
Detection Method	Visual	Same
Technology	Lateral Flow Immunoassay	Same
General Device Characteristic Differences		
Time to result	10-15 minutes	15-30 minutes
Specimen Preparation	Place swab in tube for one minute, stirring 3-4 times. Remove swab from tube, squeezing out as much liquid as possible. Place test strip in tube.	Insert swab in cassette, add lysis buffer onto swab head.

VI Standards/Guidance Documents Referenced:

Document Title	Issued by	Applicable study
Special controls for Over-the-counter test to detect SARS-CoV-2 from clinical specimens (<u>Reclassification order for DEN220028 and special controls under 21 CFR 866.3984</u>)	FDA/CDRH	All Studies
ISO 15223-1:2021 Medical devices — <i>Symbols to be used with information to be supplied by the manufacturer</i> <i>Part 1: General requirements</i>	ISO	All Studies
ISO 10993-5:2009: <i>Biological evaluation of medical devices</i> <i>Part 5: Tests for in vitro cytotoxicity</i>	ISO	Biocompatibility
ISO 11737-2: <i>Sterilization of medical devices - Microbiological methods</i> <i>Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process</i>	ISO	Sterility
ISO 11135: <i>Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices</i>	ISO	Sterility
ISO 11138: <i>Sterilization of health care products — Biological indicators</i> <i>Part 1: General requirements</i> <i>Part 2: Biological indicators for ethylene oxide sterilization processes</i>	ISO	Sterility
ISO 10993: 2008 <i>Biological evaluation of medical devices</i> <i>Part 7: Ethylene oxide sterilization residuals</i>	ISO	Sterility

VII Performance Characteristics:

A Analytical Performance:

1. Lot-to-Lot Precision:

A precision study was conducted to assess variability in test performance between days and device lots. Three (3) concentrations of inactivated SARS-CoV-2 Omicron Variant lineage B.1.1.529 were spiked into pooled nasal swab matrix (PNSM) as follows:

- Negative sample
- Below LoD sample (0.25xLoD)
- Low positive sample (1xLoD)
- Positive sample (3xLoD)

Samples were loaded onto swabs and tested on three kit lots, each tested by two operators over ten days. For the first three days of testing, each operator tested seven replicates of each sample, twice per day. For the remaining last seven days of testing, each operator tested two replicates of each sample, twice per day.

Samples were blinded and randomized for testing. Positive and negative samples demonstrated 100% agreement with expected results, and low positive samples (1xLoD) demonstrated >99% agreement. While there were differences among the three lots in positivity for the sample below the kit's limit of detection, the differences were not significant and therefore, the data were acceptable. The results are summarized below in Table 2.

Table 2. Lot-to-Lot Precision Study Summary Results

	Positive (3x LoD) (positives/ total number of samples)	Low positive (1x LoD) (positives/ total number of samples)	Below LoD (0.25xLoD) (positives/ total number of samples)	Negative (negatives/ total number of samples)
Lot 1	100% (140/140)	99.3% (139/140)	36.4% (51/140)	100% (140/140)
Lot 2	100% (140/140)	100% (140/140)	65.7% (92/140)	100% (140/140)
Lot 3	100% (140/140)	98.6% (138/140)	40% (56/140)	100% (140/140)
% agreement (95% CI)	100% (420/420) (99.1-100%)	99.3% (417/420) (97.9-99.8%)	47.4% (199/420) (42.7-52.2%)	100% (420/420) (98.5-100%)

2. Linearity:

Not applicable; the device is a qualitative assay with binary visually interpreted results.

3. Analytical Specificity/Interference:

a) **Cross-Reactivity and Microbial Interference**

Cross reactivity and microbial interference studies were conducted to evaluate the potential impact of microorganisms commonly found as either pathogens or normal flora in respiratory samples on the performance of the COVID-19 Detect Rapid Self-Test. For this testing,

commercial sources of the organisms were obtained. Three replicates of each microorganism were prepared in negative clinical matrix were tested in the absence (cross-reactivity) and presence (interference) of 3x LoD inactivated SARS-CoV-2 virus (Omicron Variant lineage B.1.1.529) with one reagent lot. Samples were loaded onto a foam swab by swirling a foam swab in a tube containing fifty (50) microliters of the sample so that the liquid was absorbed onto the swab. The swab was then processed per the instructions for use (IFU). Neither cross-reactivity nor microbial interference was observed for any of the tested microorganisms at the concentration used in the study. The results are summarized below in Table 3.

Table 3. Cross-Reactivity and Microbial Interference Testing Results

Microorganism	Concentration Tested	Cross Reactivity (positives/total number of samples)	Interference Result (positives/total number of samples)
Adenovirus 21	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
<i>Bordetella pertussis</i>	1x10 ⁶ TCID ₅₀ /mL	0/3	3/3
<i>Candida albicans</i>	1x10 ⁶ TCID ₅₀ /mL	0/3	3/3
<i>Chlamydia pneumoniae</i>	1x10 ⁶ TCID ₅₀ /mL	0/3	3/3
Enterovirus	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
<i>Haemophilus influenzae</i>	1x10 ⁶ TCID ₅₀ /mL	0/3	3/3
Human coronavirus 229E	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
Human coronavirus NL63	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
Human coronavirus OC43	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
Human Metapneumovirus	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
Influenza A	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
Influenza B	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
<i>Legionella pneumophila</i>	1x10 ⁶ TCID ₅₀ /mL	0/3	3/3
MERS-coronavirus	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
<i>Mycoplasma pneumoniae</i>	1x10 ⁶ TCID ₅₀ /mL	0/3	3/3
Parainfluenza virus 1	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
Parainfluenza virus 2	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
Parainfluenza virus 3	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
Parainfluenza virus 4a	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
Pooled human nasal wash	Neat	0/3	3/3
Respiratory Syncytial virus	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
Rhinovirus	1x10 ⁵ TCID ₅₀ /mL	0/3	3/3
SARS-CoV-1	1x10 ⁵ PFU/mL	0/3	3/3
<i>Staphylococcus aureus</i>	1x10 ⁶ CFU/mL	0/3	3/3

<i>Staphylococcus epidermidis</i>	1x10 ⁶ CFU/mL	0/3	3/3
<i>Streptococcus pneumoniae</i>	1x10 ⁶ CFU/mL	0/3	3/3
<i>Streptococcus pyogenes</i>	1x10 ⁶ CFU/mL	0/3	3/3

b) Endogenous/Exogenous Interfering Substances Study

The performance of the COVID-19 Detect Rapid Self-Test was evaluated in the presence of potentially interfering substances. Each potential interferent was prepared in PNSM in either absence or presence of 3x LoD concentration of SARS-CoV-2 Lineage B.1.1.529 using one reagent lot. Samples were loaded onto a foam swab by swirling a foam swab in a tube containing fifty (50) microliters of the sample so that the liquid was absorbed onto the swab. The swab was then processed per the IFU. Among all the substances tested, Zicam cold remedy was the only one to cause false-positive results when tested at concentrations of 2.5% v/v or above. All other substances yielded expected results, indicating they do not impact the performance of the COVID-19 Detect Rapid Self-Test. The results are summarized below in Table 4.

Table 4. Endogenous/Exogenous Interference Testing Results

Substance	Tested concentration	Negative nasal swab matrix [positives/total number of samples]	SARS-CoV-2 positive nasal swab matrix [positives/total number of samples]
Human whole blood	2.5%	0/3	3/3
Mucin	2.5 mg/mL	0/3	3/3
Throat lozenges (Vapocool containing Menthol and benzocaine)	3 mg/mL	0/3	3/3
Nasal drops (Phenylephrine)	15% v/v	0/3	3/3
Nasal drops - Afrin (Oxymetazoline)	15% v/v	0/3	3/3
Nasal spray (Cromolyn)	15% v/v	0/3	3/3
Zicam Cold Remedy	5% v/v	3/3	3/3
	2.5% v/v	3/3	3/3
	1% v/v	0/3	3/3
Alkalol Homeopathic	15% v/v	0/3	3/3
Sore throat phenol spray (Phenol)	5% v/v	0/3	3/3
Antibiotic (Mupirocin)	10 mg/mL	0/3	3/3
Saline (Sodium chloride)	15% v/v	0/3	3/3
Hand sanitizer	1% v/v	0/3	3/3
Hand soap	1% v/v	0/3	3/3
ClearLife (Luffa operculata, Sulfur, Galphimia glauca, Histaminum hydrochloricum)	15% v/v	0/3	3/3
Ethanol (solvent)	Neat	0/3	3/3
DMSO (solvent)	Neat	0/3	3/3
Leukocytes (Fresh human buffy coat)	2.5 x10 ⁶ cells/mL	0/3	3/3

<i>Corticosteroids</i>			
Budesonide	15% v/v	0/3	3/3
Nasacort (Triamcinolone)	15% v/v	0/3	3/3
Beclomethasone	15% v/v	0/3	3/3
Dexamethasone	15% v/v	0/3	3/3
Flunisolide	15% v/v	0/3	3/3
Mometasone	15% v/v	0/3	3/3
Flonase nasal spray (Fluticasone propionate)	15% v/v	0/3	3/3
<i>Antivirals</i>			
Tamiflu (Oseltamivir phosphate)	5 mg/mL	0/3	3/3
Remdesivir	5 mg/mL	0/3	3/3
Molnupiravir	5 mg/mL	0/3	3/3

4. **Assay Reportable Range:**

Not applicable; the device is a binary qualitative assay.

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

a) **Controls**

The COVID-19 Detect Rapid Self-Test has a built-in internal procedural control. This procedural control consists of chicken-IgY-labeled gold and generates a pink-red line at the “C” marked control region of the test window. The control line should always appear indicating that proper volume of sample has been added, and that membrane wicking has occurred. If the control line is absent, then the test result is invalid.

b) **Device Stability:**

i. *Real Time Stability (Shelf life):*

The stability of the COVID-19 Detect Rapid Self-Test was assessed for the intended storage conditions, 15-30 °C. Within one month of manufacturing, three device lots were stored at 30 ± 1 °C at 75 ± 5% RH to represent the worst-case scenario. Two test samples, corresponding to negative sample and positive sample at 3.5x LoD using SARS-CoV-2 (Lineage BA.2.3; Omicron Variant Culture Fluid (Isolate: USA/MD-HP24556/2022)), were tested at each time point in replicates of 5.

All study data were 100% concordant with expected results. Data collected to date in this study is presented below:

Timepoint (months)	Lot 1	Lot 2	Lot 3
0	Tested	Tested	Tested
6	Tested	Tested	Tested
6.6	Tested	Tested	Tested
9	Tested	Tested	Tested
9.9	Tested	Tested	Tested
12	Tested	<i>Not tested</i>	<i>Not tested</i>
13.2	Tested	<i>Not tested</i>	<i>Not tested</i>

Taken together, this study supports a test kit shelf-life of 9 months when stored at the intended storage temperature of 15- 30°C at the time of clearance.

ii. Shipping Stability:

The effects of shipping on the integrity of the test device were evaluated with one device lot that was manufactured within one month of study start. The device was exposed to cycles of temperature and humidity fluctuations including freeze thaw cycles. Kits were subjected to the following conditions:

- Simulated summer challenge: 60±5°C for up to 8 days.
- Simulated winter challenge: -20±5°C or colder for up to 8 days. Over the course of the first 5 days, all frozen kits were thawed daily, such that kits were subjected to up to 5 freeze-thaw (F/T) cycles.
- Control condition: room temperature (15-30°C) for duration of study.

All results were concordant with expected results supporting stability during the anticipated shipping conditions for the test.

6. **Detection Limit:**

a) **Limit of Detection**

For the limit of detection study, irradiation-inactivated SARS-CoV-2 Omicron B.1.1.529, was prepared in PNSM. Testing was performed on 2 different test kit lots. A preliminary LoD was first established in a range-finding study using 3 replicates per concentration per lot of the COVID-19 Detect Rapid Self-Test. Thereafter, the LoD was confirmed using 20 replicates per lot of 1:2, 1:4, and 1:8 serial dilution preparations of the last concentration that yielded 100% concordant results. Samples were loaded onto a foam swab by swirling a foam swab in a tube containing fifty (50) microliters of the sample so that the liquid was absorbed onto the swab. The swab was then processed per the IFU. The results are summarized in the Table 5.

Table 5. LoD Study Summary with irradiation-inactivated SARS-CoV-2 (Omicron variant)

Concentration		Lot 1		Lot 2	
TCID ₅₀ /mL	TCID ₅₀ /Swab	P	C	P	C
78	3.9	100% (3/3)	Not tested	100% (3/3)	Not tested
39	2	100% (3/3)	100% (20/20)	100% (3/3)	100% (20/20)
19.5	1	100% (3/3)	70% (14/20)	100% (3/3)	90% (18/20)
9.75	0.49	33.33% (1/3)	10% (2/20)	33.33% (1/3)	5% (1/20)
4.88	0.24	0% (0/3)	0% (0/20)	0% (0/3)	0% (0/20)
0	0	0% (0/3)		0% (0/3)	

P: Preliminary Study. C: Confirmatory LoD Study.

The limit of detection for the COVID-19 Detect Rapid Self-Test was determined to be 39 TCID₅₀/mL of sample and was achieved by all tested lots. This is equivalent to 2 TCID₅₀/swab.

b) International Standard for SARS-CoV-2 Antigen (NIBSC 21/368):

A study was performed to determine the LoD of the COVID-19 Detect Rapid Self-Test with the International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) in negative clinical matrix. The results are shown below for range finding and confirmatory LoD studies, and the LoD for the International Standard was determined to be 500 IU/mL.

Table 6. LoD Study Summary for SARS-CoV-2 antigen (NIBSC code: 21/368)

Concentration of the International Standard		Positive results (n/N)	
IU/mL	IU/Swab	P	C
4000	200	100% (3/3)	Not tested
2667	133.35	100% (3/3)	Not tested
2000	100	100% (3/3)	Not tested
1333	66.65	100% (3/3)	Not tested
1000	50	100% (3/3)	Not tested
667	33.35	100% (3/3)	100% (20/20)
500	25	100% (3/3)	95% (19/20)
400	20	0% (0/3)	0% (0/20)

P: Preliminary Study. C: Confirmatory LoD Study.

7. Inclusivity

The analytical reactivity of SARS-CoV-2 omicron variant JN.1 strain was tested with the candidate device. The viral strain was serially diluted in PNSM to a concentration near the LoD and tested in replicates of 3 with the candidate device. Samples were loaded onto a foam swab by swirling a foam swab in a tube containing 50µL of the sample so that the liquid was absorbed onto the swab. The swab was then processed per the IFU. The lowest concentrations at which 3/3 replicates were detected per lot with one (1) lot at the concentration is shown below.

The results of the inclusivity testing are presented below:

Table 7: Inclusivity testing results

SARS-CoV-2 (TCID ₅₀ /mL)	SARS-CoV-2 (TCID ₅₀ /swab)	Percent positive (%) (Number of positives/total number of positives)
1400.0	70.0	100.0 (3/3)
700.0	35.0	100.0 (3/3)
350.0	17.5	100.0 (3/3)
175.0	8.8	100.0 (3/3)
87.5	4.4	100.0 (3/3)
43.8	2.2	100.0 (3/3)
21.9	1.1	33.3 (1/3)
10.9	0.6	0.0 (0/3)
0.0	0.0	0.0 (0/3)

8. High Dose Hook Effect

No high-dose hook effect was observed with a concentration of 1.7×10^5 TCID₅₀/mL of UV-inactivated SARS-CoV-2, Omicron variant Lineage BA.2.3 tested with the COVID-19 Detect Rapid Self-Test.

9. Assay Cut-Off:

Not applicable; as the device is a qualitative assay that yields visually read binary results.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable. See section “C. Clinical Studies.”

2. Matrix Comparison:

This device is only intended for use with direct anterior nasal swab specimens. As no other specimen or sample type are claimed to be used with this device, a matrix comparison study is not applicable.

C Clinical Studies:

1. Clinical Sensitivity and Specificity:

A prospective lay person clinical study in a simulated home environment was conducted to assess the performance of the candidate test when compared to a 510(k)-cleared SARS-CoV-2 RT-PCR assay with an extraction step. The study prospectively enrolled symptomatic subjects at twelve (12) geographically diverse clinical study sites between October 2024 and March 2025.

Two anterior nasal swab samples (intended matrix) were collected from each subject (one for the candidate test and one for the comparator test) and the collection order was randomized. Comparator test samples were collected by health care professionals at the clinical study site and inserted into viral transport media per the IFU of the comparator test. Samples for the candidate antigen test were collected per the candidate 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. A total of 1,261 study subjects were enrolled in this clinical study, and 1,116 samples were deemed evaluable. 145 results were excluded from the clinical study analysis due to enrollment past 4 days post symptom onset (DPSO), not meeting enrollment criteria, protocol deviations, comparator invalid results, and comparator specimen delays.

Detailed study subject demographics are listed below.

Table 8. Demographics

Characteristic	Number (%) [N=1116]
Age (years)	
2-13	56 (5.0%)
14-24	213 (19.1%)
25-64	755 (67.7%)
>64	92 (8.2%)
Gender	
Female	683 (61.2%)
Male	433 (38.8%)
Ethnicity	
Hispanic/Latino	92 (8.2%)
Not Hispanic/Latino	1024 (91.8%)

The *COVID-19 Detect Rapid Self-Test* detected the analytes with the following percent agreements when compared to the result of the SARS-CoV-2 RT-PCR comparator assay:

Table 9. Clinical performance estimates – SARS-CoV-2

	Comparator Positives	Comparator Negatives	Total
Candidate Positives	104	0	104
Candidate Negatives	16	996	1012
Total	120	996	1116
Positive Percent Agreement (PPA) = 86.7% (104/120), 95% CI (79.4%-91.6%)			
Negative Percent Agreement (NPA) = 100.0% (996/996), 95% CI (99.6%-100.0%)			

Table 10. Clinical performance in SARS-CoV-2 positive subjects stratified by DPSO

DPSO	PPA (n/N, 95% CI)	NPA (n/N, 95% CI)
0	100.0% (2/2, 34.2% - 100.0%)	100.0% (35/35, 90.1% - 100.0%)
1	89.3% (25/28, 72.8% - 96.3%)	100.0% (204/204, 98.2% - 100.0%)
2	80.5% (33/41, 66.0% - 89.8%)	100.0% (342/342, 98.9% - 100.0%)
3	97.2% (35/36, 85.8% - 99.5%)	100.0% (278/278, 98.6% - 100.0%)
4	69.2% (9/13, 42.4% - 87.3%)	100.0% (137/137, 97.3% - 100.0%)
Overall	86.7% (104/120, 79.4% - 91.6%)	100.0% (996/996, 99.6% - 100.0%)

2. Usability and User Comprehension Study:

The usability of the test was assessed during the prospective clinical study. During this study, representative test kit users (self-testers aged 14 and above, caregiver-child pairs, and caregiver-adult pairs) were observed performing the test while using the QRI. A total of 1254 individuals were enrolled in this study. The observers recorded the proper execution of each task but did not otherwise interfere with the study subject's sample collection and testing. On an average, the critical tasks and non-critical tasks were performed at 98.93% and 99.97% respectively which met the acceptance criteria for both the critical and non-critical tasks and demonstrated that the lay users can adequately comprehend the test procedure as described in the QRI.

3. Lay-User Readability Study:

The readability study was conducted to evaluate the ability of lay users to adequately interpret device results with low positive results. This study tested the readability of the candidate device using mock devices, created by printing dye on the nitrocellulose membrane to match the test and control lines' exact locations in an unaltered test cassette.

Two panels of mock devices were created, each containing four mock devices with low positive cassettes at 1.5x limit of detection (LoD), and positive cassettes at 5x LOD. A total of 51 lay users participated, including individuals with vision impairment (e.g., glasses, contacts, glaucoma), and various age groups: 14 -20 years (13.7%), 20-29 years (29.4%), 30-55 years (35.3%), and those above 55 years (21.6%). Each participant received the QRI and 4 blinded mock devices.

Data analysis focused on accuracy in interpreting the test results, with correct interpretation defined as negative for negative sample and positive for low positive or positive sample. Percent agreement with expected results was calculated for each sample type, and 95% confidence intervals (95% CI) were determined by Wilson method.

Table 11. Lay user readability study results

	Negative	Low positive	Positive
Correct interpretation by lay user	73	71	51
Incorrect interpretation by lay user	0	9	0
Total	73	80	51
Percent agreement	100.0%	88.8%	100.0%
95% CI (Wilson method)	95%, 100.0%	80%, 94.0%	93%, 100.0%

Lay users correctly interpreted all negative and medium positive results, and 88.8% of low positive results. The 9 incorrectly interpreted low positive cassettes were distributed among eight (8) lay users 8 of the 9 false negative results were determined by individuals with vision impairment. Low positive samples may pose interpretation challenges for individuals with age-related or other vision impairments, leading to a limitation noted in the IFU for the visually interpreted COVID-19 Detect Rapid Self-Test.

D Clinical Cut-Off:

The test is a qualitative test with a binary positive/negative signal and there is no clinical cut-off for the test.

E Expected Values/Reference Range:

Not applicable. When the test is valid, it produces binary qualitative results.

F Other Supportive Performance Characteristics Data:

1. Flex Studies:

Flex studies were conducted to assess the test's robustness and the risk of false results when deviating from IFU/QRI test steps. Critical aspects of the test were assessed including test procedure variations (reading time, lysis buffer volume, method of lysis buffer application, delays and incorrect order of operational steps, incorrect swab type, incorrect testing) and variability in environmental conditions (temperature, humidity, barometric stress, lighting, angle of testing surface and kit equilibration to the room temperature).

A test panel comprised of negative samples (PNSM), and low positive samples (2x LoD prepared with SARS-CoV-2 Omicron variant lineage B.1.1.529), were used. Samples were blinded and randomized for testing. Samples were loaded onto a foam swab by swirling a foam swab in a tube containing 50µL of the sample so that the liquid was absorbed onto the swab. The swab was then processed per the IFU.

Extreme deviations from the instructions can impact the test results of samples, and result in false negative or invalid results. No significant false results were observed in the flex studies. Labeling mitigations were applied for the minor false results obtained. The studies therefore support that the test is robust when used as instructed with an insignificant risk of erroneous result.

2. Serial Testing

As a mitigation for the low performance estimates of the device after Day 4 of symptom onset, 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). These mitigations are 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.