510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K260095

B Applicant

Healgen Scientific, LLC

C Proprietary and Established Names

Heal-Check Rapid COVID-19 Antigen 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:

To obtain 510(k) clearance for the Heal-Check Rapid COVID-19 Antigen Self-Test.

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):

See Indications for Use below.

B Indication(s) for Use:

The Heal-Check Rapid COVID-19 Antigen Self-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 swab specimens from individuals with signs and symptoms of COVID-19.

This test is for use by individuals aged 14 years and 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 appropriate follow-up care from their healthcare provider.

Performance characteristics for SARS-CoV-2 were established from June 2023 to August 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

IVD- For *in vitro* diagnostic use

D Special Instrument Requirements:

Not Applicable (N/A)

IV Device/System Characteristics:

A Device Description:

The Heal-Check Rapid COVID-19 Antigen Self-Test is a lateral flow immunochromatographic assay for the qualitative detection of the SARS-CoV-2 nucleocapsid antigen from self-collected anterior nasal swab specimens from symptomatic individuals. The device is intended for over-the-counter (OTC) use. The test cassette contains a test strip composed of sample pad, conjugate pad, nitrocellulose membrane, and absorbent pad, with designated control (C) and test (T) lines for result interpretation.

Materials provided in test kit box:

- 1, 2, 4, 5, 6, 8 or 10 test cassettes
- 1, 2, 4, 5, 6, 8 or 10 sterile nasal swabs
- 1, 2, 4, 5, 6, 8 or 10 prefilled buffer tubes

- 1, 2, 4, 5, 6, 8 or 10 buffer tube tips
- 1 Quick Reference Instructions (QRI)
- Tube holder (perforate on the backside of the kit box)

Materials needed but not provided in kit box:

- Clock, timer, or stopwatch.

B Principle of Operation:

The Heal-Check Rapid COVID-19 Antigen Self-Test is an immunochromatographic lateral flow assay that detects SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens using a double antibody sandwich format. The reagent pad contains latex conjugated monoclonal antibody which recognizes and binds to the nucleocapsid protein of SARS-CoV-2 in the sample; the reaction membrane in the test line (T) contains a second antibody that recognizes another epitope of the nucleocapsid protein of SARS-CoV-2. When the sample extract is added to the sample well, the latex-monoclonal antibody conjugates dried onto the reagent pad are dissolved, bind to the nucleocapsid protein, and the antigen-antibody complex then migrates along the reaction membrane to the T line. If SARS-CoV-2 nucleocapsid antigen is present in the sample, a complex will form between the latex-monoclonal antibody and the viral antigen, which will be captured by the second specific anti-SARS-CoV-2 antibody coated on the test line region (T). To serve as a procedural control, a red line will always appear in the control line region (C), which is coated with a secondary antibody recognizing the primary antibody in the migrating sample.

Results must be interpreted between 15 and 30 minutes after adding the extracted sample to the sample well. A positive specimen will present two pink-to-red lines beside the "C" and "T" regions of the test window and indicates that SARS-CoV-2 antigen was detected. A negative specimen will present only one pink-to-red line next to the "C" region of the test window and indicates that SARS-CoV-2 antigen was not detected. The procedural control line must always appear in the "C" region. If a line in the "C" region is not visible after 30 minutes, then the result is invalid.

V Substantial Equivalence Information:

A Predicate Device Name(s):

OHC COVID-19 Antigen Self Test

B Predicate 510(k) Number(s):

K241313

C Comparison with Predicate(s):

Device & Predicate Device(s):	K260095 (Candidate Device)	K241313 (Predicate Device)
Device Trade Name	Heal-Check Rapid COVID-19 Antigen Self-Test	OHC COVID-19 Antigen Self Test
General Device Characteristic Similarities		

Intended Use/Indications for Use	The Heal-Check Rapid COVID-19 Antigen Self-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 swab specimens from individuals with signs and symptoms of COVID-19. This test is for use by individuals aged 14 years and 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 appropriate follow-up care from their healthcare provider. The performance characteristics for SARS-CoV-2 were established from June 2023 to August 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)	The OHC COVID-19 Antigen Self 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 swab specimens from individuals with signs and symptoms of COVID-19. This test is for non-prescription home use by individuals aged 14 years and 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 rule out infection with SARS-CoV-2 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 June 2023 to July 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 when a new virus or

	should be considered in situations where a new virus or variant is suspected.	variant is suspected.
Regulation Number	21 CFR 866.3984	Same
Regulatory Class	Class II	Same
Product Code	QYT	Same
Intended use setting	Over-the-counter use	Same
Usage	Single use test	Same
Specimen type	Direct anterior nasal swab	Same
Device Format	Test cassette	Same
Analyte	SARS-CoV-2 nucleocapsid protein	Same
Test Technology	Lateral flow immunoassay	Same
Test Result Type	Qualitative	Same
Result Interpretation	Visually read	Same
Controls	Internal	Same
General Device Characteristic Differences		
Time to Results	15-30 minutes	15-20 minutes

VI Standards/Guidance Documents Referenced:

Document	Title	Publisher	Applicable Study
Special Controls under 21 CFR 866.3984 (Over-the-counter test to detect SARS-CoV-2)	Reclassification order for DEN220028 and special controls under 21 CFR 866.3984	FDA/CDRH	All Studies
ISO 11135:2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices	ISO	Sterility
ISO 10993-7:2008	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals	ISO	Sterility
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	ISO	Biocompatibility
ISO 10993-5:2009	Biological Evaluation of Medical Devices – Part 5: Tests for In vitro cytotoxicity	ISO	Biocompatibility
ISO 10993-10:2013	Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization	ISO	Biocompatibility

Document	Title	Publisher	Applicable Study
ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation	ISO	Biocompatibility

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Multi-lot Precision Study:

The precision study was conducted for the Heal-Check Rapid COVID-19 Antigen Self-Test to evaluate variability across reagent lots, operators, runs, and days. Heat-inactivated SARS-CoV-2 (Isolate: USA-WA1/2020) was spiked into pooled negative clinical matrix (PNCM) to prepare negative and positive samples at 3X LoD, 1.5X LoD, and 0.9X LoD.

Samples were blinded and randomized prior to testing. Each sample (50 µL) was applied to the nasal swab and tested according to the quick reference instructions (QRI). Testing was performed using three (3) device lots, three (3) operators, two (2) runs per day, 2 replicates per run, over five (5) days, for a total of 180 replicates per concentration.

Agreement of 100% was observed for negative, 1.5X LoD, and 3X LoD samples across all lots, operators, and days.

At 0.9X LoD, an overall rate of detection of 72.8% was observed, with lot-specific detection ranging from 61.7% to 81.7%. The results met the predefined acceptance criteria with no significant differences observed by operators, by days, and by lots at all concentrations tested (Table 1).

Table 1: Summary of Lot-to-Lot Precision Study Results

Analyte	No. of Positives / No. of Samples tested (%)			Total no. of positives / Total no. of samples (%)
	Lot 1	Lot 2	Lot 3	
True Negative	0/120 (0.0%)	0/120 (0.0%)	0/120 (0.0%)	0/360 (0.0%)
SARS-CoV-2 (3X LoD)	60/60 (100.0%)	60/60 (100.0%)	60/60 (100.0%)	180/180 (100.0%)
SARS-CoV-2 (1.5X LoD)	60/60 (100.0%)	60/60 (100.0%)	60/60 (100.0%)	180/180 (100.0%)
SARS-CoV-2 (0.9X LoD)	45/60 (75.0%)	37/60 (61.7%)	49/60 (81.7%)	131/180 (72.8%)

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

a. Cross Reactivity/Microbial Interference:

Cross-reactivity and microbial interference studies were conducted to evaluate potential assay interference from respiratory pathogens and normal microbial flora. A total of 28 organisms, including viruses (17), bacteria (9), fungus (1), and pooled human nasal fluid (1) were evaluated.

For the cross-reactivity study, organisms were tested in triplicate in the absence of SARS-CoV-2. For microbial interference study, organisms were tested in triplicate in the presence of gamma-inactivated SARS-CoV-2 (USA-WA1/2020) at 2X LoD spiked in PNCM. All testing was conducted according to the QRI instructions. The concentrations tested and results are summarized in Table 2.

No cross-reactivity or microbial interference was observed for the organisms tested.

Table 2. Summary of Cross-Reactivity and Microbial Interference Study Results.

Virus/Microorganism	Concentration	Unit	# of Positive Results / of Replicates Tested	
			Cross-Reactivity (without analyte)	Interference (2X LoD SARS-CoV-2)
Human coronavirus 229E	1.00×10^5	$TCID_{50}$/mL	0/3	3/3
Human coronavirus OC43	1.00×10^5	$TCID_{50}$/mL	0/3	3/3
Human coronavirus NL63	1.00×10^5	$TCID_{50}$/mL	0/3	3/3
MERS-coronavirus	4.67×10^2	$TCID_{50}$/mL	0/3	3/3
SARS-coronavirus	1.98×10^2	$TCID_{50}$/mL	0/3	3/3
Human coronavirus HKU1[1] (Clinical samples)	1:20 Dilution	NA	0/6	6/6
Adenovirus type (e.g., C1.Ad..71)	1.00×10^6	$TCID_{50}$/mL	0/3	3/3
Human metapneumovirus (hMPV)	1.00×10^5	$TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 1	1.00×10^5	$TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 2	1.00×10^5	$TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 3	1.00×10^5	$TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 4A	1.60×10^4	$TCID_{50}$/mL	0/3	3/3
Influenza A	1.00×10^5	$TCID_{50}$/mL	0/3	3/3
Influenza B	1.00×10^5	$TCID_{50}$/mL	0/3	3/3
Enterovirus	1.00×10^5	$TCID_{50}$/mL	0/3	3/3
Respiratory syncytial virus	1.00×10^5	$TCID_{50}$/mL	0/3	3/3
Rhinovirus type 1A	1.00×10^5	$TCID_{50}$/mL	0/3	3/3
Haemophilus influenzae	1.00×10^7	CFU/mL	0/3	3/3
Streptococcus pneumoniae	1.00×10^6	CFU/mL	0/3	3/3
Streptococcus pyogenes	1.00×10^6	CFU/mL	0/3	3/3
Candida albicans	1.00×10^6	CFU/mL	0/3	3/3
Mycoplasma pneumoniae	1.00×10^7	CFU/mL	0/3	3/3
Chlamydia pneumoniae	1.00×10^7	IFU/mL	0/3	3/3
Legionella pneumophila	1.00×10^7	CFU/mL	0/3	3/3
Staphylococcus aureus	5.00×10^6	CFU/mL	0/3	3/3
Staphylococcus epidermidis	1.75×10^8	CFU/mL	0/3	3/3
Bordetella pertussis	1.00×10^7	CFU/mL	0/3	3/3
Pooled human nasal fluid	NA	NA	0/3	3/3

[1] Six (6) clinical samples confirmed positive for HKU1 by RT-PCR (Ct Range 14.3 – 26.1).

b. Endogenous/Exogenous Interference:

Endogenous and exogenous interference studies were conducted to evaluate the potential impact of commonly encountered substances on the performance of the Heal-Check Rapid COVID-19 Antigen Self-Test. A total of twenty (20) potentially interfering substances were evaluated.

For the cross-reactivity study, substances were tested in the absence of SARS-CoV-2. For the interference study, substances were tested in the presence of gamma-inactivated SARS-CoV-2 (USA-WA1/2020) at 2X LoD. Testing was conducted using three (3) or five (5) replicates, as applicable, with contrived positive samples prepared in PNCM. The concentrations tested and results are summarized in Table 3.

No cross-reactivity or interference was observed for any of the substances tested at the concentrations evaluated.

Table 3. Summary of Endogenous/Exogenous Interference Results.

Interfering Substance	Concentration Tested	# of Positives T Tested / of Replicates Tested	
		Cross-Reactivity (without analyte)	Interference (2X LoD SARS-CoV-2)
Human Whole Blood (EDTA tube)	2.5%	0/3	3/3
Leukocytes	5 x 10^6 cells/mL	0/3	3/3
Mucin, bovine submaxillary gland	5 mg/mL	0/3	3/3
Throat Lozenges (Menthol/Benzocaine)	3 mg/mL	0/3	3/3
Sore Throat Spray (5% w/v) (Phenol)	15 % v/v	0/3	3/3
Nasal Spray (Sodium Chloride with preservatives)	15% v/v	0/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	3/3
Nasal Spray (Cromolyn)	15% v/v	0/3	3/3
Nasal Spray (Phenylephrine)	15% v/v	0/3	3/3
Nasal Corticosteroids (Fluticasone Propionate)	15% v/v	0/5	5/5
Homeopathic allergy relief, or nasal wash (Histaminum hydrochloricum)	15% v/v	0/3	3/3
ZICAM Cold Remedy (Luffa operculata, Galphimia glauca, Sabadilla)	5% v/v	0/3	3/3
NasoGEL (NeilMed)	5% v/v	0/3	3/3
Afrin Nasal Spray (Oxymetazoline)	5% v/v	0/3	3/3
Tobramycin	4 µg/mL	0/3	3/3
Tamiflu (Anti-viral drug)	5 mg/mL	0/3	3/3
Mupirocin (nasal ointment)	10 mg/mL	0/3	3/3
Hand Soap	1%	0/3	3/3
Hand Sanitizer	1%	0/3	3/3
Pooled Negative Swab Matrix	NA	0/3	3/3

4. Detection Limit and Assay Reportable Range:

a. Limit of Detection (LoD):

The Limit of Detection (LoD) studies of the Heal-Check Rapid COVID-19 Antigen Self-Test was determined using serial dilutions of inactivated SARS-CoV-2 prepared in PNCM. A preliminary LoD was determined by spiking 50 µL of each diluted sample onto the collection swab head in triplicate across three lots of the test device. The confirmatory LoD study was performed at the selected preliminary LoD concentration and at concentrations above and below the preliminary LoD with an additional twenty (20) replicates. The confirmatory LoD was determined to be the lowest detectable concentration of SARS-CoV-2 at which the assay consistently produced 95% or higher positivity rate (at least 19/20 replicates). The LoD of the Heal-Check Rapid COVID-19 Antigen Self-Test with SARS-CoV-2 is summarized below in Table 4.

Table 4. Confirmatory LoD Study Results

Analyte	Isolate / Lineage	Concentration ($TCID_{50}$/mL)	Concentration ($TCID_{50}$/swab)	# Positive / # Total	# Device Lots Used
SARS-CoV-2	USA-WA1/2020 (Gamma Inactivated)	1.98×10^2	9.90	20/20	3
	USA-WA1/2020 (Heat Inactivated)	3.86×10^5	1.93×10^4	20/20	3
	Wild Type; WGFE strain (Heat Inactivated)	1.15×10^2	5.75	20/20	3

b. International Standard LoD Study:

A LoD study using the SARS-CoV-2 International Standard (NIBSC 21/368) was performed using serial dilutions prepared in PNCM. The unitage of this material has an assigned value of 5,000 International Units (IU) of SARS-CoV-2 antigen per ampoule when reconstituted per instructions. A two-fold dilution series was made to determine the preliminary LoD, which was measured using one device lot in triplicate. Testing was performed by adding 50 µL of each dilution directly to the test swab and processing the sample per the QRI instructions. The preliminary LoD was determined to be 250 IU/mL (12.5 IU/swab).

The LoD confirmatory study was performed using twenty (20) replicates at and dilutions around the preliminary LoD concentration. The LoD for the Heal-Check Rapid COVID-19 Antigen Self-Test was confirmed to be 250 IU/mL (12.5 IU/swab). Results are summarized below in Table 5.

Table 5. Summary of LoD Study Results for International Standard.

Preliminary LoD			Confirmatory LoD		
Dilution (IU/ml)	Dilution (IU/swab)	Results	Dilution (IU/ml)	Dilution (IU/swab)	Results
2000	100	3/3			
1000	50	3/3			
500	25	3/3	500	25	20/20
250	12.5	3/3	250	12.5	20/20
125	6.25	2/3	125	6.25	13/20

5. High Dose Hook Effect Study:

A high-dose hook effect study was conducted to evaluate whether high concentrations of SARS-CoV-2 produce false negative results. Heat-inactivated SARS-CoV-2 (USA-WA1/2020) was serially diluted in PNCM. Each concentration was tested in two (2) replicates per lot across three (3) lots of the candidate device. For each replicate, 50 µL of sample was applied to the dry swab and tested according to the QRI. No high-dose hook effect was observed across the concentrations evaluated (Table 6).

Table 6. Summary of High-Dose Hook Effect Study Results

Dilution	Concentration ($TCID_{50}$/mL)	Lot 1 (% Positive)	Lot 2 (% Positive)	Lot 3 (% Positive)
1:1	1.55×10^8	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)
1:10	3.09×10^7	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)
1:100	3.09×10^6	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)
Negative (PNCM)	0.0	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)

6. Inclusivity (Analytical Reactivity) Study:

Analytical reactivity of the Heal-Check Rapid COVID-19 Antigen Self-Test was evaluated to determine if the device can detect the target analytes across a variety of strains. Heat-inactivated or gamma-irradiated virus isolates were diluted in PNCM and tested at multiple concentrations. Each concentration was tested in triplicate across three (3) lots of the candidate device. The lowest concentration at which all replicates were positive (3/3 per lot) was identified for each variant (Table 7). The results demonstrate that the test can detect SARS-CoV-2 across the variants evaluated.

Table 7. Summary of Analytical Reactivity Study

Variant* (Lineage)	Isolate ID (Inactivation Method)	Lowest Variant Concentration with 3/3 Positive Replicates
Alpha (B.1.1.7)	USA/CA_CDC_5574/2020 (Heat-Inactivated)	1.00×10^2 $TCID_{50}$/mL
Beta (B.1.351)	USA/MD_HP01542/2021 (Heat-Inactivated)	2.20×10^2 $TCID_{50}$/mL
Gamma (P.1)	Brazil P.1/Japan-TY7-503/2021 (Heat-Inactivated)	1.26×10^3 $TCID_{50}$/mL
Delta (B.1.617.2)	hCoV-19/USA/MD-HP05285/2021 (Gamma-Irradiated)	2.20×10^3 $TCID_{50}$/mL
Kappa (B.1.617.1)	USA/CA-Stanford-16_S02/2021 (Heat-Inactivated)	1.90×10^2 $TCID_{50}$/mL
Omicron (B.1.1.529)	USA/MD-HP20874/2021 (Heat-Inactivated)	2.51×10^2 $TCID_{50}$/mL

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

a. Internal Controls:

The Heal-Check Rapid COVID-19 Antigen Self-Test contains a built-in internal procedural control. The appearance of the red line in the control line region (C) indicates that sufficient flow of the sample occurred and that the test reagents are functioning properly. If no visible signal appears on the control line, the test result is invalid.

b. Sample Stability Study:

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

c. Shelf-Life Stability Study:

A real-time stability study was conducted to support a 24-month shelf-life for the Heal-Check Rapid COVID-19 Antigen Self-Test under storage conditions of 2–30°C. Three (3) lots of the candidate device were stored at 2–8°C and 30 ± 3°C.Testing was performed using contrived positive samples prepared from heat-inactivated SARS-CoV-2 (Wild-type: WGFR strain) at 4X LoD and 8X LoD positive concentrations and a negative sample prepared in PNCM. Five (5) replicates per sample were tested per lot at each condition, and time point according to the QRI. Testing was conducted at baseline and at multiple time points through 31 months of storage. All samples produced expected results at each time point across all lots and storage conditions. Thus, at the time of clearance, all study data have met the protocol defined acceptance criteria, and support a shelf-life claim of 24 months at 2–30°C.

d. Transport Stability Study:

A transport stability study was conducted to evaluate the effect of summer and winter shipping conditions on the Heal-Check Rapid COVID-19 Antigen Self-Test. Three (3) lots of the candidate device were exposed to high (summer) and low (winter) temperature conditions representing worst-case shipping scenarios. The conditions tested included the following:

- **Summer Conditions**:

  Study 1: Test units in original packaging were shaken at 40°C for 2 days at room humidity, then dropped from 1 meter height 10 times (5 flat surface landings, 5 corner landings)

  Study 2: Test units in original packaging were shaken at 40°C for 3 days at room humidity, then dropped from 1 meter height 10 times (5 flat surface landings, 5 corner landings)

- **Winter Conditions:**

  Test units in original packaging were frozen at -20°C for 3 days, thawed at room temperature for 4 hours, shaken at room temperature for 3 days, then dropped from 1 meter height 10 times (5 flat surface landings, 5 corner landings)

Following exposure, kits were evaluated for physical integrity and functional performance. Testing was performed using contrived positive samples prepared from heat-inactivated SARS-CoV-2 (USA-WA1/2020) diluted in PNCM at low positive (2X

LoD), high negative (0.1X LoD), and negative samples, with five (5) replicates per sample level across three (3) lots. Each replicate was tested according to the QRI.

All kits met physical integrity acceptance criteria, and all samples produced expected results following exposure to both simulated summer and winter conditions. The results support the stability of the device under anticipated shipping conditions.

8. Assay Cut-Off:

Not applicable, the device is a binary qualitative assay.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable. See C. Clinical Studies.

2. Matrix Comparison:

The Heal-Check Rapid COVID-19 Antigen Self-Test is only intended for use with direct anterior nasal swab specimens. As no other specimen types are claimed, a matrix comparison study is not applicable.

C Clinical Studies:

1. Clinical Study Results:

A prospective clinical study was conducted at twelve (12) sites in the United States for the clinical validation of the Heal-Check Rapid COVID-19 Antigen Self-Test for the detection of SARS-CoV-2 from anterior nasal swabs. The Heal-Check Rapid COVID-19 Antigen Self-Test performance was evaluated with study subjects experiencing symptoms associated with COVID-19, within five (5) days of symptom onset. A total of 1,489 total subjects were enrolled from June 2023 to August 2025 (Table 8). Out of these there were 1,380 subjects within five (5) days of symptom onset and evaluable based upon the inclusion and exclusion criteria for the study. Each enrolled study subject either self-collected one anterior nasal swab sample (both nostrils) or had an anterior nasal swab sample collected from him/her by another lay user tester. After each swab was collected, testing was performed using the QRI of the Heal-Check Rapid COVID-19 Antigen Self-Test. Each subject had another anterior nasal swab was collected by one of the study personnel for the comparator testing, which used FDA-cleared RT-PCR assays. Swab collections for the Heal-Check Rapid COVID-19 Antigen Self-Test and comparator samples were alternated by subject. The comparator tests were performed according to their respective instructions for use (IFU). Test results from the Heal-Check Rapid COVID-19 Antigen Self-Test were compared to results obtained from the comparators (Table 9).

Table 8. Summary of Subject Demographics

Demographic	Subjects: Collecting and testing for another) (n=221)	Subjects: Self-collecting and testing (n=1159)	Overall (n=1380)
Age			
>2-<14 years of age	187 (84.6%)	0 (0.0%)	187 (13.6%)
14-24 years of age	12	207	219

	(5.4%)	(17.9%)	(15.9%)
>24-64 years of age	15 (6.8%)	857 (73.9%)	872 (63.2%)
>65 years of age	7 (3.2%)	95 (8.2%)	102 (7.4%)
Total	**221 (100.0%)**	**1159 (100.0%)**	**1380 (100.0%)**
Age: Mean (SD)	13.0 (15.5)	39.7 (15.7)	35.4 (18.5)
Age: Median [Min, Max]	9.0 [2.0, 85.0]	38.0 [14.0, 89.0]	34.0
Sex at Birth			
Female	106 (48.0%)	730 (63.0%)	836 (60.6%)
Male	115 (52.0%)	429 (37.0%)	544 (39.4%)
Total	**221 (100.0%)**	**1159 (100.0%)**	**1380 (100.0%)**
Ethnicity			
Hispanic/Latino	130 (58.8%)	450 (38.8%)	580 (42.0%)
Not Hispanic/Latino	88 (39.8%)	706 (60.9%)	794 (57.5%)
Unknown/Prefer not to answer	3 (1.4%)	3 (0.3%)	6 (0.4%)
American Indian or Alaskan Native	4 (1.8%)	4 (0.3%)	8 (0.6%)
Asian	0 (0.0%)	17 (1.5%)	17 (1.2%)
Black or African American	56 (25.3%)	302 (26.1%)	358 (25.9%)
Native Hawaiian/Pacific Islander	0 (0.0%)	0 (0.0%)	0 (0.0%)
White	144 (65.2%)	802 (69.2%)	946 (68.6%)
Unknown/Prefer not to answer	4 (1.8%)	8 (0.7%)	12 (0.9%)
Other (Mixed race/biracial)	13 (5.9%)	26 (2.2%)	39 (2.8%)
Total	**221 (100.0%)**	**1159 (100.0%)**	**1380 (100.0%)**

Table 9. Performance of Heal-Check Rapid COVID-19 Antigen Self-Test Compared to RT-PCR

	Comparator Positives	**Comparator Negatives**	**Total**
Candidate Positives	144	2	146
Candidate Negatives	22	1212	1234

	Comparator Positives	Comparator Negatives	Total
Total	166	1214	1380
Positive Percent Agreement (PPA): 86.7% (144/166): 95% CI: 80.7% - 91.1%			
Negative Percent Agreement (NPA): 99.8% (1212/1214): 95% CI: 99.4% - 100.0%			

2. Clinical Sensitivity:

   Please refer to Section C (Clinical Studies) above for clinical validation. The PPA for the test is as follows:

   SARS-CoV-2: 86.7% (144/166): 95% CI: 80.7% - 91.1%

3. Clinical Specificity:

   Please refer to Section C (Clinical Studies) above for clinical validation. The NPA for the test is as follows:

   SARS-CoV-2: 99.8% (1212/1214): 95% CI: 99.4% - 100.0%

4. Clinical Cut-Off:

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

5. Usability and Readability Study:

   a. Usability Study Results:

      A usability evaluation was conducted to assess lay users' ability to understand the Quick Reference Instructions (QRI) and correctly execute the Heal-Check Rapid COVID-19 Antigen Self-Test workflow in a simulated home environment.

      A total of 159 subjects participated in usability assessments conducted across six (6) clinical sites. Out of these subjects, 84 participants self-collected and tested their samples and 75 participants had their samples collected by another lay user.

      Subjects were assessed for their ability to perform critical and non-critical tasks during the testing process. Overall, 82.1% of all critical and 84.2% of non-critical tasks associated with the Heal-Check Rapid COVID-19 Antigen Self-Test were performed correctly. Results are summarized in Table 10 below.

      Table 10. Critical vs. Non-Critical Tasks Correctly Performed.

Steps	Steps performed correctly	Total number of steps	Percentage of steps performed correctly
Critical	915	1113	82.1%
Non- Critical	668	795	84.2%
Total	**1583**	**1908**	**83.0%**

      Overall, the majority of subjects who participated in the usability evaluation found the instructions clear and easy to follow and reported minimal difficulty collecting the sample or running the investigational test.

Following completion of the usability evaluation, all participants were issued a questionnaire to assess user comprehension of the test. The questionnaire was completed by all subjects enrolled in the usability study and evaluated understanding of key concepts, including test purpose and interpretation of results.

In the labeling and comprehension assessment of the investigational Quick Reference Instructions (QRI), all subjects understood that they should self-isolate if they test positive with the investigational test. The majority of subjects understood that they should collect a new sample and run a new test if they obtained an invalid result or performed a step incorrectly.

b. Lay User Readability Study Results:

A readability study was conducted to evaluate whether lay users could correctly interpret test results for the Heal-Check Rapid COVID-19 Antigen Self-Test in a simulated home-use environment.

A total of 159 lay users participated in interpreting blinded mock test panels representing positive (including low positive), negative, and invalid results.

Mock test panels included results at approximately 1.9X LoD (low positive), 5X LoD (positive), negative, and invalid. Each device was blinded and coded.

Overall interpretation accuracy was 94.3% (650/689; 95% CI: 92.4%–95.8%). Accuracy was lowest for low positive samples (1.9X LoD), with 90.3% (262/290) correctly interpreted. Accuracy for 5X LoD positive, negative, and invalid results was 98.1% (154/159), 96.8% (181/187), and 100.0% (53/53), respectively (Table 11).

Table 11. Interpretation of Mock Results.

Interpreted Result	**Confirmed Result**			
	1.9X LoD (Low Positive)	**5X LoD (Positive)**	**Negative**	**Invalid**
Positive	262	154	4	0
Negative	26	5	181	0
Invalid	2	0	2	53
Total	**290**	**159**	**187**	**53**
Accuracy (% Accuracy)	**262/290 (90.3%)**	**154/159 (98.1%)**	**181/187 (96.8%)**	**53/53 (100.0%)**
Overall interpretation accuracy: 650/689 = 94.3% (95% CI: 92.4%-95.8%)				

Interpretation accuracy by age group is summarized in Table 12. Lower accuracy was observed in subjects >55 years of age for 1.9X LoD positive and 5X LoD positive samples.

Table 12. Percent Accuracy of Mock Interpretation by Age Group.

Age Group	**1.9X LoD (Low Positive)**	**5X LoD (Positive)**	**Negative**	**Invalid**
14 - 19 years of age (11 Subjects)	100.0%	100.0%	100.0%	100.0%
20 – 29 years of age (24 subjects)	92.9%	100.0%	100.0%	100.0%
30 – 35 years of age (90 subjects)	92.2%	97.8%	99.0%	100.0%

Age Group	1.9X LoD (Low Positive)	5X LoD (Positive)	Negative	Invalid
>55 years of age (34 subjects)	80.6%	91.2%	87.5%	100.0%
Total	**98.6%**	**98.1%**	**97.6%**	**100.0%**

Interpretation accuracy by vision status is summarized in Table 13.

Table 13. Interpretation of Mock Results with or without Vision Impairment.

Interpreted by Subjects	Mock Results Type (Percent Accuracy)			
	1.9X LoD (Low Positive)	5X LoD (Positive)	Negative	Invalid
With visual impairments (61 subjects)	92.5%	93.4%	96.1%	100.0%
Without visual impairments (98 subjects)	89.1%	99.0%	97.3%	100.0%

D Other Supportive Study/Device Information:

1. Flex Studies:

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

2. Serial Testing:

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

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

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

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

- Performance of Screening for SARS-CoV-2 using Rapid Antigen Tests to Detect Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infection: findings from the Test Us at Home prospective cohort study –

  https://www.medrxiv.org/content/10.1101/2022.08.05.22278466v1

E Expected Values/Reference Range:

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

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 to the predicate.