April 13, 2026

Healgen Scientific, LLC
Dung Nguyen
Director, Regulatory & Clinical Affairs
3818 Fuqua St.
Houston, TX 77047

Re: K260095
Trade/Device Name: Heal-Check Rapid COVID-19 Antigen 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: January 12, 2026
Received: January 13, 2026

Dear Dung Nguyen:

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

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

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

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH BRIGGS -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K260095

Device Name
Heal-Check Rapid COVID-19 Antigen Self-Test

Indications for Use *(Describe)*
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.

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

Heal-Check Rapid COVID-19 Antigen Self-Test

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In accordance with 21 CFR 807.92, the following 510(k) Summary for the Heal-Check Rapid COVID-19 Antigen Self-Test is provided.

Submitter Information

Applicant/Submitter:	Healgen Scientific LLC 3818 Fuqua St Houston, TX 77047
Contact Person:	Dung Nguyen Director, Regulatory Affairs and Clinical Affairs Healgen Scientific LLC Tel: 310-704-2697 Email: dung.nguyen@healgen.com
Date Prepared:	April 9, 2026

A. 510(k) Number

K260095

B. Purpose for Submission

New 510(k) device clearance for the Heal-Check Rapid COVID-19 Antigen Self-Test

C. Measurand

SARS-CoV-2 nucleocapsid protein antigen

D. Type of Test

Qualitative lateral flow immunoassay

E. Identification of the Device

Trade Name:	Heal-Check Rapid COVID-19 Antigen Self-Test
Common Name:	Over-the-Counter COVID-19 Antigen Test
Classification Name:	Over-the-counter test to detect SARS-CoV-2 from clinical specimens
Regulation Number:	21 CFR 866.3984
Classification:	Class II
Product Code:	QYT
Panel:	Microbiology
Predicate Device:	OHC COVID-19 Antigen Self Test (K241313)

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F. Intended Use / Indications for Use

1. Intended 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.

2. Indications for Use:

   See Intended Use

3. Special Conditions for Use Statement(s):

   OTC - Over The Counter

4. Special Instrument Requirement(s):

   None

G. Device Description

The Heal-Check Rapid COVID-19 Antigen Self-Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.

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H. Test Principle

The Heal-Check Rapid COVID-19 Antigen Self-Test is an immunochromatographic membrane assay that detects SARS-CoV-2 nucleoprotein antigens in anterior nasal swab specimens using highly sensitive monoclonal antibodies.

The test device is known as a test cassette, comprised of a casing and a test strip. The cassette has a sample well and a result window. The letters "C" and "T" are printed on the cassette next to the window for the control line and test line, respectively.

The test strip is composed of the following parts: sample pad, reagent pad, reaction membrane, and absorbing pad. 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 the 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 migrate along with 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). Absence of the test line (T) suggests a negative result. 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 (see **Figure 1**).

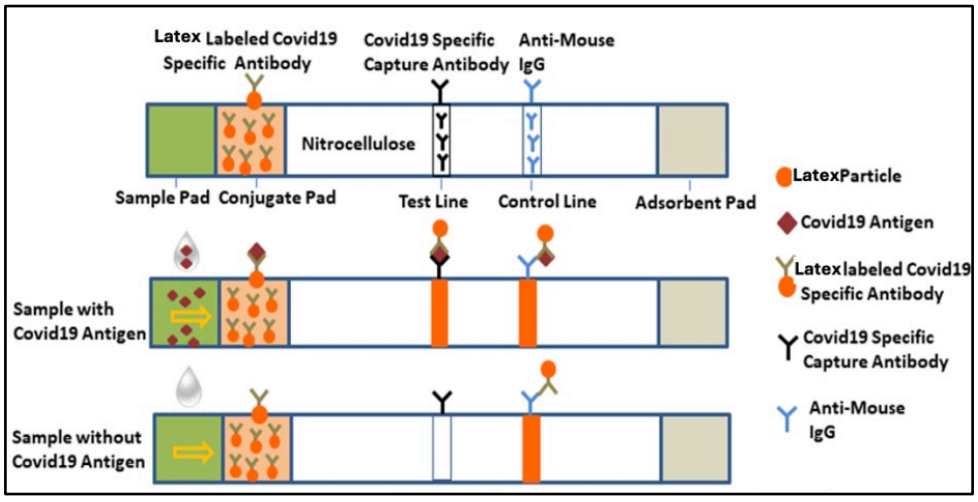

Figure 1: Schematic of the Heal-Check Rapid COVID-19 Antigen Self-Test Strip

Results must be interpreted between 15 and 30 minutes. A positive specimen will present two pink-to-red lines beside the "C" and "T" regions of the test window. A positive result 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. A negative result 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.

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I. Substantial Equivalence

The proposed Heal-Check Rapid COVID-19 Antigen Self-Test has similar indications for use and uses the same fundamental technology as the legally marketed device, the OHC COVID Antigen Self Test (K241313).

Table 1. Comparison of the Proposed Device and Predicate Device

Specification	**Proposed Device:** Heal-Check Rapid COVID-19 Antigen Self-Test	**Predicate Device:** OHC COVID-19 Antigen Self Test (K241313)
Intended 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	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

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Specification	**Proposed Device:** Heal-Check Rapid COVID-19 Antigen Self-Test	**Predicate Device:** OHC COVID-19 Antigen Self Test (K241313)
	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.	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 variant is suspected.
Prescription Use or Over-the-Counter	Over-the-counter (OTC)	Over-the-counter (OTC)
End User	Lay user	Lay user
Disease	COVID-19	COVID-19
Intended Use Population	Symptomatic individuals 14 years of age and older testing themselves and adults testing individuals aged 2 years and older.	Symptomatic individuals 14 years of age and older testing themselves and adults testing individuals aged 2 years and older.
Sample	Anterior nasal swab specimen	Anterior nasal swab specimen
Assay Principle	Lateral flow	Lateral flow
Qualitative or Quantitative	Qualitative	Qualitative
Organism Detected	SARS-CoV-2	SARS-CoV-2
Format	Test cassette	Test cassette
Controls	Internal control	Internal control
Time to Result	15 - 30 minutes	15 - 20 minutes
Results	Positive, Negative, or Invalid	Positive, Negative, or Invalid
Interpretation	Visually read	Visually read

As shown in **Table 1** above, the proposed device, Heal-Check Rapid COVID-19 Antigen Self-Test, and the predicate device have the same intended use. The proposed device, Heal-Check Rapid COVID-19 Antigen Self-Test and the predicate device have the same technological characteristics. Both devices are lateral flow immunoassays which are visually read and require no instrumentation or mobile applications. Both devices detect the SARS-CoV-2 nucleocapsid protein from a lay user-collected anterior swab specimen from individuals with signs and symptoms of COVID-19, aged 2 years and older.

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J. Performance Characteristics

1. Analytical Performance

Analytical studies were performed to assess the performance characteristics and the substantial equivalence of the proposed device, Heal-Check Rapid COVID-19 Antigen Self-Test, to the predicate device. The performance studies are described below.

a. Precision

The precision study was conducted to determine the variability between-lot, between-operator, between-run, and between-day. Three sample levels (Negative, 1.5x LoD, and 3x LoD) were tested at a single site with 3 operators over 5 days, i.e. 2 replicates × 2 runs x 3 lots x 3 operators per sample level. Three (3) test lots were used in this study to assess lot-to-lot variability. **Table 2a** summarizes the results of the study, demonstrating there was no difference in results between days, runs, lots, and operators.

Table 2a. Results of the Precision Study

Lot	Negative		1.5x LoD		3x LoD	
	Correct Reads/Total	% Agreement	Correct Reads/Total	% Agreement	Correct Reads/Total	% Agreement
1	60/60	100.0%	60/60	100.0%	60/60	100.0%
2	60/60	100.0%	60/60	100.0%	60/60	100.0%
3	60/60	100.0%	60/60	100.0%	60/60	100.0%
Total	**180/180**	**100.0%**	**180/180**	**100.0%**	**180/180**	**100.0%**

A supplemental study was performed to evaluate between-lot, between-operator, between-run, between-day and total precision using a sample with a concentration lower than 1x LoD (C_{95} concentration). The study was conducted at a single site with 3 operators and 3 device lots. Two sample levels (Negative, and 0.9x LoD) were tested over 5 days, i.e. 2 replicates x 2 runs x 3 lots x 3 operators per sample level. As shown in **Table 2b**, the total agreement was 72.8% for the 0.9x LoD sample, which is expected to be within 50 - 95%.

Table 2b. Results of the Supplemental Precision Study

Lot	Negative		0.9x LoD	
	Correct Reads/Total	% Agreement	Correct Reads/Total	% Agreement
1	60/60	100.0%	45/60	75.0%
2	60/60	100.0%	37/60	61.7%
3	60/60	100.0%	49/60	81.7%
Total	**180/180**	**100.0%**	**131/180**	**72.8%**

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b. Limit of Detection

LoD studies determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates test positive. Stock concentrations of SARS-CoV-2 virus, were spiked into pooled negative clinical matrix (PNCM) and serially diluted. A preliminary LoD test was performed by spiking 50 µL of each diluted sample onto the sample collection swab head in triplicate. The confirmatory LoD test was performed at the selected preliminary LoD concentration and at concentrations above and below the preliminary LoD with an additional 20 replicates on the Heal-Check Rapid COVID-19 Antigen Self-Test. The Limit of Detection of the Heal-Check Rapid COVID-19 Antigen Self-Test with SARS-COV-2 is summarized in **Table 3**.

Table 3. LoD Results Summary

Analyte	Isolate / Lineage	LoD Concentration ($TCID_{50}$/mL)	LoD 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
	SARS-CoV-2 Wild-Type: WGFE (Heat Inactivated)	1.15×10^2	5.75	20/20	3

c. International Standard for SARS-CoV-2 antigen (NIBSC 21/368)

Furthermore, the LoD was evaluated using the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) in real clinical matrix of pooled swab specimens. Initially, a preliminary LoD was performed in range finding studies, and a confirmatory LoD test was then conducted to confirm the preliminary LoD concentration and additional dilutions bracketing the preliminary concentration. It was determined that the LoD of the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) for the Heal-Check Rapid COVID-19 Antigen Self-Test was determined to be 250 IU/mL (12.5 IU/swab).

d. Linearity/assay reportable range

Not applicable. This is a qualitative assay.

e. Assay Cut-Off:

Not applicable. This is a qualitative visually read assay without numeric raw data.

f. High Dose Hook Effect

The hook effect study was designed to determine whether the presence of a high concentration of the SARS-CoV-2 virus in a sample would result in a negative test result, a phenomenon known as the hook effect. All high titer samples, including the sample with 1.55×10^8 $TCID_{50}$/mL virus, did not

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show inhibition, indicating that there is no hook effect for samples at least up to 1.55×10^8 $TCID_{50}$/mL virus.

g. *Inclusivity (Analytical Reactivity)*

Six (6) SARS-CoV-2 variants (Alpha, Beta, Delta, Gamma, Kappa, and Omicron) were serially diluted to determine if the test can reliably detect these variants at the highly diluted concentrations. These variants were each diluted three times, and each dilution was tested by an operator using three kit lots. As shown in **Table 4**, all variants were tested positive for all three replicates in three lots at the concentrations of ~10^2 - 10^3 $TCID_{50}$/mL.

Table 4. Summary of Variant Inclusivity

SARS-CoV-2 Variant	Sub-lineage	Lowest Concentration Tested Positive
Alpha	B.1.1.7	1.00 x 10^2 $TCID_{50}$/mL
Beta	B.1.351	2.20 x 10^2 $TCID_{50}$/mL
Delta	B.1.617.2	2.20 x 10^3 $TCID_{50}$/mL
Gamma	P1	1.26 x 10^3 $TCID_{50}$/mL
Kappa	B.1.617.1	1.90 x 10^2 $TCID_{50}$/mL
Omicron	B.1.1.529	2.51 x 10^2 $TCID_{50}$/mL

A plan has been established at Healgen to perform monitoring for the emergence of any circulating variants of public health concern.

h. *Analytical Specificity/Interference*

Cross-Reactivity and Microbial Interference

Various microorganisms were evaluated for cross-reactivity and microbial interference by wet testing with the Heal-Check Rapid COVID-19 Antigen Self-Test. No cross-reactivity and no microbial interference was observed for any of the listed organisms when tested at the concentrations listed in **Table 5**.

Table 5. Microorganisms Tested for Cross-Reactivity and Microbial Interference

Microorganism	Concentration Tested	Cross-Reactivity	Interference
Human coronavirus 229E	1.00 x 10^5 $TCID_{50}$/mL	No	No
Human coronavirus OC43	1.00 x10^5 $TCID_{50}$/mL	No	No
Human coronavirus NL63	1.00 x 10^5 $TCID_{50}$/mL	No	No
MERS-coronavirus	4.67 x 10^2 $TCID_{50}$/mL	No	No
SARS-coronavirus	1.98 x 10^2 $TCID_{50}$/mL	No	No
Human coronavirus HKU1* (clinical samples)	1:20 dilution	No	No
Adenovirus type (e.g., C1.Ad.71)	1.00 x 10^6 $TCID_{50}$/mL	No	No
Human Metapneumovirus (hMPV)	1.00 x 10^5 $TCID_{50}$/mL	No	No
Parainfluenza virus 1	1.00 x 10^5 $TCID_{50}$/mL	No	No

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Microorganism	Concentration Tested	Cross-Reactivity	Interference
Parainfluenza virus 2	1.00 x 10^5 $TCID_{50}$/mL	No	No
Parainfluenza virus 3	1.00 x 10^5 $TCID_{50}$/mL	No	No
Parainfluenza virus 4A	1.60 × 10^4 $TCID_{50}$/mL	No	No
Influenza A	1.00 x10^5 $TCID_{50}$/mL	No	No
Influenza B	1.00 x 10^5 $TCID_{50}$/mL	No	No
Enterovirus	1.00 x 10^5 $TCID_{50}$/mL	No	No
Respiratory syncytial virus (RSV)	1.00 x 10^5 $TCID_{50}$/mL	No	No
Rhinovirus type 1A	1.00 x 10^5 $TCID_{50}$/mL	No	No
Haemophilus influenzae type b (Eagan)	1.00 x 10^7 CFU/ mL	No	No
Streptococcus pneumoniae, Z022	1.00 x 10^6 CFU/mL	No	No
Streptococcus pyogenes, Z018	1.00 x 10^6 CFU /mL	No	No
Candida albicans, Z006	1.00 x 10^6 CFU /mL	No	No
Mycoplasma pneumoniae, M129	1.00 x 10^7 CCU/mL	No	No
Chlamydia pneumoniae, TW-183	1.00 x 10^7 IFU/mL	No	No
Legionella pneumophila	1.00 x 10^7 CFU/mL	No	No
Staphylococcus aureus	5.00 x 10^6 CFU/mL	No	No
Staphylococcus epidermidis	1.75 x 10^8 CFU/mL	No	No
Bordetella pertussis, A639	1.00 x 10^7CFU/mL	No	No
Pooled human nasal fluid	N/A	No	No
*Six (6) clinical samples confirmed positive for HKU1 by RT-PCR (Ct Range: 14.3 - 26.1)			

Endogenous/Exogenous Interfering Substances

Substances that may be present in respiratory samples were tested to determine if interference may occur with the Heal-Check Rapid COVID-19 Antigen Self-Test. The interfering substances were mixed with pooled negative clinical nasal matrix or with SARS-CoV-2 in pooled negative clinical nasal matrix, resulting in 2x LoD concentration. A summary of the results is shown in **Table 6**.

Table 6. Potential Interfering Substances for Respiratory Samples

Substance	Final Concentration Tested	Cross-Reactivity	Interference
Human Whole Blood (EDTA tube)	2.5%	No	No
Leukocytes	5 x 10^6 cells/mL	No	No
Mucin, bovine submaxillary gland	5 mg/mL	No	No
Throat Lozenges (Menthol/Benzocaine)	3 mg/mL	No	No
Sore Throat Spray (5% w/v) (Phenol)	15 % v/v	No	No
Nasal Spray (Sodium Chloride with preservatives)	15% v/v	No	No
Nasal Spray (Oxymetazoline)	15% v/v	No	No
Nasal Spray (Cromolyn)	15% v/v	No	No

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Substance	Final Concentration Tested	Cross-Reactivity	Interference
Nasal Spray (Phenylephrine)	15% v/v	No	No
Nasal Corticosteroids (Fluticasone Propionate)	15% v/v	No	No
Homeopathic allergy relief, or nasal wash (Histaminum hydrochloricum)	15% v/v	No	No
ZICAM Cold Remedy (Luffa operculata, Galphimia glauca, Sabadilla)	5% v/v	No	No
NasoGEL (NeilMed®)	5% v/v	No	No
Afrin Nasal Spray (Oxymetazoline)	5% v/v	No	No
Tobramycin	4 µg/mL	No	No
Tamiflu (Anti-viral drug)	5 mg/mL	No	No
Mupirocin (nasal ointment)	10 mg/mL	No	No
Hand Soap	1%	No	No
Hand Sanitizer	1%	No	No
Pooled Negative Swab Matrix	NA	No	No

i. *Traceability, Stability and Expected Values (Controls, Calibrators, or Methods)*

Real Time Stability:
A panel of standard samples including 8x LoD, 4x LoD and Negative were used for testing. The data supports the claimed 24-month shelf life.

Transport Stability:
Simulated winter and summer transport temperature conditions were used to evaluate the worst-case shipping and handling of unopened components of the Heal-Check Rapid COVID-19 Antigen Self-Test over an extended period. The studies showed that all physical integrity inspections and functional test results met the pre-determined acceptance criteria. The results support the conclusion that the assay can maintain the quality performance after going through the worst conditions of winter and summer shipping.

Internal Controls:
The test strip enclosed in the test device independently features an internal control, denoted directly on the test device as "C" for user interface. The test strip specific control line is needed to indicate that the test strip is working adequately in each lay user performed test. The control must be positive for valid test results to demonstrate that the test reagents are functional and the test performed correctly. If the control line is not visible, the sample result is invalid.

External Controls:
External Control testing is not performed by lay users and is therefore not applicable to OTC tests. External controls are therefore not included in the test kit.

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j. Flex Studies

Flex studies were performed to evaluate the robustness of the Heal-Check Rapid COVID-19 Antigen Self-Test. Testing was performed with negative samples and with low positive samples (2x LoD). The following flex conditions were assessed:

- Various Sample Volumes
- Sample Mixing and Squeezing
- Various Light Conditions
- Result Reading Time
- Cassette Position During Testing
- Bubble Formation in Sample
- Time of Swab in Extraction Buffer
- Temperature and Humidity Extremes
- Open Kit Stability

The studies support that the Heal-Check Rapid COVID-19 Antigen Self-Test is robust in the intended use condition with an insignificant risk of erroneous result when performed by a lay user.

2. Clinical Performance

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 (COVID-19) 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 1,380 evaluable subjects (60.6% female and 39.4% male) were enrolled from June 2023 to August 2025. 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 Quick Reference Instructions (QRI) of the Heal-Check Rapid COVID-19 Antigen Self-Test. Each subject had another anterior nasal swab 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. Results are shown in **Tables 7 and 8**.

Table 7. Heal-Check Rapid COVID-19 Antigen Self-Test Results vs. Molecular Comparator

Heal-Check Rapid COVID-19 Antigen Self-Test	Composite Comparator		Total
	Positive	Negative	
Positive	144	2	146
Negative	22	1212	1234
Total	**166**	**1214**	**1380**

Positive Percent Agreement = (144/166) = 86.7% (95% CI: 80.7% - 91.1%)
Negative Percent Agreement = (1212/1214) = 99.8% (95% CI: 99.4% - 100.0%)

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Table 8. Summary of Subject Demographics

Age Group	Number of Samples Tested	Antigen Positives	Composite Comparator Positives	% Positive (by Comparator
≥ 2 - <14 years	187	12	16	8.6%
14 - 24 years	219	12	14	6.4%
> 24 - 64 years	872	107	123	14.1%
≥ 65 years	102	13	13	12.7%
Total	**1380**	**144**	**166**	**12.0%**

3. Human Factor Study

The study objective was to evaluate the usability of the Heal-Check Rapid COVID-19 Antigen Self-Test and to evaluate the labeling and comprehension of the subject test QRI when performed by lay users in a simulated home environment.

A total of 159 subjects participated in the human factors assessment. Out of these 159 subjects, 84 performed self-collection, and 75 had their collection performed by another lay user. Every participant had to complete a comprehension and labeling questionnaire in addition to interpreting the mock panel device results. Individuals with visual impairments were included in interpreting the mock test results. Additionally, 94.3% (650/689 tests) of the mock tests were interpreted correctly.

Overall, the subjects who participated in the human factors assessment found the instructions clear and easy to follow and found the sample collection easy to perform, as well as having no difficulty reading the test results. Most of the subjects had no difficulty in interpreting the mock test results. In the labeling and comprehension assessment of the investigational test QRI, all subjects understood that the investigational test was for COVID-19 testing, and they understood that they should self-isolate if they tested positive with the investigational test. The majority of the subjects also understood that they should collect a new sample and run a new test if they had an invalid result.

K. 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

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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

L. Conclusion

The data presented in this 510(k) is complete and demonstrate that the proposed device Heal-Check Rapid COVID-19 Antigen Self-Test is substantially equivalent to the predicate device (OHC COVID-19 Antigen Self Test (K241313). The proposed device complies with the applicable special controls for over-the counter test to detect SARS-CoV-2 from clinical specimens. Based on the comparison of the intended use, technological characteristics, and analytical and clinical performance data of the proposed device, Healgen concludes that the proposed device does not raise new issues and effectiveness and is substantially equivalent to the predicate device.