Tianyang Liu
Director of Regulatory and Policy
880 W Maude Ave
Sunnyvale, California 94085

May 31, 2024

Re: K233842
Trade/Device Name: iHealth COVID-19 Antigen Rapid 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: December 4, 2023
Received: December 4, 2023

Dear Tianyang Liu:

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

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

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

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

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,

Silke Schlottmann -S

Digitally signed by Silke Schlottmann -S
Date: 2024.05.31 15:51:47 -04'00'

Silke Schlottmann, Ph.D.
Deputy Assistant Director
Bacteriology Respiratory and Medical Countermeasures Branch
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233842

Device Name
iHealth COVID-19 Antigen Rapid Test

Indications for Use *(Describe)*
The iHealth COVID-19 Antigen Rapid Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 within the first 6 days of symptom onset. This test is for non-prescription home use by individuals aged 15 years or older testing themselves, or adults testing individuals aged 2 years or older.
The iHealth COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.
All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens.
This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.
The performance characteristics for SARS-CoV-2 were established from October 2022 to June 2023 when the COVID-19 variant Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

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.

510(k) Summary

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

1.0 Submitter's Information

Name: iHealth Labs, Inc.
Address: 880W Maude Ave Sunnyvale, CA 94085 USA
Phone number: (408) 398 0318
Contact: Tianyang Liu
Contact email: policy@ihealthlabs.com
Date Prepared: May 31, 2024

2.0 Device Information

Device trade name: iHealth COVID-19 Antigen Rapid Test
Device Common Name: Coronavirus Antigen Detection Test

3.0 Classification

Product code: QYT
Classification Regulation: 21 CFR 866.3984 - Over-The-Counter Test To Detect SARS-Cov-2 From Clinical Specimens
Classification: Class II
Review Panel: Microbiology

4.0 Predicate Device Information

510(k) number	K230828
Manufacturer	ACON Laboratories,Inc
Trade/Proprietary Name	Flowflex COVID-19 Antigen Home Test
Classification Regulation	21 CFR 866.3984 - Over-The-Counter Test To Detect SARS-CoV-2 From Clinical Specimens
Classification	Class II
Product Code	QYT

5.0 Device Description

The iHealth COVID-19 Antigen Rapid Test employs lateral flow immunoassay technology. Using this test allows for the rapid detection of nucleocapsid protein from SARS-CoV-2.

To begin the test, a self-collected anterior nares swab sample in individuals aged 15 and older or individuals between the age of 2 to 14 with a swab collected by a parent or guardian is inserted into a tube that has been pre-filled with reagent. The reagent in the tube interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The liquid in the tube, now containing the specimen, is added to the Sample Port of the COVID-19 Test Card.

If the extracted specimen contains SARS-CoV-2 antigens, a pink-to-purple T Line, along with a pink-to-purple C Line will appear on the COVID-19 Test Card indicating a positive result. If SARS-CoV-2 antigens are not present, or present at very low levels, only a pink-to-purple C Line will appear.

6.0 Intended Use

The iHealth COVID-19 Antigen Rapid 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 6 days from symptom onset. This test is for non-prescription home use by individuals aged 15 years or older testing themselves, or adults testing individuals aged 2 years or older.

The iHealth COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from October 2022 to June 2023 when the COVID-19 variant Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

7.0 Comparison with Predicate Device

Characteristics	Subject Device	Predicate Device
Product Name	iHealth COVID-19 Antigen Rapid Test	Flowflex COVID-19 Antigen Home Test
510(K) Number	K233842	K230828
Product Code	QYT	QYT
Regulation Number	21 CFR 866.3984	21 CFR 866.3984
Regulatory Class	Class II	Class II
Assay Target	COVID-19 nucleocapsid protein antigen	COVID-19 nucleocapsid protein antigen
Intended Use	The iHealth COVID-19 Antigen Rapid 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 6 days from symptom onset. This test is for non-prescription home use by individuals aged 15 years or older testing themselves, or adults testing individuals aged 2 years or older. The iHealth COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2. All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using 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	The Flowflex COVID-19 Antigen Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 within the first 6 days of 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. The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS CoV-2. All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV2. 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 coinfection 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

Characteristics	Subject Device	Predicate Device
	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 October 2022 to June 2023 when the COVID-19 variant Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.	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 December 2022 to March 2023 when SARSCoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
Analyte	SARS-CoV-2 nucleocapsid protein antigen	SARS-CoV-2 nucleocapsid protein antigen
Intended Use Population	Individuals with symptoms of COVID-19	Individuals with symptoms of COVID-19
Prescription or OTC	OTC	OTC
Usage	Single use test	Single use test
Specimen Type	Anterior nasal swab specimens	Anterior nasal swab specimens
Assay Result	Qualitative	Qualitative
Technology	Lateral flow immunoassay	Lateral flow immunoassay
Rapid Test	Yes	Yes
Result Interpretation	Visually read	Visually read
Instrument	No	No
Time to Result	15-30 min	15-30 min
Storage Condition	2-30°C	2-30°C

8.0 Performance Summary

8.1 Precision/Reproducibility

The purpose of the study was to assess between-site and between-lot variability of three different lots of the iHealth COVID-19 Antigen Rapid Test. Three (3) levels of heat-inactivated SARS-CoV-2 were spiked in negative clinical matrix (NCM, Nasal fluid diluted in 1:3 Saline) as follows:

A. Negative, NCM
B. Low positive (1x LoD)
C. Positive (3x LoD)

The lot-to-lot precision of the iHealth COVID-19 Antigen Rapid Test was evaluated by using three (3) product lots. A series of coded, contrived samples were prepared as negative, low positive (1xLoD), and moderate positive (3xLoD) using heat inactivated SARS-CoV-2. Each sample level was tested in triplicate in each run per day with three (3) operators at three (3) CLIA waived sites for 5 non-consecutive days. The agreement of obtained results with expected results was 100% for all samples across all lots, operators, and days. Variability in results was not observed between the three independently manufactured lots.

Precision/Reproducibility Study - Summary Results			
Site	**True Negative**	**Low Positive (1x LoD)**	**Positive (3x LoD)**
Site 1 (External, 3 operators)	135/135	135/135	135/135
Site 2 (External, 3 operators)	135/135	135/135	135/135
Site 3 (External, 3 operators)	135/135	135/135	135/135
Total	405/405	405/405	405/405
% Agreement	100%	100%	100%
95% CI	99.1-100%	99.1-100%	99.1-100%

8.2 Limit of Detection (LOD)

The LoD of the iHealth COVID-19 Antigen Rapid Test was established by using limiting dilutions of heat inactivated SARS-CoV-2 virus (BA.5, Omicron Variant). The virus was spiked into negative clinical matrix prepared by mixing raw nasal fluid in saline (1:2) that was confirmed as SARS-CoV-2 negative by RT-PCR.

At each dilution, 50 µL of sample was added to swabs and then tested through the full assay workflow, from processing in the extraction reagent to reading the test result. Testing was performed with 5 replicates per concentration. The estimated LoD was found from testing the initial 5 different concentrations. Using this preliminary concentration, the LoD was confirmed with a 3-fold dilution series, using three test lots tested on consecutive days The LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time (concentration at which at least 19 out of 20 replicates tested positive) for each lot.

The iHealth COVID-19 Antigen Rapid Test LOD in natural nasal swab matrix is 1.33×10^4 $TCID_{50}$/mL. Based upon the testing procedure for this study, the LoD of iHealth COVID-19 Antigen Rapid Test $TCID_{50}$/mL equates to 665 $TCID_{50}$/swab.

The 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) was also tested to determine the LoD of the iHealth COVID-19 Antigen Rapid Test with a standardized material for SARS-CoV-2.

A preliminary LoD concentration with the WHO standard material was determined for the iHealth COVID-19 Antigen Rapid Test by testing a series of two-fold dilutions starting at 4000 IU/mL. Three replicates using three test kit lots were tested for this two-fold dilution series, flowed by an additional series of two-fold dilutions to refine the preliminary LoD. The preliminary LoD was then confirmed by testing an additional twenty (20) replicates with each of 3 test lots.

Limit of Detection - Summary Results				
Virus Strain	**LoD in NCM**	**LoD per Swab**	**#Positive/ #total Tested**	**Percent Detected (%)**
Omicron Variant	1.33×10^4 $TCID_{50}$/mL	665 $TCID_{50}$/swab	60/60	100%
WHO Standard (NIBSC 21/368)	4.00×10^2 IU/mL	20 IU/swab	59/60	98.3%

8.3 Cross Reactivity (Analytical Specificity) and Microbial Interference

The potential cross-reactivity (exclusivity) of a panel of common organisms was evaluated with SARS-CoV-2 negative samples using the iHealth COVID-19 Antigen Rapid Test. Potential microbial interference was evaluated with samples containing heat inactivated SARS-CoV-2 virus (BA.5, Omicron Variant) sample at approximately 2 x LoD.

A total of 53 commensal and pathogenic microorganisms (22 bacteria and 31 viruses) that may be present in the nasal cavity were evaluated in this study. Each of the organism and virus were tested in five replicates in the absence or presence of heat inactivated SARS-CoV-2 virus.

No cross-reactivity or interference was observed with the microorganisms.

Cross Reactivity (Analytical Specificity) and Microbial Interference - Summary Results			
List of Organism	**Concentration tested**	**Cross-reactivity results**	**Microbial interference results**

Human coronavirus 229E		4.50×10^4 $TCID_{50}$/mL	No cross-reactivity	No interference
Human coronavirus OC43		1.36×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Human coronavirus NL63		2.84×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
MERS-coronavirus		27.1(Ct value)	No cross-reactivity	No interference
SARS-coronavirus		1×10^5 PFU/mL	No cross-reactivity	No interference
Human coronavirus HKU1		33.8 (Ct value)*	No cross-reactivity	No interference
Adenovirus)	Adenovirus Type 1	2.82×10^6 $TCID_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 4	2.84×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 7A	3.16×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 8	1.13×10^5 U/mL	No cross-reactivity	No interference
	Adenovirus Type 31	1.13×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 41	3.80×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Human Metapneumovirus (hMPV)	Human Metapneumovirus 3 (hMPV-3) Type B1	0.94×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human Metapneumovirus 4 (hMPV-4) Type B2	3.33×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human Metapneumovirus 9 (hMPV-9) Type A1	1.13×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Parainfluenza virus	Parainfluenza Virus Type 1	3.80×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 2	3.39×10^6 $TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 3	1.15×10^6 $TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 4A	1.13×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 4B	9.55×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Influenza A & B	Influenza A H3N2	1.13×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Influenza B Victoria	1.26×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Enterovirus	Enterovirus Type 68	2.84×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Enterovirus Type 71	1.13×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference

Respiratory syncytial virus	Respiratory Syncytial Virus Type A (RSV-A)	1.05×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Respiratory Syncytial Virus Type B (RSV-B)	1.51×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Rhinovirus Type 1A		1.13×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Haemophilus influenzae		1.42×10^8 CFU/mL	No cross-reactivity	No interference
Streptococcus pneumoniae		7.22×10^7 CFU/mL	No cross-reactivity	No interference
Streptococcus pyogenes		4.60×10^8 CFU/mL	No cross-reactivity	No interference
Candida albicans		1.31×10^7 CFU/mL	No cross-reactivity	No interference
Pooled human nasal wash – representative of normal respiratory microbial flora		-	No cross-reactivity	No interference
Bordetella pertussis		1.16×10^9 CFU/mL	No cross-reactivity	No interference
Mycoplasma pneumoniae		2.16×10^8 CCU/mL	No cross-reactivity	No interference
Chlamydia pneumoniae		1.33×10^8 IFU/mL	No cross-reactivity	No interference
Legionella pneumophila		1.42×10^9 CFU/mL	No cross-reactivity	No interference
Staphylococcus aureus		1.42×10^8 CFU/mL	No cross-reactivity	No interference
Staphylococcus epidermidis		6.84×10^8 CFU/mL	No cross-reactivity	No interference
Mycobacterium tuberculosis		1.21×10^7 CFU/mL	No cross-reactivity	No interference
Pseudomonas aeruginosa		7.09×10^8 CFU/mL	No cross-reactivity	No interference
Streptococcus salivarius		1.35×10^8 CFU/mL	No cross-reactivity	No interference
Corynebacterium diphtheriae		3.43×10^7 CFU/mL	No cross-reactivity	No interference
Escherichia coli		8.16×10^8 CFU/mL	No cross-reactivity	No interference
Lactobacillus Acidophilus		6.58×10^7 CFU/mL	No cross-reactivity	No interference
Moraxella catarrhalis		5.92×10^7 CFU/mL	No cross-reactivity	No interference
Neisseria elongata		1.07×10^9 CFU/mL	No cross-reactivity	No interference
Neisseria meningitidis serogroup A		2.04×10^7 CFU/mL	No cross-reactivity	No interference
Neisseria meningitidis serogroup B		9.15×10^7 CFU/mL	No cross-reactivity	No interference
Neisseria meningitidis serogroup C		7.90×10^7 CFU/mL	No cross-reactivity	No interference

Epstein-Barr virus	0.97×10^7 cp/mL	No cross-reactivity	No interference
Mumps virus	9.55×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Cytomegalovirus (CMV)	1.13×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Measles virus	1.23×10^7 $TCID_{50}$/mL	No cross-reactivity	No interference
* Note: one HKU1 NP clinical sample has been tested in 5 replicates			

8.4 Endogenous Interfering Substances

Substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the iHealth COVID-19 Antigen Rapid Test.

The SARS-CoV-2 target concentration in the positive samples was approximately 2 x LoD. All samples were tested in 5 replicates and produced expected results, demonstrating that the iHealth COVID-19 Antigen Rapid Test performance was not affected by any of the 31 potentially interfering substances at the tested concentration.

Endogenous Interfering Substances - Summary Results			
Substance	**Concentration in negative/positive sample**	**Cross-reactivity**	**Interference**
Throat lozenges, oral anesthetic and analgesic (Benzocaine)	3mg/mL	No cross-reactivity	No interference
Throat lozenges, oral anesthetic and analgesic (Menthol)	3mg/mL	No cross-reactivity	No interference
Sore throat spray (Phenol)	5% w/v	No cross-reactivity	No interference
Mucin : bovine submaxillary gland, type I-S or pooled mucous (Purified mucin protein)	2.5 mg/mL	No cross-reactivity	No interference
Whole Blood (human)	2.5%	No cross-reactivity	No interference
Leukocytes	4.8×10^6 cells/mL	No cross-reactivity	No interference
Zinc (common ingredient in many nasal sprays)	5% v/v	No cross-reactivity	No interference
Nasal drops (Phenylephrine)	15% v/v	No cross-reactivity	No interference
Nasal sprays (Cromolyn)	15% v/v	No cross-reactivity	No interference
Afrin (Oxymetazoline)	15% v/v	No cross-reactivity	No interference
Saline nasal spray (Sodium chloride with preservatives)	15% v/v	No cross-reactivity	No interference
Nasal corticosteroids (Beclomethasone dipropionate)	15% v/v	No cross-reactivity	No interference

Nasal corticosteroids (Dexamethasone)	15% v/v	No cross-reactivity	No interference
Nasal corticosteroids (Flunisolide)	15% v/v	No cross-reactivity	No interference
Nasocort Allery 24 hour (Triamcinolone)	15% v/v	No cross-reactivity	No interference
Rhinocort (Budesonide /Glucocorticoid)	15% v/v	No cross-reactivity	No interference
Nasal corticosteroids (Mometasone furoate)	15% v/v	No cross-reactivity	No interference
Nasal corticosteroids (Fluticasone Propionate)	15% v/v	No cross-reactivity	No interference
(Homeopathic Luffa opperculata Galphimia glauce)	1.25%	No cross-reactivity	No interference
Nasal gel (Luffa opperculata sulfur)	1.25%	No cross-reactivity	No interference
Homeopathic allergy relief, or nasal wash (Galphimia glauca)	15% v/v	No cross-reactivity	No interference
Homeopathic allergy relief, or nasal wash (Histaminum hydrochloricum)	15% v/v	No cross-reactivity	No interference
Homeopathic allergy relief, or nasal wash(Alkalol)	15% v/v	No cross-reactivity	No interference
Homeopathic allergy relief, or nasal wash (Zicam)	15% v/v	No cross-reactivity	No interference
Anti-viral drugs (Tamiflu)	5mg/mL	No cross-reactivity	No interference
Anti-viral drugs (Remdesivir)	5mg/mL	No cross-reactivity	No interference
Anti-viral drugs (Molnupiravir)	5mg/mL	No cross-reactivity	No interference
Antibiotic, nasal ointment (Mupirocin)	10mg/mL	No cross-reactivity	No interference
Hand sanitizer	15% v/v	No cross-reactivity	No interference
Hand soap	15% v/v	No cross-reactivity	No interference
Biotin*	200 ng/mL	No cross-reactivity	No interference

8.5 Hook Effect

There is no Hook effect at 3.98×10^6 $TCID_{50}$/mL corresponding to 300x LoD, which is the highest concentration that have been tested.

8.6 Inclusivity (Analytical Reactivity)

The inclusivity of the iHealth COVID-19 Antigen Rapid Test was evaluated with 14 strains of SARS-CoV-2 representing temporal, geographic, and genetic diversity within the currently circulating subtypes and lineages.

Inclusivity (Analytical Reactivity) - Summary Results	
SARS-CoV-2 Variant	**Lowest Variant Concentration with 5/5 positive replicates**

	[$TCID_{50}$/mL]
SARS-CoV-2 virus (USA-WA1/2020)	4.57×10^3
B.1.1.7 (Alpha)	$9.55x\ 10^3$
B.1.351 (Beta)	3.80×10^3
P.1 (Gamma)	1.7×10^3
B.1.617.2 (Delta)	1.26×10^4
B.1.1.529 (Omicron)	5.01×10^2
BA.2. (Omicron)	1.0×10^3
BA.2.3 (Omicron)	1.17×10^3
BA.4 (Omicron)	6.31×10^3
BA.4.6 (Omicron)	1.00×10^4
BA.5(Omicron)	3.98×10^3
BQ.1(Omicron)	2.0×10^3
BQ.1.1(Omicron)	7.94×10^4
XBB (Omicron)	1.0×10^3

8.7 Flex Studies

To assess the robustness of the iHealth COVID-19 Antigen Rapid Test, flex studies were conducted that assessed all major aspects of the test procedure (e.g., swab extraction time, drops of sample added to test cassette, development time, delay in sample analysis, swab agitation, sample buffer agitation) and variability of environmental test conditions that the test may be subjected to when in use (e.g., various temperature and humidity stress, cassette disturbance, sample/reagent temperature, lighting). Testing was performed with contrived positive nasal swabs prepared by diluting heat inactivated SARS-CoV-2 virus into negative clinical nasal swab matrix at 2x LoD. The studies support that the test is robust in the intended use condition with an insignificant risk of erroneous results.

9.0 Clinical Testing Summary

Clinical performance characteristics of the iHealth COVID-19 Antigen Rapid Test were evaluated in a total of eight (8) investigational sites throughout the U.S. A total of 915 individuals with signs and symptoms of COVID-19 within the first six (6) days of symptom onset completed the study and obtained a valid result. Each subject was provided an iHealth COVID-19 Antigen Rapid Test., Subjects fifteen (15) years and older collected an anterior nasal sample by themselves, conducted the test, interpreted and reported the result. The parents of subjects two (2) to fourteen (14) years of age collected the anterior nasal sample, conducted the test, interpreted and recorded the test result for the child. The iHealth COVID-19 Antigen Rapid Test results were compared to a highly sensitive molecular FDA EUA Authorized SARS-CoV-2 assays to determine test performance. The iHealth COVID-19 Antigen Rapid Test when conducted by a lay user correctly identified 88.9% of positive samples. Additionally, the iHealth COVID-19 Antigen Rapid Test correctly identified 99.9% of negative samples. The performance is shown in the following

table.

iHealth COVID-19 Antigen Rapid Test	Comparator Method		
	Positive	Negative	Total
Positive	104	1[b]	108
Negative	13[a]	797	810
Total	117	798	915
Positive Agreement: (104/117) 88.9%; 95% Confidence Interval: 81.9% to 93.4%			
Negative Agreement: (797/798) 99.9%; 95% Confidence Interval: 99.3% to 100.0%			

[a] Of the 13 false negative samples, 1 of them was negative on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay, 12 of them was positive on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay.
[b] Of the 1 false positive sample, this sample was positive on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay.

Age and gender distribution and positive rate of symptomatic subjects within first 6 days of symptom onset				
Age Group (years)	Female	Male	Positive	Positivity Rate % (total positive/total tested)
2 to 13	63	66	5	3.9% (5/129)
14 to 24	139	94	33	14.2% (33/233)
25 to 64	323	206	72	13.6% (72/529)
≥65	16	8	7	29.2% (7/24)
Total	541	374	117	12.8% (117/915)

Positive results broken down by days since symptom onset				
Days Since Symptom Onset	RT-PCR Positive (+)	iHealth test Positive (+)	PPA	95 % Confidence Interval
1	4	2	50.0%	15.0% - 85.0%
2	32	32	100.0%	89.0% - 100.0%
3	37	34	91.9%	78.7% - 98.2%
4	25	22	88.0%	70.0% -95.8%
5	12	9	75.0%	46.7% - 91.1%
6	7	5	71.4%	35.9% - 91.7%
Total	117	104	88.9%	81.9% - 93.4%

10.0 Conclusion

Based on the data submitted in this traditional 510(k) submission, the device has been shown to be substantially equivalent in term of intended use, design, technological characteristics and assay performance to the predicate device K230828.