Board Agenda Item #	III G: Action Item
Date:	January 20, 2022
To:	Magnolia Public Schools - Board of Directors
From:	Alfredo Rubalcava, CEO & Superintendent
Staff Lead:	Steve Budhraja Ed.D, Chief Financial Officer
RE:	Procurement of Antigen Rapid Test Kits for MSA Sites and Home Office

Proposed Board Recommendation

Motion to approve the purchase of 5,000 Antigen Covid - 19 Rapid Test Kits from Aotek Inc at a cost of $21.00 per box, each box containing 2 kits. After careful evaluation of multiple vendors, staff has determined that these kits provide the best option for tests at the most affordable price. The total cost includes 5,000 test kits, sales tax and delivery fees. These supplies are critical given the current Covid – 19 omnivariant and the need to protect all staff, students and others.

Budget Implications

Not to exceed $115,775 to be paid from Elementary and Secondary School Emergency Relief Fund (ESSER) funds.

Exhibits (attachments):

Summary of quotes from multiple vendors in order to identify best possible procurement solution.

I. Aotek Inc, offers Antigen test the lead time is immediately upon issuance of purchase order- **IHealth Home COVID-19 Antigen Rapid Test** = 2per @ $21.00 per box. No minimum case count $21.00 per = **$115,775.00** including sales taxes and shipping cost
Below is a brief video showing how to administer the test and read results:
https://youtu.be/qBt_H4Gc-rU

II. The Filo Group, offers Antigen test the lead time is TBD. - **Genbody COVID-19 AG Home Test = Boxes of 25 test = $287.50**. No minimum test $287.50 per box of 25 = $287.50 = **$57,500** (one pack of test contains 25 units which is not practical for our setup and operations.

III. Office Depot, offers Antigen test the lead time is 3 Weeks after order is placed: **IHealth Home COVID-19 Antigen Rapid Test** = 2per @ $19.49per box. **Minimum 7680 pallet count** $19.49per = **$147,334.40** not including sales taxes and shipping cost

IV. California Supply and Solutions, offers Antigen test the lead time is immediately upon issue of purchase order- **Celltrion DiaTrust COVID-19 Ag Home Test** = 2per @ $24.00per box. Minimum 5000 to get the $12.00 per under 5000 cost @ $28.00per box $24.00per = **$120,000** not including sales taxes and shipping cost

a. OR

Access Bio – Care Start COVID-19 Antigen Home Test – 1 Kit = 2 test /232 Kits (464 tests)/BOX 20 Boxes/Pallet = 4640 Kits (9,280 tests) = $**111,360 not including sales taxes and shipping**
https://youtu.be/r6juU4wMz_g

Attachments:

- ✓ IHealth Medical Fact Sheets
- ✓ List of FDA approved fact sheets
- ✓ GenBody Covid-19 Fact Sheet
- ✓ Aotek Pricing Sheet
- ✓ CareStart Medical Facts Sheets

AO APPAREL INC

201 East 36th STREET, Suite 12D
NEW YORK, NY 10016
TEL: 212-912-0988

01/13/2022

To:
Magnolia Educational and Research Foundation
250 E 1st St
Suite 1500
Los Angeles, CA 90012

From:
Peter Cicero
AO INC.

Quote:

5,000 x 2 pack iHealth Test Kits $11.50 per test = 10,000 Tests Total

$115,000.00

Freight = $800.00

Total = $115,800.00

iHealth®
COVID-19
Antigen Rapid Test

COVID-19 ANTIGEN AT HOME TEST ALLOWS EFFECTIVE SCREENING OF COVID-19 INFECTION WITH 15-MINUTE PROCESSING TIME

PRODUCT FEATURES:

- Easy to administer - Shallow Nasal Swab
- Detects multiple strains - including Delta variant
- Rapid results in 15 minutes - without having to send to a lab
- Failed tests can be immediately retested.
- Simple & easy to test on a reoccurring/daily basis with no wait time.
- No special equipment required.
- Detect SARS-CoV-2 nucleocapsid protein antigen
- No special storage or transportation requirements

90 PACKS/CARTON, 2 TESTS/PACK

UPC #	856362005890
SKU #	COV-AG-2
Model #	ICO-3000
Packs Per Carton	90
Tests Per Pack	2
Single Package Dimensions (LxWxH)	6.18 × 3.19 × 0.71 Inches
Single Package Weight (lb)	0.13
Carton Dimension (LxWxH)	13.1 x 11.8 x 10.8 Inches
Carton Weight (lb)	12.8
Packs per Pallet	7,560
Tests per Pallet	15,120
Pallet Dimensions	40 x 48 x 62 Inches
Total weight	1120 lbs

EN

iHealth®

COVID-19 Antigen Rapid Test Instruction for use

Model: ICO-3000

This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA).
Please read all the information in this instruction for use before performing the test.
For use with anterior nasal swab specimens.
For In Vitro Diagnostic (IVD) Use Only.

Download App & Open App

Scan the QR code to download the "iHealth COVID-19 Antigen Rapid Test" App through your smartphone (iOS12.0+, Android 6.0+).

For a full list of compatible smartphones visit:
https://ihealthlabs.com/pages/support-ICO3000

Register and Log into The App

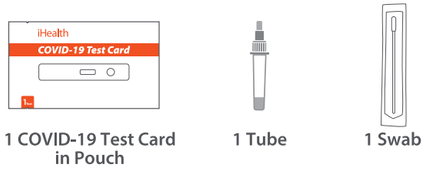
Watch Video in App

Each step has a corresponding instructional video in the App. Watch the video and perform the test according to the instructions.

Step by Step Instructions

1 Prepare Materials

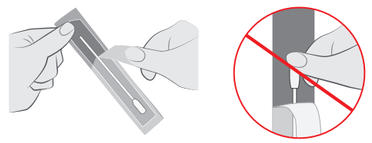
Open the package, take out the COVID-19 Test Card in Pouch, the Tube filled with the extraction buffer and the Swab. When you are ready to proceed with the test, open the foil pouch of the COVID-19 Test Card.



1 COVID-19 Test Card in Pouch | 1 Tube | 1 Swab

2 Collect Sample

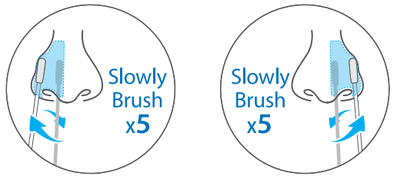
a. Remove the swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for later use.



b. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril.

Note:
With children, the maximum depth of insertion into the nostril may be less than 3/4 of an inch, and you may need to have a second person to hold the child's head while swabbing.

c. Firmly and slowly brush against insides of nostril in a circular motion against the nasal wall at least 5 times. Take at least 15 seconds to collect the specimen and be sure to collect any nasal drainage on the swab. Using the same swab, repeat the same sample collection procedure for the other nostril. Be sure to brush BOTH nostrils with the **SAME SWAB**.

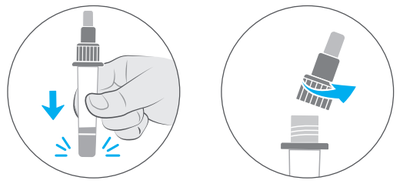


Right Nostril | Left Nostril

Note:
Failure to swab properly may cause false negative results.

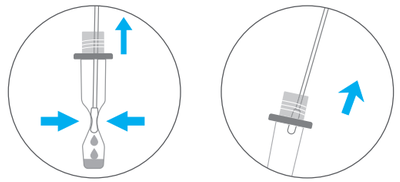
3 Process Sample

a. Tap the tube vertically on the table and twist the large orange cap to open the tube.



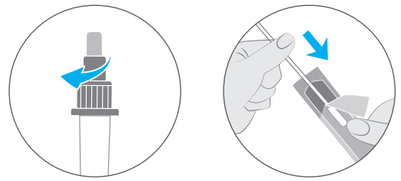
b. Insert the swab into the tube, touch the bottom of the tube with the swab tip, and stir at least 15 times.

c. Squeeze the sides of the tube to express as much liquid as possible from the swab, and then remove the swab.



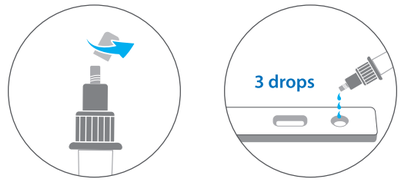
Note:
If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly (i.e., potentially resulting in a false negative result).

d. Screw back the large orange cap, put the swab back into the package. Safely dispose of the swab and the package.



4 Add Sample

Twist to open the small white cap of the tube. Add 3 drops of sample to the Sample Port of the COVID-19 Test Card. Screw back the small white cap.



Note:
A false negative or invalid result may occur if too little solution is added to the test card.

5 Wait 15 Minutes

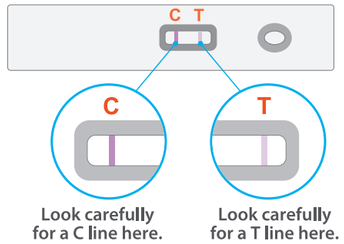
Start the timer by clicking the "Start Timer" button, immediately after adding sample to the Sample Port. The result will be ready in 15 minutes.

Note:
Do NOT interpret your test result until after your 15-min timer has completed, as the T line may take as long as 15 minutes to appear.

6 Read Result

Results should not be read after 30 minutes (Result shown at 2x magnification).

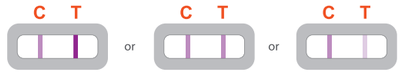
Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.



Note: The T line can be extremely faint.

7 Test Result Explanation

Positive Result



A POSITIVE result must show BOTH a C line and a T line. A positive result means that viral antigens from COVID-19 were detected and the individual is positive for COVID-19.

Below are photos of actual positive tests. Please note that the T line may be faint.

Persons who test positive should self-isolate and seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary.

Negative Result

A **NEGATIVE** result will show ONLY a C line. A negative result means that viral antigens from COVID-19 were not detected and that the individual is presumed negative for COVID-19.

- Please note that negative results do not rule out COVID-19.
- In case of negative test result: Continue to follow all social distancing recommendations and take protective measures. If suspicions of infection persist and/or your first test is negative, repeat the test after 1-2 days and consult your healthcare provider or local COVID-19 center.
- Note: A negative result is presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Individuals without symptoms that test negative should be tested again with at least 24 hours and no more than 48 hours between tests. Additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with as close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

Invalid Result

If there is NO LINE, or if there is ONLY a T line, the test is INVALID. Invalid result means that the test did not function correctly. You will need to retest with a new test kit. If upon retesting, the test result is still invalid, contact your doctor or local COVID-19 center. An invalid result does not indicate if the individual did or did not have COVID-19 and should be repeated.

8 Dispose the Test Kit

After test is completed, dispose the kit components in trash.

9 Report Test Result

Report the result following the App instructions or share your test result with your healthcare provider.

In the USA:

(1) This test is intended to be used as an aid to the clinical diagnosis of a current COVID-19 infection, Do not use this test as the only guide to manage your illness.
(2) In USA - This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA). This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other virus or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

iHealth®

COVID-19 Antigen Rapid Test Instructions for Use

Model: ICO-3000

This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA).
Please read this instruction for use before using the test.
For use with anterior nasal swab specimens.
For In Vitro Diagnostic (IVD) Use Only.

INTENDED USE

The iHealth® COVID-19 Antigen Rapid Test is a lateral flow assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older with symptoms of COVID-19 within the first seven (7) days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first seven (7) days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

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

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the iHealth® COVID-19 Antigen Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results are presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with as a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting or by following the mobile application instructions for self-reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The iHealth® COVID-19 Antigen Rapid Test is authorized for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older. The iHealth® COVID-19 Antigen Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

FREQUENTLY ASKED QUESTIONS

Will this test hurt?
No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a healthcare provider.

What are the known and potential risks and benefits of this test?
Potential risks include:
– Possible discomfort during sample collection.
– Possible incorrect test results.
Potential benefits include:
– The results, along with other information, can help your healthcare provider make informed recommendations about your care.
– The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What is serial testing?
Serial testing is when a single person is tested for COVID-19 more than once. Because antigen tests are less sensitive than other COVID-19 tests and false results may occur, repeated testing may identify individuals with COVID-19 more reliably than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce spread of infection. Additional testing with molecular COVID-19 test may be necessary, depending on your individual risk factors and test results.

It is important that you work with your healthcare provider to help you understand the next steps you should take. Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.

Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms. Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

What is the difference between an antigen and molecular test?
An antigen test, such as the iHealth® COVID-19 Antigen Rapid Test, detects proteins from the virus. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests are very specific for the virus, but not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider on whether an additional test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have a COVID-19.

How accurate is this test?
The iHealth® COVID-19 Antigen Rapid Test was compared to an FDA authorized molecular SARS-CoV-2 test using fresh self-collected or parent/guardian collected anterior nasal swab specimens and healthcare provider collected NP swab specimens. Subjects 2 years or older with or without symptoms participated in this study. The iHealth COVID-19 Antigen Rapid Test correctly identified 33 out of 35 (94.3%) of symptomatic positive samples and correctly identified 102 out of 104 (98.1%) of symptomatic negative samples in this study.

Please note that the accuracy of this test may decrease the longer you have had symptoms of infection, as the amount of virus in the sample decreases. In general, molecular RT-PCR tests are more sensitive than antigen tests and may be able to more reliably detect cases with less SARS-CoV-2, the virus that causes COVID-19.

What if you test positive?
A positive test result means that antigens from COVID-19 were detected and it is very likely you currently have COVID-19. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive you should self-isolate at home per CDC recommendations to stop spreading the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. Seek follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

What if you test negative?
A negative test result indicates no antigens for COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 and negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative. If you receive a negative result, you should test again in 24-48 hours. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 status after testing or think you may need follow up testing, please contact your healthcare provider.

For other updated FAQ information, please see the company website: https://www.ihealthlabs.com
For more information on EUAs go here: https://www.fda.gov/emergency-preparednessand-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
For up-to-date information on COVID-19, please visit the CDC COVID-19 website: https://www.cdc.gov/coronavirus/2019-ncov/index.html

WARNINGS AND PRECAUTIONS

- Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- This test is intended for diagnosis of coronavirus infection by detecting COVID-19 antigen but should not be used as a sole criterion for the determination of SARS-CoV-2 infection. Other laboratory tests and clinical information (signs and symptoms) should be used and considered for diagnosis.
- Do not use on anyone under 2 years old.
- Children aged 2-14 years should be tested by an adult.
- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- Do not use any test component after the expiration date which is printed on the outer packaging.
- Do not use the COVID-19 Test Card if the pouch is damaged or if the seal is broken.
- Do not reuse any test component.
- To obtain accurate results, the test must be performed as indicated in the application (iHealth COVID-19 Antigen Rapid Test) and/or Instructions for Use.
- Once the COVID-19 Test Card is removed from the pouch, perform the test as soon as possible. Use the COVID-19 Test Card within 1 hour after opening the foil pouch.
- Inadequate or inappropriate sample collection may yield false test results.
- Do not touch the tip of the swab before and after collecting the sample from the nostrils.
- Insert the swab into the tube right after taking the sample.
- Test samples immediately after collection, but no more than 4 hours after specimen collection before placement into extraction buffer or up to 2 hours after placement into extraction buffer, if kept at room temperature. Be sure to read test result after 15 minutes. Do not read results after 30 minutes.
- Be sure to read test result within 15-30 minutes.
- Do not ingest extraction liquid.
- Keep test kit and components out of the reach of children and pets before and after use.
- Avoid contact with skin and eyes.
- The reagent in the extraction liquid contains ProClin® 300 which may cause an allergic skin reaction in some people. If the solution makes contact with the skin or eye, wash/flush with copious amounts of water. If skin irritation or rash occurs get medical advice/attention.

STORAGE AND OPERATION CONDITIONS

Store iHealth® COVID-19 Antigen Rapid Test in a dry place between 36-86 °F (2-30 °C). Ensure all test components are at room temperature 65-86 °F (18-30 °C) before use. It is stable before the expiration date marked on the packaging.

HAZARDOUS INGREDIENTS FOR REAGENT SOLUTION

The Extraction Reagent contains potentially harmful chemicals (see table below). If the solution contacts the skin or eye, flush with copious amounts of water.
If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222

Chemical Name	Harms (GHS Code) for each ingredient	Concentration
Triton X-100 / 9002-93-1	Harmful if swallowed (H302) Cause skin irritation (H315) Causes serious eye damage (H318)	0.1%
ProClin® 300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction (H317)	0.05%

Manufactured for iHealth Labs, Inc.
120 San Lucar Ct , Sunnyvale, CA 94086, USA
1-855-816-7705 www.ihealthlabs.com

Made in China

Rev.11/2021

Lesia Nwankwo <lnwankwo@magnoliapublicschools.org>

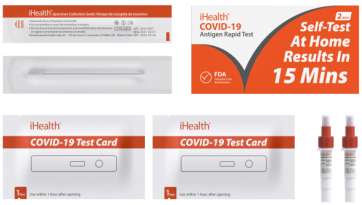
Covid-19 Rapid AT-HOME Self Test Kits (OTC & POC) - AO INC.

1 message

Peter Cicero AO INC <peter.cicero@aotex.com> Tue, Dec 21, 2021 at 5:42 AM
Reply-To: peter.cicero@aotex.com
To: lcharles@magnoliapublicschools.org

COVID-19 ANTIGEN TESTS	COST
Abbott BinaxNow COVID-19 Antigen AT HOME Rapid Test (OTC)	$13.50 per test - Immediate Shipping
Quidel QuickVue COVID-19 Antigen AT HOME Rapid Test (OTC)	$12.50 per test - Immediate Shipping. **2024 Expiration Date**
Indicaid COVID-19 Antigen AT HOME Rapid Test (OTC)	$9.50 per test - Immediate Shipping
FlowFlew COVID-19 Antigen AT HOME Rapid Test (OTC)	$9.50 per test - Immediate Shipping **2023 Expiration Date**
iHealth COVID-19 Antigen AT HOME Rapid Test (OTC)	$8.50 per test - Immediate Shipping
INDICAID COVID-19 Antigen SELF SWAB Rapid Test (POC)	$5.95 per test - Immediate Shipping
3PLY Disposable ADULT Mask L1	$1.95/ 50 ct. box
3PLY Disposable KIDS Mask L1 (FDA)	$3.50 / 50 ct box
	Scaled pricing for +250K
KN95 FDA Approved COLOR WHITE	$0.60 each
3M N95 Masks	Email for costing
GLOVES	COST

Exam Grade Nitrile Gloves	$11.50 / 100 ct box**
	500 Case Minimum
Chemo Grade Nitrile Gloves	$12.00 / 100 ct box**
	100 Case Minimum
Kimberly-Clark KC500 Nitrile Gloves (6MIL/CHEMO RATED)	$17.00 / 100 ct box
General Purpose Vinyl Gloves	$3.50 / 100 ct box



Contact:

Peter Cicero
Managing Partner - AO Inc.
Email: Peter.Cicero@aotex.com
PH: 330-651-5529

iHealth® COVID-19 Antigen Rapid Test

Healthcare Provider Instructions for Use

Model: ICO-3000

For use with anterior nasal swab specimens
For in vitro Diagnostic Use Only
This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA)

INTENDED USE

The iHealth® COVID-19 Antigen Rapid Test is a lateral flow assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

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

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the iHealth® COVID-19 Antigen Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions,

including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with as a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting or by following the mobile application instructions for self-reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The iHealth® COVID-19 Antigen Rapid Test is authorized for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older. The iHealth® COVID-19 Antigen Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

PRODUCT DESCRIPTION

The iHealth® COVID-19 Antigen Rapid Test requires the following elements for operation.

Materials provided in the Test Kit:

Kit components	Quantity		
	2 tests Kit	**5 tests Kit**	**40 tests Kit**
COVID-19 Test Card(s)	2 ea/box	5 ea/box	40 ea/box
Nasal Swab(s)	2 ea/box	5 ea/box	40 ea/box
Tube(s)	2 ea/box	5 ea/box	40 ea/box
Lay User Instruction for Use	1 ea/box	1 ea/box	1 ea/box

For Healthcare Provider Instructions for Use, please see the company website: https://www.ihealthlabs.com

COVID-19 Test Card(s) Tube(s) Swab(s)

iHealth® COVID-19 Antigen Rapid Test components

Materials required but are not provided in the kit:

- Smartphone (supplied by the user. iOS 12 or above. android 6.0 or above)
- User is required to download the “iHealth COVID-19 Antigen Rapid Test” App for iOS or Android phones. User should follow the step-by-step instructions in-app to complete the test.

PRINCIPLE OF PROCEDURES

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 samples in individuals aged 15 and older or individuals between the age of 2 to 14 a swab collected by a parent or guardian is inserted into the Tube. The liquid in tube interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The liquid in 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.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA).
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Laboratories within the United States and its territories are required to report results to the appropriate public health authorities

- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- This test is intended as an aid in the diagnosis of COVID-19 by detecting viral antigens, but should not be used as a sole criterion for the determination of SARS-CoV-2 infection. Other laboratory tests and clinical information (signs and symptoms) should be used and considered for diagnosis.
- Do not use any test component after the expiration date which is printed on the outer packaging.
- Do not use the COVID-19 Test Card if the pouch is damaged or if the seal is broken.
- Do not reuse any test component.
- To obtain accurate results, the test must be performed as indicated in the Instructions for Use.
- Inadequate or inappropriate sample collection may yield false test results.
- Do not touch the tip of the swab before and after collecting the sample from the nostrils.
- Test samples immediately after collection, but no more than 4 hours after specimen collection before placement into extraction buffer or up to 2 hours after placement into extraction buffer, if kept at room temperature.
- Be sure to read test result after 15 minutes. Do not read results after 30 minutes.
- Do not ingest extraction liquid
- Keep test kit and components out of the reach of children and pets before and after use.
- Avoid contact with skin and eyes.
- The reagent in the extraction liquid contains ProClin® 300 which may cause skin and eye irritation. If the solution makes contact with the skin or eye, wash/flush with copious amounts of water. If skin irritation or rash occurs get medical advice/attention.
- Dispose of used specimens and test components in accordance with Federal, State, and Local requirements.

Important Notes

This test kit is intended to be used as an aid in the clinical diagnosis of a **current COVID-19 infection**. Do not use this test kit as the only guide to manage your illness.

LIMITATIONS

- Do not use on anyone under 2 years old.
- Children aged 2-14 years should be tested by an adult.
- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect

COVID-19, especially when you do not have any symptoms.

- The test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test.
- Failure to follow the test procedure correctly may results in false negative or false positives results and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not exclude co-infection with other pathogens.
- Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
- Negative results should be treated as presumptive and confirmed with an FDA-authorized molecular assay, if necessary, for clinical management.
- Performance of nasal swabs collected from patients without symptoms or other epidemiological reasons to suspect COVID-19 infection or for serial screening, when tested twice over two to three days with at least 24 but not more than 48 hours between tests has not yet been determined; a study to support use will be completed.
- If the differentiation of specific coronaviruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after seven days are more likely to be negative compared to RT-PCR.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between May, 2021 and October, 2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- The iHealth® COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.
- False negative results may occur in individuals who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin. Biotin levels of 1 µg/mL and greater have been demonstrated to result in false negative test results

Hazardous Ingredients for Reagent Solution

The Extraction Reagent contains potentially harmful chemicals (see table below). If the test solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: visit https://www.poison.org/contact-us Or call 1-800-222-1222.

Chemical Name	Harms (GHS Code) for each ingredient	Concentration
Triton X-100/9002-93-1	Harmful if swallowed (H302) Cause skin irritation(H315) Cause serious eye damage(H318)	0.1%
ProClin® 300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction (H317)	0.05%

STORAGE CONDITIONS

Store iHealth® COVID-19 Antigen Rapid Test in a dry location between 36-86 °F (2-30 °C). Ensure all test components are at room temperature 65-86 °F (18-30 °C) before use. The COVID-19 Test Card inside the foil pouch should be used within 1 hour after opening. The iHealth® COVID-19 Antigen Rapid Test is stable before the expiration date marked on the packaging.

QUALITY CONTROL

A procedural internal control is built in the “control line (c)” of the device and is used to ensure that the applied specimen has migrated well into the device. It is coated with goat anti-rabbit IgG and a red colored line should appear after sample was added.

TEST PROCEDURE

Download App: Scan the QR code (below) to download the “iHealth COVID-19 Antigen Rapid Test” App through your Smartphone (iOS12.0+, Android 6.0+). For a full list of compatible smartphone visit: https://ihealthlabs.com/pages/support-ICO3000

Register and Log Into The App

Watch Video in App: Each step has a corresponding instructional video in the App. Watch the video and perform the test according to the instructions.

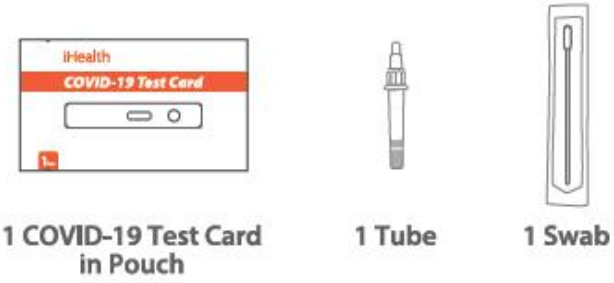
Instructions

The instructions provided here include all the steps of the test. Specific, detailed video instructions on how to perform this test are in the “iHealth COVID-19 Antigen Rapid Test”

App.

1) Prepare Materials

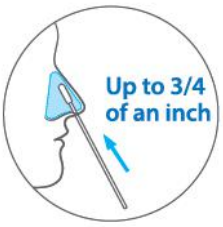
Open the package, take out the COVID-19 Test Card in Pouch, the Tube filled with the extraction buffer and the Swab. When you are ready to proceed with the test, open the foil pouch of the COVID-19 Test Card.



2) Collect Sample

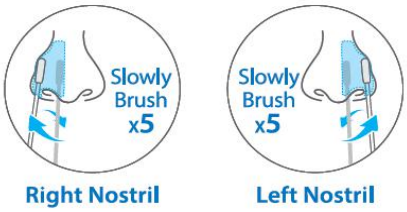
1. Remove the swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for later use.

2. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril.



Note: With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child's head while swabbing.

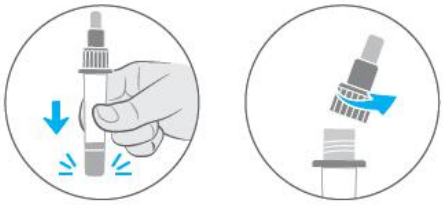
3. Firmly and slowly brush against insides of nostril in a circular motion against the nasal wall at least 5 times. Using the same swab, repeat the same sample collection procedure for the other nostril. Take at least 15 seconds to collect the specimen and be sure to collect any nasal drainage on the swab. Be sure to brush BOTH nostrils with the **SAME SWAB.**



Note: Failure to swab properly may cause false negative results.

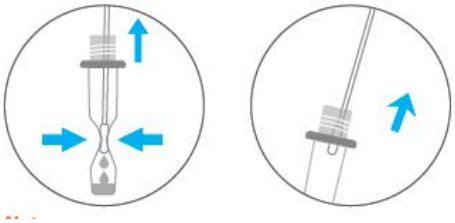
3) Process Sample

1. Tap the tube vertically on the table and twist the large orange cap to open the tube.



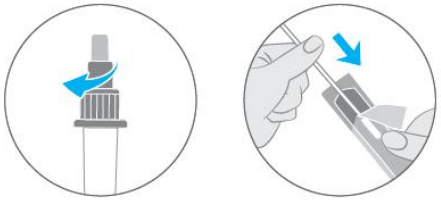
2. Insert the swab into the tube, touch the bottom of the tube with the swab tip, and stir at least 15 times.

3. Squeeze the sides of the tube to express as much liquid as possible from the swab, and then remove the swab.



Note: If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly (i.e., potentially resulting in a false negative result).

4. Screw back the large orange cap, put the swab back into the package. Safely dispose of the swab and the package.



4) Add Sample

Twist to open the small white cap of the tube. Add 3 drops of sample to the Sample Port of the COVID-19 Test Card. Screw back the small white cap.

Note: A false negative or invalid result may occur if too little solution is added to the test card.

5) Wait 15 minutes

Start the timer by clicking the “Start Timer” button, immediately after adding sample to the Sample Port. The result will be ready in 15 minutes.

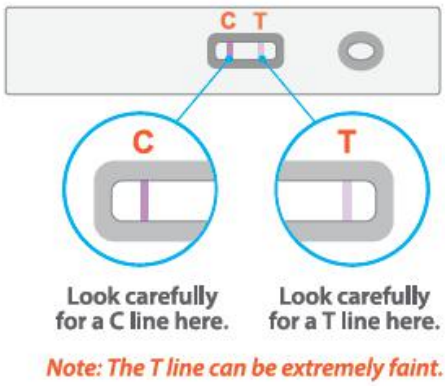
Note: DO NOT interpret your test result until after your 15-min timer has completed, as the T line may take as long as 15 minutes to appear.

6) Read Result

Results should not be read after 30 minutes.

Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes

Result shown at 2x.



7) Test Result Explanation

Positive Result

A **POSITIVE** result must show BOTH a C line and a T line. A positive result means that viral antigens from COVID-19 were detected and the individual is positive for COVID-19.

Below are photos of actual positive tests. Please note that the T line may be faint.

- Persons who test positive should self-isolate and seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary.

Negative Result

A **NEGATIVE** result will show ONLY a C line. A negative result means that viral antigens from COVID-19 were not detected and that the individual is presumed negative for COVID-19.

- Please note that negative results do not rule out COVID-19.
- In case of negative test result: Continue to follow all social distancing recommendations and take protective measures. If suspicions of infection persist and/or your first test is negative, repeat the test after 1 - 2 days and consult your healthcare provider or local COVID-19 center.
- Note: A negative result is presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed.
- Individuals without symptoms that test negative should be tested again with at least 24 hours and no more than 48 hours between tests. Additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with as close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of

infection.

Invalid Result

If there is NO LINE, or if there is ONLY a T line, the test is **INVALID**. Invalid result means that the test did not function correctly. **You will need to retest with a new test kit.** If upon retesting, the test result is still invalid, contact your doctor or local COVID-19 center. An invalid result does not indicate if the individual did or did not have COVID-19 and should be repeated.

8) Dispose the Test Kit
After test is completed, dispose of all kit components in trash.

9) Report Test Result
Report the result following the App instructions or share your test result with your healthcare provider.

CLINICAL PERFORMANCE

Clinical performance characteristics of iHealth® COVID-19 Antigen Rapid Test was evaluated in a total of five (5) investigational sites throughout the U.S. A total of 139 individuals with signs and symptoms of COVID-19 within the first seven (7) days of symptom onset completed the study and obtained a valid result. Each Subject was provided a iHealth® COVID-19 Antigen Rapid Test. Under the observation of a clinical site staff member trained as a proctor, subjects fifteen (15) years and older independently collected an anterior nasal sample, conducted the test, interpreted and reported their self-test 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 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 94.3% of positive samples. Additionally, the iHealth® COVID-19 Antigen Rapid Test correctly identified 98.1% of negative samples. The performance is shown in the following table.

iHealth® COVID-19 Antigen Rapid Test	Comparator Method		
	Positive	Negative	Total
Positive	33	2[b]	35
Negative	2[a]	102	104

Total	35	104	139
Positive Agreement: (33/35) 94.3% 95% Confidence Interval: 81.4% to 98.4%			
Negative Agreement: (102/104) 98.1% 95% Confidence Interval: 93.3% to 99.5%			
[a] Of the 2 false negative samples, one was positive on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay, the other one was negative on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay. [b] Of the 2 false positive samples, one was negative on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay, the other was inconclusive on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay.			

2 samples generated an invalid COVID-19 Antigen Rapid Test result.

Age and gender distribution and positive rate of symptomatic subjects within first 7 days of symptom onset				
Age Group (years)	Female	Male	Positive	Positivity Rate % (total positive/total tested)
2 to 13	6	8	3	21.4% (3/14)
14 to 24	15	12	3	11.1% (3/27)
25 to 64	46	44	28	31.1% (28/90)
≥65	5	3	1	12.5% (1/8)
Total	72	67	35	25.2% (35/139)

Positive results broken down by days since symptom onset				
Days Since Symptom Onset	RT-PCR Positive (+)	iHealth test Positive (+)	PPA	95 % Confidence Interval
1	1	1	100.0%	20.7% - 100.0%
2	3	3	100.0%	43.8% - 100.0%
3	3	2	66.7%	20.8% - 93.9%
4	5	5	100.0%	56.6% -100.0%
5	12	12	100.0%	75.7% - 100.0%
6	6	6	100.0%	61% - 100.0%
7	5	4	80.0%	37.6% - 96.4%
All specimens	35	33	94.3%	81.4% - 98.4%

Additional asymptomatic individuals and individuals beyond the seven days of symptom onset were tested, but excluded from the primary performance calculations because they were not included in the intended use. A higher proportion of low positive specimens were observed in these populations, resulting in PPAs between of 85-88% in these individuals.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LOD)

The LOD of iHealth® COVID-19 Antigen Rapid Test was established by using limiting dilutions of heat inactivated SARS-CoV-2 virus(USA-WA1/2020) sample. The strain was spiked into clinical matrix prepared by mixing raw nasal fluid in saline and confirmed again as SARS-CoV-2 negative by RT-PCR.

The estimated LoD found from the initial 4 different concentrations test by testing 5 replicates. At each dilution, samples were added to swabs and then tested through the full assay workflow, from processing in the extraction reagent to read test result.

A concentration was chosen between the last dilution to give five positive results and the first to give five negative results. Using this concentration, the LoD was further refined with a 2-fold dilution series. 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).

The iHealth® COVID-19 Antigen Rapid Test LOD in natural nasal swab matrix is 20×10^3 $TCID_{50}$/mL.

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(USA-WA1/2020) sample at approximately 3 x LoD.

A total of 38 commensal and pathogenic microorganisms (13 bacteria and 25 viruses) that may be present in the nasal cavity were evaluated in this study. Each of the organism and viruses 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 following microorganisms when tested at the concentration presented in the table below.

List of Organism		Concentration tested	Cross-reactivity results	Microbial Interference results
Other high priority pathogens from the	Human coronavirus 229E	$3.74\times10^4TCID_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus OC43	$2.51\times10^5TCID_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus NL63	$1.36\times10^5TCID_{50}$/mL	No cross-reactivity	No interference
	MERS-coronavirus	$1.36\times10^5TCID_{50}$/mL	No cross-reactivity	No interference

same genetic family				
High priority organisms likely in the circulating area	Adenovirus Type 1	$2.04\times10^{7}TCID_{50}/mL$	No cross-reactivity	No interference
	Adenovirus Type 4	$2.09\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Adenovirus Type 7A	$2.04\times10^{7}TCID_{50}/mL$	No cross-reactivity	No interference
	Adenovirus Type 8	$1.13\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Adenovirus Type 31	$1.13\times10^{5}U/mL$	No cross-reactivity	No interference
	Adenovirus Type 41	$9.36\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Human Metapneumovirus 3(hMPV-3) Type B1	$3.11\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Human Metapneumovirus 4(hMPV-4) Type B2	$5.25\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Human Metapneumovirus 9(hMPV-9) Type A1	$9.36\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Parainfluenza Virus Type 1	$6.30\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Parainfluenza Virus Type 2	$7.55\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Parainfluenza Virus Type 3	$2.29\times10^{6}TCID_{50}/mL$	No cross-reactivity	No interference
	Parainfluenza Virus Type 4A	$4.50\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Parainfluenza Virus Type 4B	$1.36\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Influenza A H3N2 Virus	$1.13\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Influenza B Virus	$3.74\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Enterovirus Type 68	$7.55\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Enterovirus Type 71	$2.29\times10^{6}TCID_{50}/mL$	No cross-reactivity	No interference
	Respiratory Syncytial Virus Type A (RSV-A)	$1.90\times10^{6}TCID_{50}/mL$	No cross-reactivity	No interference
	Respiratory Syncytial Virus Type B (RSV-B)	$3.74\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Rhinovirus Type 1A	$9.36\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Haemophilus influenzae	$6.75\times10^{8}CFU/mL$	No cross-reactivity	No interference
	Streptococcus pneumoniae	$1.80\times10^{8}CFU/mL$	No cross-reactivity	No interference
	Streptococcus pyogenes	$2.04\times10^{9}CFU/mL$	No cross-reactivity	No interference
	Candida albicans	$3.15\times10^{8}CFU/mL$	No cross-reactivity	No interference
	Pooled human nasal wash – representative of normal respiratory microbial flora	-	No cross-reactivity	No interference
	Bordetella pertussis	$3.22\times10^{9}CFU/mL$	No cross-reactivity	No interference
	Mycoplasma pneumoniae	$1.35\times10^{8}CFU/mL$	No cross-reactivity	No interference
	Chlamydia pneumoniae	$8.65\times10^{7}IFU/mL$	No cross-reactivity	No interference
	Legionella pneumophila	$7.10\times10^{9}CFU/mL$	No cross-reactivity	No interference
	Staphylococcus aureus	$3.23\times10^{9}CFU/mL$	No cross-reactivity	No interference
	Staphylococcus epidermidis	$1.24\times10^{9}CFU/mL$	No cross-reactivity	No interference
	Mycobacterium tuberculosis	$1.15\times10^{8}CFU/mL$	No cross-reactivity	No interference
	Pneumocystis jirovecii (PJP)	$3.17\times10^{8}CFU/mL$	No cross-reactivity	No interference

An in-silico analysis was performed using the Basic Local Alignment Search Tool (BLASTp) managed by the National Center for Biotechnology Information (NCBI) for Human Coronavirus HKU1, Mycobacterium tuberculosis, Pneumocystis jirovecii and SARS-CoV-1

- Human Coronavirus HKU1 shows 36.74% homology across 82% of the nucleocapsid sequence(see Annex 2 and 3), which is relatively low. However, cross-reactivity cannot be ruled out.
- *Mycobacterium tuberculosis* shows no protein sequence homology with nucleocapsid sequence. Therefore, while cross-reactivity is highly unlikely, it cannot be completely ruled out.
- *Pneumocystis jirovecii* shows no protein sequence homology with nucleocapsid sequence. Therefore, while cross-reactivity is highly unlikely, it cannot be completely ruled out.
- SARS-CoV-1 shows 90.52% homology across 100% of the nucleocapsid sequence. Therefore, cross-reactivity is highly likely.

Endogenous Interfering Substances

The following 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 3 x LoD. All samples tested in 5 replicates produced expected results, demonstrating that the iHealth® COVID-19 Antigen Rapid Test performance was not affected by any of the 26 potentially interfering substances listed in the table below at the concentrations tested.

Substance	Concentration in negative/positive sample	Cross-reactivity	Interference
Whole Blood	4%	No cross-reactivity	No interference
Mucin	0.5%	No cross-reactivity	No interference
Chloraseptic (Menthol)	1.5 mg/mL	No cross-reactivity	No interference
Chloraseptic (Benzocaine)	1.5 mg/mL	No cross-reactivity	No interference
Naso GEL (NeilMed)	5% v/v	No cross-reactivity	No interference
CVS Nasal Drops (Phenylephrine)	15% v/v	No cross-reactivity	No interference
Afrin (Oxymetazoline)	15% v/v	No cross-reactivity	No interference
CVS Nasal Spray (Cromolyn)	15% v/v	No cross-reactivity	No interference
Zicam	5% v/v	No cross-reactivity	No interference
Homeopathic (Alkalol)	1:10 dilution	No cross-reactivity	No interference
Sore Throat Phenol Spray	15% v/v	No cross-reactivity	No interference
Tobramycin	4 μg/mL	No cross-reactivity	No interference

Mupirocin	10 mg/mL	No cross-reactivity	No interference
Fluticasone Propionate	5% v/v	No cross-reactivity	No interference
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No cross-reactivity	No interference
Nasocort Allergy 24 hour （Triamcinolone）	15% v/v	No cross-reactivity	No interference
NeilMed SinuFlow Ready Rinse （Sodium chloride, Sodium bicarbonate）	15% v/v	No cross-reactivity	No interference
NeilMed SinuFrin Plus （Oyxmetazoline HCl）	15% v/v	No cross-reactivity	No interference
Neo-Synephrine （Phenylephrine ,hydrochloride)	15% v/v	No cross-reactivity	No interference
Rhinocort (Budesonide /Glucocorticoid)	15% v/v	No cross-reactivity	No interference
Saline nasal spray (Saline)	15% v/v	No cross-reactivity	No interference
Zanamivir	282.0 ng/mL	No cross-reactivity	No interference
Biotin	1.0 μg/mL	No cross-reactivity	No interference
Laundry Detergent (C12-15 pareth-7 and sodium laureth-12 sulfate)	1% v/v	No cross-reactivity	No interference
Dish-washing Liquid (Sodium lauryl sulfate)	1% v/v	No cross-reactivity	No interference
Bleach (Sodium Hypochlorite)	1%v/v	No cross-reactivity	No interference

Hook Effect

No high dose hook effect was observed when tested with a concentration of 1.15x 10^7 $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus with the iHealth® COVID-19 Antigen Rapid Test .

Usability Study

iHealth conducted a study to evaluate whether a home user can follow instructions provided and can successfully perform the test steps for the iHealth® COVID-19 Antigen Rapid Test, including nasal swab collection, adding sample to a test card, and correctly interpreting the results.

105 lay users, including self-collection (n=52) and collection for other lay user (n=53), participated in the study, and were instructed to self-collect or collect a sample from others (include children), complete the required procedural steps, and interpret the test results unassisted in a simulated home setting. After the simulated test, all the participants completed the knowledge assessment questionnaire and usability questionnaire.

The overall success of every task completed by all subjects enrolled was determined by unassisted professional observation. Subjects performed 96.8% (718/742) of steps/tasks

correctly, and performed 98.1% (1414/1442) of knowledge assessment questionnaires correctly. More than 90% of all the participants stated the device is easy to use, including sample collection, performing the test, reading and understanding the result. 94.29% of the participants stated the instructions provided were easy to read and understood.

Flex study

The robust use of iHealth® COVID-19 Antigen Rapid Test was demonstrated by ten (10) Flex studies: delay in result reading, extraction liquid volume variability, swab mixing expression variability, temperature and humidity, impact of light sources, test device held at different orientation and disturbance during analysis.

CUSTOMER HELPLINE

If you have any questions about the iHealth® COVID-19 Antigen Rapid Test or your result, please contact our toll-free Customer Helpline on 1-855-816-7705.

SYMBOLS IN USE

 Caution

 Do not Reuse

 Consult Instructions for Use


In Vitro Diagnostic Medical Device

 Storage Temperature Limitation


Keep in a dry place

 Keep away from direct sunlight

 Do not use if package is damage

Manufacturer

Manufactured for iHealth Labs, Inc.
120 San Lucar Ct , Sunnyvale, CA 94086, USA
1-855-816-7705 www.ihealthlabs.com
Made in China

Rev.11/2021

November 5, 2021

Jack Feng
iHealth Labs, Inc.
120 San Lucar Ct.
Sunnyvale, CA 94086

Device:	iHealth COVID-19 Antigen Rapid Test
EUA Number:	EUA210470
Company:	iHealth Labs, Inc.
Indication:	Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with: Self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. Adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset Self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

Dear Mr. Feng:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in

[1] For ease of reference, this letter will use the term "you" and related terms to refer to iHealth Labs, Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the iHealth COVID-19 Antigen Rapid Test, used for the indication identified above.

vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the "iHealth COVID-19 Antigen Rapid Test Healthcare Provider Instructions for Use" identified below.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a lateral flow assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

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[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. Your product does not differentiate between SARS-CoV and SARS-CoV-2.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with your product should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.

Negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting or by following the mobile application instructions for self-reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the Centers for Disease Control and Prevention (CDC).

Your product is performed using anterior nasal (nares) swab samples from individuals aged 2 years or older. The individual using your product is instructed to download, register and log into the mobile application (App) and follow the step-by-step based instructions on the iHealth

COVID-19 Test App on a compatible smartphone.[5] When using your product, the individual first opens the foil pouch containing COVID-19 Test Card. The swab is then removed from its packaging and the individual collects an anterior nasal swab sample by inserting the swab into the nostril and firmly and slowly brushing the insides of the nasal wall in a circular motion at least 5 times, taking at least 15 seconds to collect the specimen, before repeating the process in the second nostril. The swab is then immediately inserted into the tube and stir at least 15 times. The swab is then removed while pressing against the sides of the tube and the tube capped with the cap. The liquid in tube interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in your product. Three drops of the solution are applied into the Sample Port of the COVID-19 Test Card. The individual then starts the 15 minute timer. If the extracted specimen contains SARS-CoV-2 antigens, a pink-to-purple T (Test) Line, along with a pink-to-purple C (Control) Line will appear on the COVID-19 Test Card indicating a positive result. This control line indicates that the sample has migrated across the membrane as intended and indicates that the test was correctly performed. Test results are interpreted visually after 15 minutes based on the presence or absence of visually detectable colored lines at the control line (C) and/or test line (T).

The iHealth COVID-19 Antigen Rapid Test includes the following materials or other authorized materials (as may be requested under Condition L below): COVID-19 Test Card(s), Nasal Swab(s), Tube(s) and the lay user "iHealth COVID-19 Antigen Rapid Test Instructions for Use."

Your product includes an internal control test line ("C") that must generate the expected result for a test to be considered valid, as outlined in the "iHealth COVID-19 Antigen Rapid Test Instruction for use" and the "iHealth COVID-19 Antigen Rapid Test Healthcare Provider Instructions for Use."

The labeling entitled "iHealth COVID-19 Antigen Rapid Test Healthcare Provider Instructions for Use," the "iHealth COVID-19 Antigen Rapid Test Instruction for use," and the "iHealth COVID-19 Antigen Rapid Test" box labels (2, 5 or 40-pack) (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the "iHealth COVID-19 Test" software App and the following fact sheet pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Professionals[6]: iHealth Labs, Inc. - iHealth COVID-19 Antigen Rapid Test

The above described product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable

[5] Compatible smartphone includes Apple iPhone running Operation System (iOS) 12 or later versions of the iOS, and Android Phones running Android 6.0 or later versions. Additional smartphone models as may be requested, and for which you receive appropriate authorization, in accordance with Condition L. below.

[6] Note that the information typically found in a Fact Sheet for Individuals is contained in the authorized "iHealth COVID-19 Antigen Rapid Test Instructions for Use " that will be available to end users as set forth in the Conditions of Authorization (Section IV).

federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

iHealth Labs, Inc. (You) and Authorized Distributor(s)[7]

A. Your product must comply with the following labeling requirements: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 21 CFR 809.10(b)(5), (7), and (8); appropriate limitations on the use of the device

[7] "Authorized Distributor(s)" are identified by you, iHealth Labs, Inc., in your EUA submission as an entity allowed to distribute the iHealth COVID-19 Antigen Rapid Test.

including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make available the "iHealth COVID-19 Antigen Rapid Test Instruction for use" for your product in the shipped kit using the "iHealth COVID-19 Antigen Rapid Test" box labels and electronically on your website(s).

C. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.

D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or the authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number of tests distributed to each location.

F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You and authorized distributor(s) using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

iHealth Labs, Inc. (You)

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

K. You must make the authorized "iHealth COVID-19 Antigen Rapid Test Healthcare Provider Instructions for Use" and the Fact Sheet for Healthcare Professionals electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "iHealth COVID-19 Antigen Rapid Test Healthcare Provider Instructions for Use" and Fact Sheet for Healthcare Professionals in paper form, and after such request, promptly provide the requested labeling at no additional cost.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the product released for distribution meet the clinical and analytical performance claimed in the authorized labeling.

O. If requested by FDA, you must submit your lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide them within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[8] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must evaluate the clinical performance of your product to support the serial screening claim in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling

[8] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

S. You must complete your previously agreed upon automatic test reporting-related software updates to the iHealth COVID-19 Test App within 3 months of this letter and notify DMD/OHT7-OIR/OPEQ/CDRH upon implementation. Upon implementation, you must ensure automatic test result reporting is available, using the iHealth COVID-19 Test App, to relevant public health authorities in accordance with local, state, and federal requirements.

T. You must submit to FDA a summary report within 90 calendar days of product launch summarizing the results of any testing performed using your product during that timeframe, including how many products were distributed, the positivity rate for specimens tested with your product, and how many individuals reported results to their healthcare provider as encouraged by the "iHealth COVID-19 Antigen Rapid Test Instructions for Use," along with any proposed corrective action, as necessary.

U. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

V. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

W. You must submit your product for any FDA-recommended independent evaluation to confirm the performance characteristics of your test, if requested by FDA. After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Conditions Related to Printed Materials, Advertising and Promotion

X. All descriptive printed matter, advertising, and promotional materials relating to the use

of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

Y. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

Z. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____
Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure

FACT SHEET FOR HEALTHCARE PROVIDERS

iHealth Labs Inc. **November 5, 2021**

iHealth® COVID-19 Antigen Rapid Test

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the iHealth® COVID-19 Antigen Rapid Test.

The iHealth® COVID-19 Antigen Rapid Test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

All individuals who use this assay are required to receive and should carefully review the iHealth® COVID-19 Antigen Rapid Test Instruction for Use before they use the test.

What are the symptoms of COVID-19?

Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days. For further information on the symptoms of COVID-19 please see the link provided in the "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

This Test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with symptoms of COVID-19 within the first seven (7) days of symptom onset, or with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

- The iHealth® COVID-19 Antigen Rapid Test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples

from individuals aged 15 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

- The iHealth® COVID-19 Antigen Rapid Test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.
- The iHealth® COVID-19 Antigen Rapid Test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, or adult collected anterior nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 control precautions are available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined in the CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19). For additional information, refer to CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) (see links provided in "Where can I go for updates and more information" section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?

A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the patient is very likely to be infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

The iHealth® COVID-19 Antigen Rapid Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

Test results are automatically reported through the "iHealth COVID-19 Antigen Rapid Test" App to relevant public health authorities in accordance with local, state, and federal requirements.

All healthcare providers must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?

A negative test result for this test means that antigens

from SARS-CoV-2 were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. In symptomatic patients, specimens collected after day 5 of illness may be more likely to be negative compared to a RT-PCR assay. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative test result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC's *Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings* (Interim Guidance) (see links provided in "*Where can I go for updates and more information*" section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in November 2020.The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

What do I need to know about Serial Testing in Asymptomatic Individuals?

In asymptomatic individuals, serial testing may assist in identifying infected individuals and facilitate timely infection control practices. A negative test result does not rule out infection but repeat testing over two or three days may decrease the risk of false negative results. Additional clinical studies are underway to assess the performance of rapid antigen tests when used with serial testing. An initial negative test result should be the first of a minimum of two tests. An asymptomatic individual undergoing serial testing with two or more negative results may require ongoing serial testing or confirmatory testing, depending on patient history and potential exposures. An asymptomatic individual undergoing serial testing with one or more positive results indicates that SARS-CoV-2 antigen is present, but does not rule out coinfection with other pathogens.

Additional confirmatory testing with a molecular test for negative results may be necessary if there is a high

likelihood of SARS-CoV-2 infection, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection. For additional recommendations regarding confirmation of antigen test results, please refer to the CDC's Interim Guidance for Antigen Testing for SARS-CoV-2 (see links provided in "*Where can I go for updates and more information?*" section).

What is an EUA?

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless it is terminated or the authorization is revoked (after which the test may no longer be used).

What are the approved available alternatives?

There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medicaldevices/device-advice-comprehensive-regulatoryassistance/medical-device-databases.

A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatoryand-policy-framework/emergency-use-authorization.

Where can I go for updates and more information?

CDC webpages:

General:
https://www.cdc.gov/coronavirus/2019-ncov/index.html

Symptoms:
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html

Information for Laboratories:
https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html

Laboratory Biosafety:
https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html

Isolation Precautions in Healthcare Settings:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

Specimen Collection:
https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html

Infection Control:

https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

Discontinuation of Isolation:

https://www.cdc.gov/coronavirus/2019-ncov/hcp/dispositionin-home-patients.html

FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs:(includes links to patient/individual fact sheets and manufacturer's instructions)

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

Distributor Contact Information:

iHealth Labs, Inc.
120 San Lucar Ct, Sunnyvale, CA 94086, USA
1-855-816-7705 www.ihealthlabs.com


For use under an Emergency Use Authorization only.
Abbott
BinaxNOW™
COVID-19 Ag CARD
2C 30°C 40 IVD
℞ Only REF 195-000
BinaxNOW COVID-19 Ag CARD
Abbott


1 TEST
Flowflex
COVID-19 Antigen Home Test
Easy to Use
Accurate
Quick Results

Form **W-9**
(Rev. October 2018)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

▶ Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give Form to the requester. Do not send to the IRS.

Print or type. See Specific Instructions on page 3.

1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank.
AO Apparel Inc

2 Business name/disregarded entity name, if different from above

3 Check appropriate box for federal tax classification of the person whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor or single-member LLC ☑ C Corporation ☐ S Corporation ☐ Partnership ☐ Trust/estate

☐ Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ▶ _____

Note: Check the appropriate box in the line above for the tax classification of the single-member owner. Do not check LLC if the LLC is classified as a single-member LLC that is disregarded from the owner unless the owner of the LLC is another LLC that is not disregarded from the owner for U.S. federal tax purposes. Otherwise, a single-member LLC that is disregarded from the owner should check the appropriate box for the tax classification of its owner.

☐ Other (see instructions) ▶

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any) _____

Exemption from FATCA reporting code (if any) _____

(Applies to accounts maintained outside the U.S.)

5 Address (number, street, and apt. or suite no.) See instructions.
201 East 36th Street, 12D

Requester's name and address (optional)

6 City, state, and ZIP code
New York, NY 10016

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. Also see *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number
[ ][ ][ ] - [ ][ ] - [ ][ ][ ][ ]

or

Employer identification number
8 2 - 2 2 9 8 3 7 5

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here Signature of U.S. person ▶ [signature] Date ▶ 02/10/2021

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid)
- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See What Is backup withholding, *later.*

MAGNOLIA EDUCATIONAL & RESEARCH FOUNDATION

Lesia Nwankwo <lnwankwo@magnoliapublicschools.org>

RE: COVID Test Kits, KN95's and AIR PURIFIERS

1 message

ecrawford@casupplysolutions.com <ecrawford@casupplysolutions.com> Thu, Jan 13, 2022 at 7:28 AM
To: Lesia Nwankwo <lnwankwo@magnoliapublicschools.org>

Good morning Lesia,

Below is the CareStart Covid test kit we will offer to school districts at the discounted price.

Please note these are moving quickly so availability is subject to change. If you need an official quote let me know!

Item # CARESTART-2- $12.00/test (2 tests/kit- $24.00)

<u>Here's the breakdown per pallet:</u>

1 Kit = 2 tests

232 Kits (464 tests) / Box

20 Boxes / Pallet = 4640 Kits (9,280 tests)

Thank you,


AccessBio
CareStart™
COVID-19
ANTIGEN
HOME TEST
FAST RESULT
Results in 10 minutes
10min
EASY TESTING
A Simple Nasal Swab
C
T
COVID-19
Ag
For use with or without symptoms
2 Tests


CareStart™
COVID-19
ANTIGEN
HOME TEST
Kit Components
CareStart™ COVID-19 Ag Home Test - 2ea
Extraction Vial Tube - 2ea
Extraction Vial Cap - 2ea
Nasal Swab - 2ea
Quick Reference Instructions & Fact Sheet for Individuals included
(01)00850010224712
(10)CP21G01
(17)122021
LOT CP21G01
EXP DEC 2021
Made in the USA

November 22, 2021

Sang Joon Han
Associate Principal Scientist, Division of R&D
Access Bio, Inc.
65 Clyde Road, Suite A
Somerset, NJ 08873

Device:	*CareStart* COVID-19 Antigen Home Test
EUA Number:	EUA210314
Company:	Access Bio, Inc.
Indication:	Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with: Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. Adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

Dear Sang Joon Han:

On August 2, 2021, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the *CareStart* COVID-19 Antigen Home Test pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C.

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Access Bio, Inc.

§360bbb-3) for the indication stated in the letter.[2] Based on your request, FDA granted updates to the authorized labeling on August 23, 2021.[3]

On October 26, 2021, you requested to amend this EUA. Based on that request, and having concluded that revising the August 2, 2021, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the August 2, 2021, letter in its entirety with the revisions incorporated.[4] Accordingly, your product[5] is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[6]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA

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[2] The August 2, 2021, letter authorized the *CareStart* COVID-19 Antigen Home Test for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens from individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection when tested twice over two or three days with at least 24 hours and not more than 48 hours between tests. This test is authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal swab samples from individuals aged 2 years or older.

[3] On August 23, 2021, your request was granted to update the authorized labeling for the *CareStart* COVID-19 Antigen Home Test with various edits and clarifications, including a new QR code used to access the mobile application and to make those same edits to the authorized brand name labeling.

[4] The revisions to the August 2, 2021, letter and authorized labeling include: (1) updates to the intended use to include use of your product with "*self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset*," "*adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset,*" and "*self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests,*" (2) update the outer box labels and Instructions for Use (IFU) limitations section to reflect the updates to the intended use, (3) offer the test kit with 1-test option, in addition to the 2-test, 4-test and 20-test options currently offered, (4) Update Condition of Authorization Q. and S. below to give a 1 month extension and Condition of Authorization R. below to give a 6 month extension, and (5) updates to the letter and fact sheets to reflect the updated intended use and for consistency with language used in more recent authorizations.

[5] For ease of reference, this letter will use the term "your product" to refer to the *CareStart* COVID-19 Antigen Home Test, that will also be offered under the authorized distributor brand name of "on/go COVID-19 Antigen Self-Test," used for the indication identified above.

[6] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

relied upon is included in the "*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use" identified below.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[7]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal (nares)

[7] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease. Individuals who test positive with your product should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive, and confirmation with a molecular assay for patient management, may be performed if necessary. Negative results do not rule out SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the Centers for Disease Control and Prevention (CDC).

Your product is performed using anterior nasal (nares) swab samples from individuals aged 14 years or older or adult-collected anterior nasal (nares) swab samples from individuals age 2 years or older. The individual using your product has the option to follow the "*CareStart* COVID-19 Antigen Home Test User Instructions" provided with the kit or follow step-by-step mobile application-based instructions by downloading the "on/go App" onto a compatible smartphone.[8] When using your product, the individual unpacks the tray containing all the test components, before removing the test device from its pouch and placing it on a flat clean surface. The extraction vial is then opened and inserted into the tray in an upright position. The swab is then removed from its pouch and the individual collects an anterior nasal (nares) swab sample by inserting the swab into the nostril and rotating at least 5 times for a total of 15 seconds before

[8] Compatible smart phone includes Apple iPhone running Operation System (iOS) 13 or later versions of the OS, and Android Phones running Android10 or later versions. Additional smart phone models as may be requested, and for which you receive appropriate authorization, in accordance with Condition L. below.

repeating in the second nostril. The swab is then inserted into the extraction vial and rotated vigorously at least 5 times before being removed and the vial capped. The contents of the extraction vial are then mixed before three drops are applied to the sample well of the test device. When the anterior nasal (nares) swab specimen migrates in the test strip, SARS-CoV-2 viral antigens present in the sample bind to anti-SARS-CoV-2 nucleocapsid protein antibodies conjugated to indicator and capture particles in the test strip forming an immune complex. The immune complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip. Test results are interpreted visually after 10 minutes based on the presence or absence of visually detectable purple and blue colored lines. Upon completion of the test and result interpretation the user should share their results with their healthcare provider.

The *CareStart* COVID-19 Antigen Home Test kit includes the following materials or other authorized materials packed and sealed in a tray: Test Device (pouched with desiccant), extraction vial and cap, Nasal Swab, Quick Reference Instructions, and Fact Sheet for Individuals.

Your product includes an internal control test line that must generate the expected result for a test to be considered valid, as outlined in the "*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use."

The labeling entitled "*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use," the "*CareStart* COVID-19 Antigen Home Test User Instructions" (Quick Reference Instructions) and the "*CareStart* COVID-19 Antigen Home Test" box labels (1-test, 2-tests, 4-tests and 20-tests) (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the "on/go App" software application, and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling"[9]:

- Fact Sheet for Healthcare Professionals: Access Bio, Inc. - *CareStart* COVID-19 Antigen Home Test
- Fact Sheet for Individuals: Access Bio, Inc. - *CareStart* COVID-19 Antigen Home Test

The above described product, when accompanied by authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

[9] The "authorized labeling" listed in this paragraph (and elsewhere) specifically refers to the labeling for the *CareStart* COVID-19 Antigen Home Test; however, "authorized labeling" under this letter also includes these specific pieces of labeling when entitled with the authorized distributor brand name of "on/go COVID-19 Antigen Self-Test," as would be the case with other authorized distributor brand names added in accordance with Condition L. below.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Access Bio, Inc. (You) and Authorized Distributor(s)[10]

A. Your product must comply with the following labeling requirements: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 21 CFR 809.10(b)(5), (7), and (8); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make available the "*CareStart* COVID-19

[10] "Authorized Distributor(s)" are identified by you, Access Bio, Inc., in your EUA submission as an entity allowed to distribute your product.

Antigen Home Test User Instructions" and the "Fact Sheet for Individuals" for your product in the shipped kit using the applicable "*CareStart* COVID-19 Antigen Home Test" box label (1-test, 2-tests, 4-tests or 20-tests) and make these two documents electronically available on your website.

C. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.

D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or the authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number of tests distributed to each location.

F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You and authorized distributor(s) using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Access Bio, Inc. (You)

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

K. You must make the authorized "*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use" and the "Fact Sheet for Healthcare Professionals" electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use" and "Fact Sheet for Healthcare Professionals" in paper form, and after such request, promptly provide the requested labeling at no additional cost.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the product released for distribution meet the clinical and analytical performance claimed in the authorized labeling.

O. If requested by FDA, you must submit your lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide them within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[11] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must further develop your mobile phone application or website to further facilitate results reporting by the individual using your product and submit to FDA such application or website within 1 month of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission of the mobile phone application or website to, and review of and concurrence with the developed mobile phone application or website by FDA, you must update the authorized labeling. Such labeling updates will be made in consultation with, and require concurrence of, FDA.

R. You must evaluate the clinical performance of your product to support the serial

[11] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

screening claim in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. You must evaluate the usability of the "*CareStart* COVID-19 Antigen Home Test User Instructions" with individuals using only the paper instructions of your product in an FDA agreed upon post authorization study within 1 month of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling, as applicable, to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

T. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling accordingly. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

U. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

V. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Conditions Related to Printed Materials, Advertising and Promotion

W. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

X. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

Y. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens; and,
- This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure

For use under an Emergency Use Authorization (EUA) only
For use with anterior nasal swab specimens
For *in vitro* diagnostic use only

CareStart™

COVID-19 Antigen Home Test

Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen

Healthcare Provider Instructions for Use

Intended Use

The CareStart™ COVID-19 Antigen Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigens from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease. Individuals who test positive with the *CareStart*™ COVID-19 Antigen Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive and confirmation with a molecular assay for patient management, may be performed if necessary. Negative results do not rule out SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LVID) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The *CareStart*™ COVID-19 Antigen Home Test is authorized for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older. The *CareStart*™ COVID-19 Antigen Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Principles of the Test

The *CareStart*™ COVID-19 Antigen Home Test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2 in self-collected anterior nasal (nares) swab specimens.

Nasal swabs require a sample preparation step in which the sample is eluted into the extraction buffer solution. Extracted swab sample is added to the sample well of the test device to initiate the test. When the swab sample migrates in the test strip, SARS-CoV-2 viral antigens bind to anti-SARS-CoV-2 nucleocapsid protein antibodies conjugated to indicator and capture particles in the test strip forming an immune complex. The immune complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip.

The user should perform the test following the in-app self-paced, step-by-step instructions or Quick Reference Instructions.

Test results are interpreted visually at 10 minutes after sample loading followed by the instructions. The presence of two colored lines in the control line region "C" and test line region "T" indicates COVID-19 positive. The presence of one colored line in the control line region "C" indicates COVID-19 negative. No appearance of a colored line in the control region "C" indicates an invalid test. Results should not be read after 15 minutes.

Quality Control

- The *CareStart*™ COVID-19 Antigen Home Test contains a built-in internal procedural control that is included in the test device. A purple-colored line appearing in the control region "C" is designed as an internal procedural control. The appearance of the

procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. If the procedural control line does not develop in 10 minutes, the test result is considered invalid and retesting with a new device is recommended. If the internal procedural control line is still absent in the retest, please contact the Technical Support at +1-888-898-1270 (Available Hours: Mon. to Fri.: 8 a.m. – 5 p.m.) or TShelp@accessbio.net (24/7 available).

- The unique barcode on the test device contains essential device information and captured during the test process using mobile application to ensure test validity. In the event the barcode is not valid for any reason, the user is presented with a final screen indicating the fail reason by one of the below:
  Invalid: Barcode Not Found
  Invalid: Test Expired
  Invalid: Test Barcode Invalid
  Invalid: Test Previously Used

Reagents and Materials

Materials provided

All following required components for single-use are packed and sealed in a tray.

- a test device: foil pouched test device containing one test strip which is encased in plastic device cassette with a desiccant.
- an extraction vial and cap: the extraction vial contains 500 µL of extraction buffer solution.
- a nasal swab: swab for anterior nasal specimen collection.

Quick Reference Instructions and Fact Sheet for Individuals are also included in each box.

CareStart™ COVID-19 Antigen Home Test is available in the following packaging configuration: 1 test (REF: RCPM-00171), 2 tests (REF: RCPM-00271), 4 tests (REF: RCPM-00471), or 20 tests (REF: RCPM-02071)

Materials required but not provided

- Smartphone (supplied by the user): For a list of compatible smartphone OS systems, visit www.accessbio.net/app.
- Mobile application: Prior to testing, the user should download the free mobile application, on/go™ App, for iOS or Android smartphones.
- Timer

Warnings and Precautions

- For *in vitro* diagnostic use only.
- This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA).
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for the detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- Children aged 13 years old and younger should be tested by a parent or legal guardian.
- Wear a safety mask or other face-covering when collecting anterior nares swab specimen from a child or another individual.
- Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.
- In order to obtain accurate results, the user must follow the instructions for use.
- Immediately use after opening the test device in the pouch.
- Keep the test device on a flat surface during the testing.
- Keep testing kit and kit components away from children and pets before and after use.
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas of the nasal cavity when collecting specimens.
- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results. If specimen storage is necessary, swabs can be placed into the extraction vial for up to four hours. Specimens should not be stored dry.
- When collecting a nasal swab sample, use only the Nasal Swab provided in the kit.
- Keep foreign substances and household cleaning products away from the test during the testing process. Contact with foreign substances and household cleaning products may result in an incorrect test result.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Handle all specimens as though they contain infectious agents.
- Do not operate your test outside of storage conditions.
- Do not use on anyone under 2 years of age.
- Do not close the App during processing as it may cause an error and you will need a new test kit.
- Do not interpret the test result before 10 minutes and after 15 minutes starting the test.

- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- Do not use if the test device package is damaged.
- Do not touch the tip (specimen collection area) of the swab.
- Do not use the kit contents beyond the expiration date.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.
- Eye and skin contact with the extraction solution should be avoided.
- Extraction solution should not be ingested.
- The extraction solution in the vial contains potentially harmful chemicals (see table below). If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222.

Chemical Name/CAS	**Harms (GHS Code) for each Ingredient**
Sodium Tetraborate Pentahydrate/12179-04-3	H319 Causes serious eye irritation. H360 May damage fertility or the unborn child.
Ethylenediaminetetraacetic acid (EDTA)/13235-36-4	H302 Harmful if swallowed. H318 Causes serious eye damage.
Sodium Chloride (NaCl)/ 7647-14-5	None
Triton X-100/9002-93-1	H302 Harmful if swallowed. H315 Causes skin irritation. H318 Causes serious eye damage. H410 Very toxic to aquatic life with long-lasting effects.
N-Lauroylsarcosine sodium salt/137-16-6	H315 Causes skin irritation. H318 Causes serious eye damage. H330 Fatal if inhaled.

Storage and Stability

- Store the test kit as packaged between 1 ~ 30°C.
- The test device must remain in the sealed pouch until use.
- Do not freeze any contents of the kit.

Disposal

Dispose of all used test kit components and patient samples in household trash.

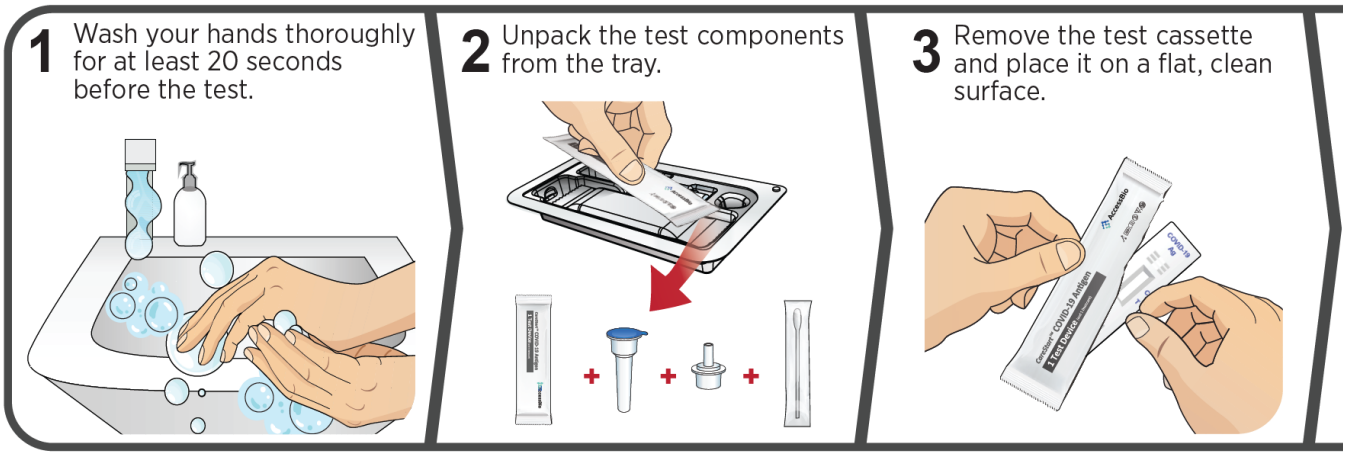
Specimen Collection and Handling

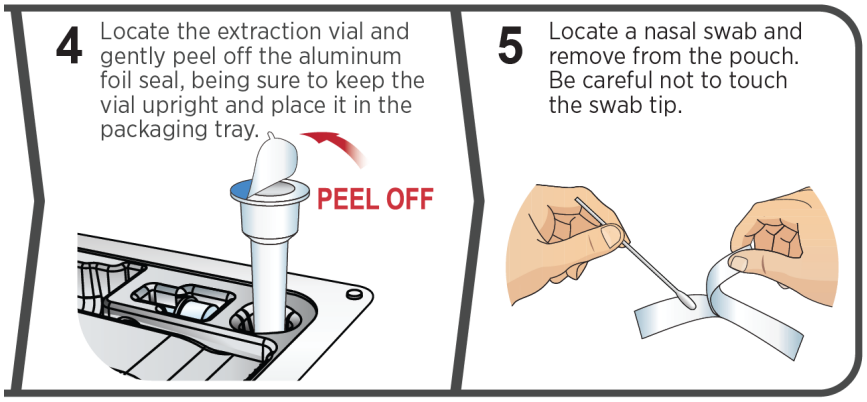
Acceptable specimen type for testing with the *CareStart*™ COVID-19 Antigen is a direct anterior nasal (nares) swab specimen. It is essential that correct specimen collection and preparation methods be followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results. Process the test swab sample immediately after collection (specimens are stable up to 4 hours in extraction buffer). Refer to the CDC Interim Guidelines

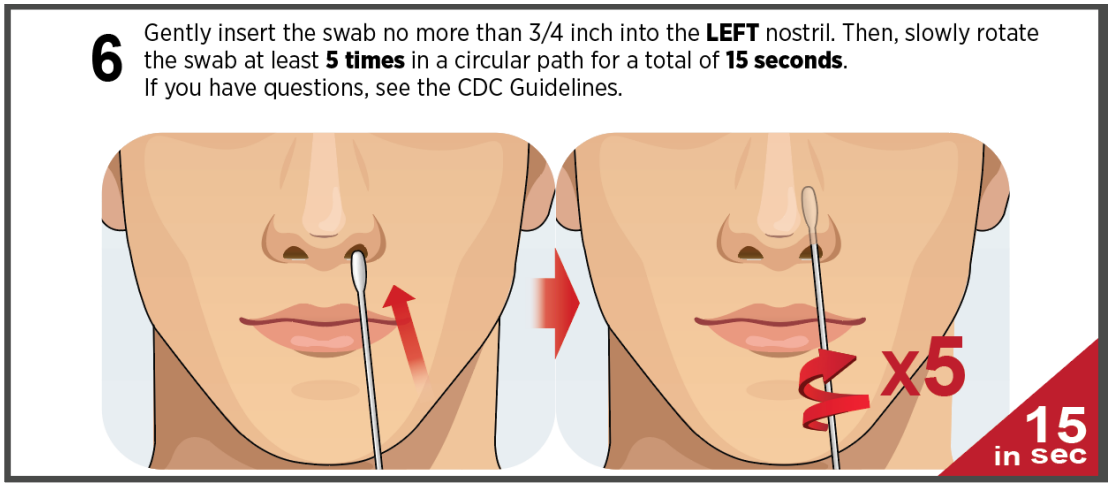
for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)
https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Instructions for Running the Test

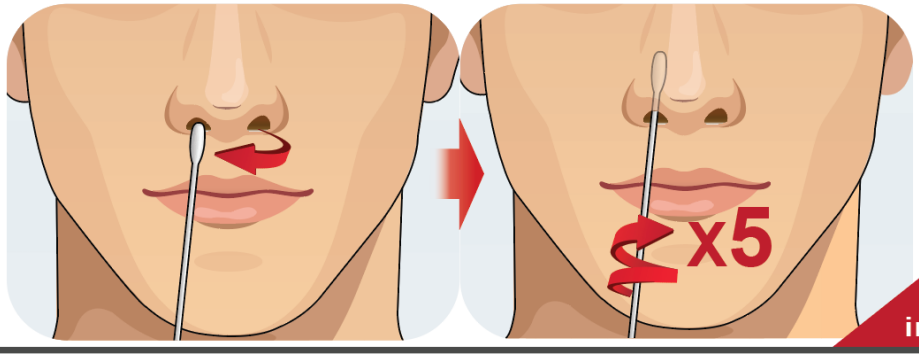
IMPORTANT: Do not open kit components until instructions to do so. Follow the in-app self-paced, step-by-step instructions or paper instructions printed on the QRI as below.



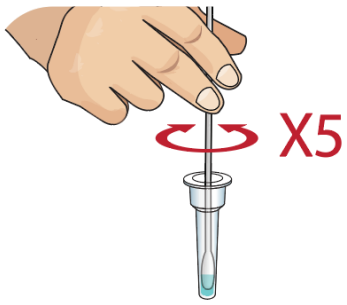




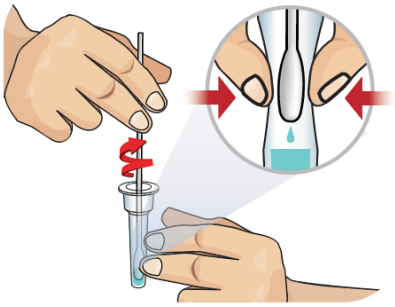
7 Gently remove the swab from the LEFT nostril and place directly into the **RIGHT** nostril, repeating the process of rotating at least **5 times** in a circular path for a total of **15 seconds**. Remove the swab from the RIGHT nostril.



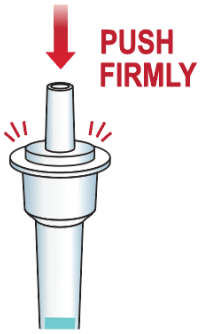
8 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



9 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Discard the swab in trash.

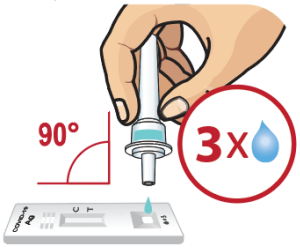


10 Close the vial by pushing the cap firmly onto the vial.



11 With your finger, mix thoroughly by flicking the bottom of the vial.

12 Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow **THREE (3)** drops of sample to fall into the sample well.



13 **Start a timer.**
Read the result at **10 minutes**.
The test result should not be read after 15 minutes.

IMPORTANT
Do not move or lift the test cassette during this time. Do not exit the mobile app during this process.

If used for serial testing and the test result is negative, a second test should be obtained two or three days with at least 24 hours and no more than 48 hours between tests.

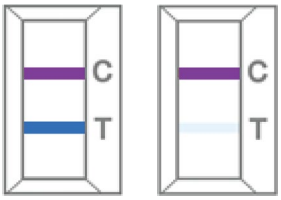
Interpretation of Results

The test results will be interpreted by visual reading following the in-app interpretation instructions or provided Quick Reference Instructions.

NOTE: The test results should be read by visual and interpreted at 10 minutes after the sample application and the reading and interpretation of the results should not exceed 15 minutes as it may yield inaccurate results.

COVID-19 Detected (Positive):

One purple-colored line next to "C" and one blue-colored line next to "T" indicates COVID-19 positive result.



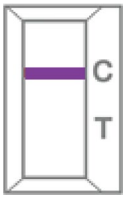
NOTE: The color intensity of the blue-colored test line will vary depending on the amount of SARS-CoV-2 nucleocapsid protein antigen present in the sample. Any faint blue-colored line in the test line should be considered as positive.

A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the patient is very likely to be infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines. Additional confirmatory testing with a molecular

test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Not Detected (Negative):

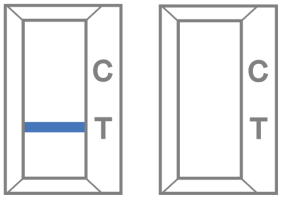
One purple-colored line only next to "C" indicates a negative result.



Negative results do not rule out SARS-CoV-2 infection. Individuals without symptoms that test negative should be tested again with at least 24 hours and no more than 48 hours between tests. All negative results are considered presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed. The amount of antigen in a sample may decrease as the duration of illness increases. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary, for patient management.

Invalid:

Invalid barcode or absence of a purple-colored line next to "C". Re-test with a COVID-19 test may be needed.
An invalid test result indicates that your test has experienced an error and unable to interpret the result of the test. You will need to retest with a new test or consult a healthcare professional. If you still have symptoms, you should self-isolate at home and avoid contact with others prior to the retest



For questions, or to report a problem, please call Technical Support at +1-888-898-1270 (Available Hours: Mon. to Fri.: 8 a.m. – 5 p.m.) or TShelp@accessbio.net (24/7 available).

Limitations

1. This test will indicate the presence of SARS-CoV-2 nucleocapsid protein antigen in the specimen from both viable and non-viable SARS-CoV-2 virus. Test performance depends on

the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.

2. The detection of SARS-CoV-2 nucleocapsid antigen is dependent upon proper specimen collection, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
3. False negative results may occur in patients who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin (> 10 mg per day). Biotin levels of 2.5 µg/mL and greater have been demonstrated to result in false negative test results.
4. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
5. False negative results are more likely after seven days or more of symptoms.
6. Interpretation of any result after 15 minutes may yield inaccurate test results.
7. This test and the results from this test do not establish that the user has acquired immunity to COVID-19.
8. Extracted specimens are stable for 4 hours in extraction buffer at room temperature.
9. Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to determine infection status.
10. Negative results are presumptive in symptomatic individuals, do not rule out COVID-19 and it may be necessary to obtain additional testing with a molecular assay, if needed for patient management.
11. This device has been evaluated for use with human specimen material only.
12. False-negative results may occur if the concentration of the target antigen in the clinical specimen is below the detection limits of the device.
13. This device is a qualitative test and does not provide information on the viral concentration present in the specimen.
14. This test cannot rule out diseases caused by other bacterial or viral pathogens.
15. The prevalence of infection will affect the test's predictive values.
16. False positive results may occur, particularly in individuals without COVID-19 symptoms and/or individuals who live in areas with low numbers of COVID-19 and without known exposure to COVID-19.
17. Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely during peak activity when the prevalence of the disease is high. False-positive test results are more likely during the periods of low SARS-CoV-2 activity when prevalence is moderate to low.
18. Performance of nasal swabs collected from individuals without symptoms or other epidemiological reasons to suspect COVID-19 or for serial screening, when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests has not been determined, a study to support use will be completed.

19. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
20. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March 2021 and May 2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
21. Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
22. There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
23. Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.

Performance Characteristics

Clinical Performance

The clinical performance characteristics of the *CareStart*™ COVID-19 Antigen Home Test using anterior nasal swab specimen were evaluated at seven (7) geographically diverse study sites in the U.S. between March 2021 and May 2021 against an FDA Emergency Use Authorized RT-PCR molecular assay as a comparator method. Subjects self-sampled and self-tested using the *CareStart*™ COVID-19 Antigen Home Test in a simulated home setting utilizing only the labeling provided with the test. A total of 153 subjects were evaluated in this study. The CareStart™ COVID-19 Antigen Home Test when conducted by a lay user correctly identified 87% of positive samples and 98% of negative samples. The overall clinical performance is shown in the following tables.

CareStart™ COVID-19 Antigen Home Test clinical performance against the comparator method

CareStart™ COVID-19 Antigen Home Test	Comparator		
	Positive	Negative	Total
Positive	26	3[a]	29
Negative	4[b]	120	124
Total	30	123	153
Positive Percent Agreement (PPA)	87% (26/30) (95% CI: 70%-95%)		
Negative Percent Agreement (NPA)	98% (120/123) (95% CI: 93%-99%)		

[a]COVID-19 was detected in 0/3 False Positive specimens using the Quidel Lyra SARS-CoV-2 Assay

[b]*COVID-19 was not detected in 2/4 False Negative specimens using the Quidel Lyra SARS-CoV-2 Assay*

Patient Demographics

Age Group	*CareStart*™ COVID-19 Antigen Home Test		
	Female	Male	Positivity Rate % (total positive / total tested)
2-13 Years of Age	6	2	0.0% (0/8)
14-24 Years of Age	16	10	15.4% (4/26)
25-64 Years of Age	69	34	22.3% (23/103)
≥65 Years of Age	9	7	12.5% (2/16)
Total	100	53	13.9% (29/153)

Positive results are broken down by days since onset of symptoms:

Days Since Symptom Onset	PPA (95% CI)	NPA (95% CI)
Asymptomatic	70.0% (7/10) (95% CI: 39.7%-89.2%)	97.6% (123/126) (95% CI: 93.2%-99.2%)
0-1	100% (5/5) (95% CI: 56.6%-100%)	96.8% (30/31) (95% CI: 83.8%-99.4%)
0-2	100% (11/11) (95% CI: 74.1%-100%)	94.8% (55/58) (95% CI: 85.9%-98.2%)
0-3	100% (20/20) (95% CI: 83.9%-100%)	96.3% (78/81) (95% CI: 89.7%-98.7%)
0-4	92.0% (23/25) (95% CI: 75.0%-97.8%)	97.1% (100/103) (95% CI: 91.8%-99.0%)
0-5	92.6% (25/27) (95% CI: 76.6%-97.9%)	97.3% (108/111) (95% CI: 92.4%-99.1%)
0-6	89.7% (26/29) (95% CI: 73.6%-96.4%)	97.3% (109/112) (95% CI: 92.4%-99.1%)
0-7	86.7% (26/30) (95% CI: 70.3%-94.7%)	97.5% (116/119) (95% CI: 92.9%-99.1%)
0-14	86.7% (26/30) (95% CI: 70.3%-94.7%)	97.6% (120/123) (95% CI: 93.1%-99.2%)

Invalid Test Rate: The overall invalid result rate within a total of 172 subjects that performed testing in a clinical study was 2.9% (5/172).

Analytical Sensitivity: Limit of Detection (LoD)

The LoD for direct nasal swab was established using gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (NR-52287). The strain was spiked into the pooled human nasal swab matrix obtained from multiple healthy volunteers eluted in PBS and confirmed as SARS-CoV-2 negative by RT-PCR to prepare positive samples. The estimated LoD found from the initial two-fold serial dilution test was confirmed by testing 20 replicates. The confirmed LoD for direct swab was 2.8 x 10^3 $TCID_{50}$/ml.

Analytical Specificity: Cross Reactivity (Exclusivity) and Microbial Interference

The potential cross-reactivity (exclusivity) of a panel of common organisms was evaluated with SARS-CoV-2 negative samples using the *CareStart*™ COVID-19 Antigen Home Test. Potential microbial interference was evaluated with samples containing gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 at approximately 3x LoD. A total of 10 bacteria were tested at a target concentration of approximately 10^7 cfu/ml with the exception of *Mycoplasma pneumoniae*, which was tested at a final concentration of 1.5 x 10^3 cfu/ml. The 18 viruses were tested at

concentrations between $10^{5.2}$ and $10^{7.9}$ $TCID_{50}$/ml. All negative samples gave negative results at the concentrations of the potentially cross-reactive common organisms tested showing no cross-reactivity with *CareStart*™ COVID-19 Antigen Home Test assay. All samples with SARS-CoV-2 strain tested positive showing no microbial interference at the concentrations of the potentially interfering common organisms tested.

Potential Cross-Reactant		
Adenovirus 1	MERS-Coronavirus, Irradiated Lysate	*Bodetella pertussis*
Adenovirus 7	Parainfluenza virus type 1	*Candida albicans*
Enterovirus 71, Tainan/4643/1998	Parainfluenza virus type 2	*Chlamydophila pneumoniae*
Human coronavirus (OC43)	Parainfluenza virus type 3	*Haemophilus influenzae*
Human coronavirus (229E)	Parainfluenza virus type 4	*Legionella pneumophila*
Human coronavirus (NL63)	Respiratory syncytial virus Type B	*Mycoplasma pneumoniae*
Human metapneumovirus (hMPV)	Rhinovirus	*Staphylococcus aureus*
Influenza A/Michigan/45/2015	SARS-Coronavirus	*Staphylococcus epidermidis*
Influenza B/Wisconsin/01/2010	Pooled human nasal wash	*Streptococcus pneumoniae*
		Streptococcus pyogenes, Group A

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, *in silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

https://blast.ncbi.nlm.nih.gov/Blast.cgi?PAGE=Proteins&PROGRAM=blastp&BLAST_PROGRAMS=blastp&PAGE_TYPE=BlastSearch&BLAST_SPEC=blast2seq&DATABASE=n/a&QUERY=&SUBJECTS=

- The homology between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 nucleocapsid protein is relatively low, at 36.7% across 86.4% of sequences, but cross-reactivity cannot be ruled out.
- The homology between SARS-CoV-2 nucleocapsid protein and *Mycobacterium tuberculosis* total protein (3,991 proteins) is relatively low, homology-based cross-reactivity cannot be ruled out.
- The homology between SARS-CoV-2 nucleocapsid protein and *Pneumocystis jirovecii* total protein (3,745 proteins) is relatively low, homology-based cross-reactivity cannot be ruled out.
- The homology between SARS-CoV-2 nucleocapsid protein and human coronavirus 229E nucleocapsid protein is relatively low, at 28.8% across 72.1% of sequences, but cross-reactivity cannot be ruled out. However, a result of the cross-reactivity wet study showed that CareStart™ COVID-19 Antigen Home Test had no cross-reactivity against human coronavirus 229E.

- No homologous protein was detected as a result of in silico assay with all the proteins (686 proteins) of *Mycoplasma pneumoniae* and the nucleocapsid protein (NP) of SARS-CoV-2, however cross-reactivity cannot be ruled out.

Endogenous Interfering Substances Effect

To assess substances with the potential to interfere with the performance of the *CareStart*™ COVID-19 Antigen Home Test, positive and negative samples were tested with the addition of potentially interfering substances. The SARS-CoV-2 target concentration in the positive samples was approximately 2x LoD. All samples tested produced expected results, demonstrating that the *CareStart*™ COVID-19 Antigen Home Test performance was not affected by any of the 35 potentially interfering substances listed in the table below at the concentrations tested.

Potential Interfering Substances	Concentration	Potential Interfering Substances	Concentration
Acetaminophen	10 mg/ml	Oseltamivir Phosphate (Tamiflu)	5mg/ml
Acetyl salicylic acid	15 mg/ml	OTC Nasal Spray (Alkaol)	1:10 dilution
Beclomethasone	0.5 mg/ml	OTC Nasal Spray (Cromolyn Sodium)	15%
Benzocaine	5 mg/ml	OTC Naso GEL (NeilMed)	5%
Budesonide	2 mg/ml	OTC Sore Throat Phenol Spray	5%
Chlorpheniramine maleate	5 mg/ml	OTC Throat drop (Halls)	15%
Dexamethasone	1 mg/ml	OTC Throat drop (Ricola)	15%
Dextromethorphan HBr	2 mg/ml	OTC Nasal spray (Afrin)	15%
Diphenhydramine HCl	5 mg/ml	OTC Nasal spray (VicksSinex)	15%
Ephedrine HCl	10 mg/ml	OTC Nasal spray (Zicam)	15%
Flunisolide	5 mg/ml	Oxymetazoline HCl	10 mg/ml
Fluticasone	1 mg/ml	Phenylephrine HCl	5 mg/ml
Guaiacol Glyceryl Ether	20 mg/ml	Phenylpropanolamine	5 mg/ml
Histamine Dihydrochloride	10 mg/ml	Tobramycin	1 mg/ml
Menthol	10 mg/ml	Triamcinolone	1 mg/ml
Mometasone	1 mg/ml	Whole Blood	4%
Mucin	2%	Zanamivir	1 mg/ml
Mupirocin	1 mg/ml		

The interfering effects of biotin concentrations ranging between 625 ng/mL and 10 µg/mL were tested in a separate study. Biotin concentrations up to 1.25 µg/ml did not lead to false results. Biotin concentrations ≥2.5 µg/ml can cause false-negative COVID-19 results with the *CareStart*™ COVID-19 Antigen Home Test.

High-dose Hook Effect

The *CareStart*™ COVID-19 Antigen Home Test was tested up to 10^6 $TCID_{50}$/ml of gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 strain and no high-dose hook effect was observed.

Technical Support

For questions, or to report a problem, please call Technical Support at +1-888-898-1270 (Available Hours: Mon. to Fri.: 8 a.m. – 5 p.m.) or TShelp@accessbio.net (24/7 available).

Description of Symbols

Symbol	Descriptions
IVD	*In vitro* diagnostic medical device Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device.
	Consult instructions for use Indicates the need for the user to consult the instructions for use.
	Manufacturer Indicates the medical device manufacturer.
LOT	Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Do not re-use Indicates a medical device that is intended for one use, or uses on a single patient during a single procedure.
	Use by date Indicates the date after which the medical device is not to be used.
Rx	Prescription-only

Symbol	Descriptions
REF	Catalog number Indicates the manufacturer's catalog number so that the medical device can be identified.
	Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Date of manufacture Indicates the date when the medical device was manufactured.
	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.
	Do not use if the package is damaged Indicates a medical device that should not be used if the package has been damaged or opened.
Σ	Contains sufficient for <n> tests Indicates the total number of IVD tests that can be performed with the IVD.

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Effective Date: Nov. 22, 2021

November 22, 2021

Sang Joon Han
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Device:	*CareStart* COVID-19 Antigen Home Test
EUA Number:	EUA210314
Company:	Access Bio, Inc.
Indication:	Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with: Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. Adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

Dear Sang Joon Han:

On August 2, 2021, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the *CareStart* COVID-19 Antigen Home Test pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C.

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Access Bio, Inc.

§360bbb-3) for the indication stated in the letter.[2] Based on your request, FDA granted updates to the authorized labeling on August 23, 2021.[3]

On October 26, 2021, you requested to amend this EUA. Based on that request, and having concluded that revising the August 2, 2021, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the August 2, 2021, letter in its entirety with the revisions incorporated.[4] Accordingly, your product[5] is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[6]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA

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[2] The August 2, 2021, letter authorized the *CareStart* COVID-19 Antigen Home Test for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens from individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection when tested twice over two or three days with at least 24 hours and not more than 48 hours between tests. This test is authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal swab samples from individuals aged 2 years or older.

[3] On August 23, 2021, your request was granted to update the authorized labeling for the *CareStart* COVID-19 Antigen Home Test with various edits and clarifications, including a new QR code used to access the mobile application and to make those same edits to the authorized brand name labeling.

[4] The revisions to the August 2, 2021, letter and authorized labeling include: (1) updates to the intended use to include use of your product with "*self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset*," "*adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset,*" and "*self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests,*" (2) update the outer box labels and Instructions for Use (IFU) limitations section to reflect the updates to the intended use, (3) offer the test kit with 1-test option, in addition to the 2-test, 4-test and 20-test options currently offered, (4) Update Condition of Authorization Q. and S. below to give a 1 month extension and Condition of Authorization R. below to give a 6 month extension, and (5) updates to the letter and fact sheets to reflect the updated intended use and for consistency with language used in more recent authorizations.

[5] For ease of reference, this letter will use the term "your product" to refer to the *CareStart* COVID-19 Antigen Home Test, that will also be offered under the authorized distributor brand name of "on/go COVID-19 Antigen Self-Test," used for the indication identified above.

[6] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

relied upon is included in the "*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use" identified below.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[7]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal (nares)

[7] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease. Individuals who test positive with your product should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive, and confirmation with a molecular assay for patient management, may be performed if necessary. Negative results do not rule out SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the Centers for Disease Control and Prevention (CDC).

Your product is performed using anterior nasal (nares) swab samples from individuals aged 14 years or older or adult-collected anterior nasal (nares) swab samples from individuals age 2 years or older. The individual using your product has the option to follow the "*CareStart* COVID-19 Antigen Home Test User Instructions" provided with the kit or follow step-by-step mobile application-based instructions by downloading the "on/go App" onto a compatible smartphone.[8] When using your product, the individual unpacks the tray containing all the test components, before removing the test device from its pouch and placing it on a flat clean surface. The extraction vial is then opened and inserted into the tray in an upright position. The swab is then removed from its pouch and the individual collects an anterior nasal (nares) swab sample by inserting the swab into the nostril and rotating at least 5 times for a total of 15 seconds before

[8] Compatible smart phone includes Apple iPhone running Operation System (iOS) 13 or later versions of the OS, and Android Phones running Android10 or later versions. Additional smart phone models as may be requested, and for which you receive appropriate authorization, in accordance with Condition L. below.

repeating in the second nostril. The swab is then inserted into the extraction vial and rotated vigorously at least 5 times before being removed and the vial capped. The contents of the extraction vial are then mixed before three drops are applied to the sample well of the test device. When the anterior nasal (nares) swab specimen migrates in the test strip, SARS-CoV-2 viral antigens present in the sample bind to anti-SARS-CoV-2 nucleocapsid protein antibodies conjugated to indicator and capture particles in the test strip forming an immune complex. The immune complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip. Test results are interpreted visually after 10 minutes based on the presence or absence of visually detectable purple and blue colored lines. Upon completion of the test and result interpretation the user should share their results with their healthcare provider.

The *CareStart* COVID-19 Antigen Home Test kit includes the following materials or other authorized materials packed and sealed in a tray: Test Device (pouched with desiccant), extraction vial and cap, Nasal Swab, Quick Reference Instructions, and Fact Sheet for Individuals.

Your product includes an internal control test line that must generate the expected result for a test to be considered valid, as outlined in the "*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use."

The labeling entitled "*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use," the "*CareStart* COVID-19 Antigen Home Test User Instructions" (Quick Reference Instructions) and the "*CareStart* COVID-19 Antigen Home Test" box labels (1-test, 2-tests, 4-tests and 20-tests) (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the "on/go App" software application, and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling"[9]:

- Fact Sheet for Healthcare Professionals: Access Bio, Inc. - *CareStart* COVID-19 Antigen Home Test
- Fact Sheet for Individuals: Access Bio, Inc. - *CareStart* COVID-19 Antigen Home Test

The above described product, when accompanied by authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

[9] The "authorized labeling" listed in this paragraph (and elsewhere) specifically refers to the labeling for the *CareStart* COVID-19 Antigen Home Test; however, "authorized labeling" under this letter also includes these specific pieces of labeling when entitled with the authorized distributor brand name of "on/go COVID-19 Antigen Self-Test," as would be the case with other authorized distributor brand names added in accordance with Condition L. below.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Access Bio, Inc. (You) and Authorized Distributor(s)[10]

A. Your product must comply with the following labeling requirements: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 21 CFR 809.10(b)(5), (7), and (8); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make available the "*CareStart* COVID-19

[10] "Authorized Distributor(s)" are identified by you, Access Bio, Inc., in your EUA submission as an entity allowed to distribute your product.

Antigen Home Test User Instructions" and the "Fact Sheet for Individuals" for your product in the shipped kit using the applicable "*CareStart* COVID-19 Antigen Home Test" box label (1-test, 2-tests, 4-tests or 20-tests) and make these two documents electronically available on your website.

C. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.

D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or the authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number of tests distributed to each location.

F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You and authorized distributor(s) using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Access Bio, Inc. (You)

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

K. You must make the authorized "*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use" and the "Fact Sheet for Healthcare Professionals" electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "*CareStart* COVID-19 Antigen Home Test Healthcare Provider Instructions for Use" and "Fact Sheet for Healthcare Professionals" in paper form, and after such request, promptly provide the requested labeling at no additional cost.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the product released for distribution meet the clinical and analytical performance claimed in the authorized labeling.

O. If requested by FDA, you must submit your lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide them within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[11] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must further develop your mobile phone application or website to further facilitate results reporting by the individual using your product and submit to FDA such application or website within 1 month of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission of the mobile phone application or website to, and review of and concurrence with the developed mobile phone application or website by FDA, you must update the authorized labeling. Such labeling updates will be made in consultation with, and require concurrence of, FDA.

R. You must evaluate the clinical performance of your product to support the serial

[11] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

screening claim in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. You must evaluate the usability of the "*CareStart* COVID-19 Antigen Home Test User Instructions" with individuals using only the paper instructions of your product in an FDA agreed upon post authorization study within 1 month of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling, as applicable, to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

T. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling accordingly. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

U. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

V. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Conditions Related to Printed Materials, Advertising and Promotion

W. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

X. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

Y. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens; and,
- This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure

GenBody Inc.
CHANGE AND INNOVATION

COVID-19 Ag

Quick Immunoassay

GenBody COVID-19 Ag

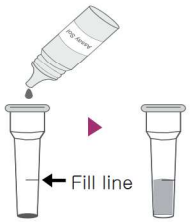
Detection kit for SARS-CoV-2 antigen

The pandemic of COVID-19 has been already announced by WHO (World Health Organization). The symptoms of COVID-19 are diverse, but generally include fatigue, fever, cough, loss of smell and taste and breathing difficulties. The symptoms of COVID-19 start to show in the period of 1 to 14 days after exposure to the virus. Even though the molecular test (RT-PCR) has become the standard method for the diagnosis of this disease, a lot of clinic systems need more simple and convenient methods due to several limitations of molecular test.

GenBody COVID-19 Ag is an immunochromatographic assay kit for the qualitative detection of SARS-CoV-2 antigen in nasopharyngeal and oropharyngeal swab from human. This kit is simply used to detect the SARS-CoV-2 virus, providing results in 10 to 20 mins. One of the best advantages of this kit is inexpensive despite high sensitivity and specificity.

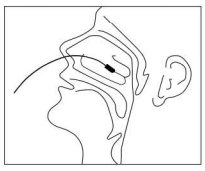
Assay Procedure

Preparation of Extraction solution



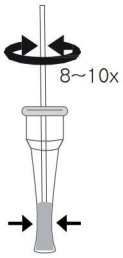
Bring swabs, specimens, and test kit to 15-30 min prior to use.
Add the Extraction Solution to the Fill Line indicated on the Extraction Tube (400 µL).

Nasopharyngeal swab



Nasopharyngeal swab collection: Collect the specimens from the patient using the provided swab.

Insert the nasopharyngeal swab samples into the extraction solution.



Mix by squeezing the tube and simultaneously rotating the swab 8-10 times.

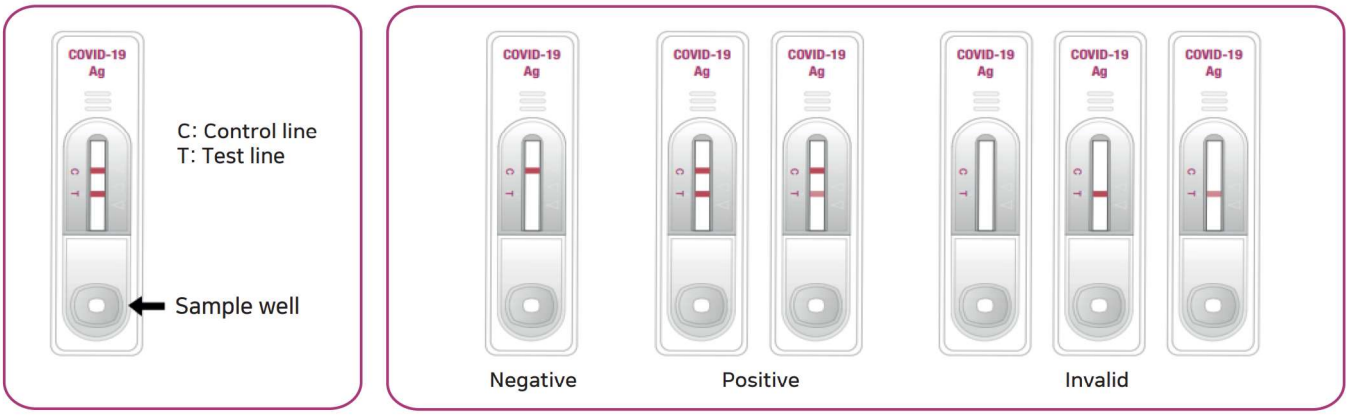
Remove the swab from the extraction tube while pressing the swab against the side of the tube to extract the solution. Place the disposable dropper cap on the extraction tube.

Add 4 drops (~100 uL) of the solution to the center of the sample well of the test device.

15~20 min

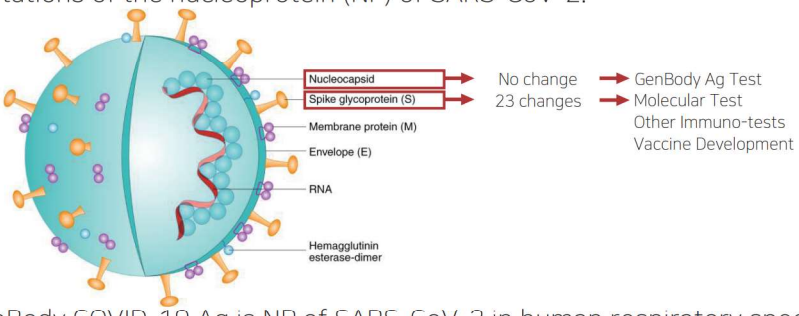
Read the test between 15-20 min after the addition of the sample. Treat samples, swab, tube and test device as biohazardous waste.

Interpretation of the Results



Diagnosis of GenBody COVID-19 Ag kit for the SARS-CoV-2 variants

- Current variants of SARS-CoV-2: mainly mutated in spike protein (SP).
- Total 23 mutated positions by SNPs (single-nucleotide polymorphisms) or deletion.
- Very less or none mutations of the nucleoprotein (NP) of SARS-CoV-2.



- Target protein of GenBody COVID-19 Ag is NP of SARS-CoV-2 in human respiratory specimens.
  → No effect to diagnose from these kinds of SARS-CoV-2 variants.
- In summary, GenBody COVID-19 Ag can surely detect the current variants of SARS-CoV-2.

*Reference
1. Leonid Y. et al. Structural and functional analysis of the D614G SARS-CoV-2 spike protein variant. Cell (2020) 183, p739-751.
2. Andrew R. et al. Preliminary genomic characterization of an emergent SARS-CoV-2 lineage in the UK defined by a novel set of spike mutations. nCoV-2019 Genomic Epidemiology (2020) https://virological.org/t/preliminary-genomic-characterisation-of-an-emergent-sars-cov-2-lineage-in-the-uk-defined-by-a-novel-set-of-spike-mutations/563

Clinical evaluation

- Under the strict IRB regulation, we collected and performed the clinical studies using total 506 patient's samples (493 specimens : Ct ≤ 30, 13 specimens : Ct > 30) which were confirmed to be COVID-19 positive and its negative in Korea (2 sites) and in USA (1 site). The method of confirmation was RT-PCR kit (Korean/US FDA-EUA approved).

n = 493 (Ct ≤ 30)		Molecular test (RT-PCR)		Total
		Positive	Negative	
GenBody COVID-19 Ag	Positive	119	4	123
	Negative	4	366	370
Total		123	370	493

- Sensitivity = 96.8% (95% CI: 91.9% to 99.1%), (Ct > 30: Less than 50%)
- Specificity = 98.9% (95% CI: 97.3% to 99.7%)
- PPV (Positive Predictive Value) = 96.8%
- NPV (Negative Predictive Value) = 98.9%

n = 285		Real-Time PCR				Total
		Positive			Negative	
		Asymptomatic	*Day 1~6	*Day 7~		
GenBody COVID-19 Ag	Positive	5	48	24	3	80
	Negative	1	4	3	197	205
Total		6	52	27	200	285

*Day after the onset of symptoms.

- Sensitivity = 83.3% (Asymptomaticcases)
  92.3% (95% CI = 81.5% to 97.9%) at Day 1~6
  88.9% (95% CI = 70.8% to 97.7%) at after Day 7
- Specificity = 98.5% (95% CI = 95.7% to 99.7%)

Ordering Information

Cat no.	Product Name	Package	Box Size (mm)	Carton Size(mm)
COVAG025	GenBody COVID-19 Ag	25 Tests/Kit	250 x 125 x 90	570 x 390 x 520

GBAGEN2106-Rev.0

GenBody Inc.
CHANGE AND INNOVATION
GenBody Building, 3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungnam, 31077, Korea
Tel : +82-41-523-8990 | Fax : +82-41-523-8991 | Website : www.genbody.co.kr

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes	Authorized Setting(s)1	Authorization Documents2
01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card	Lateral Flow, Visual Read	H, M, W	HCP, Patients, IFU
01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test	Lateral Flow, Visual Read, Prescription Home Testing, Telehealth Proctor Supervised	Home, H, M, W	HCP, IFU, IFU (Home Test)
01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)
01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card 2 Home Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Telehealth Proctor Supervised, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)
01/07/2022	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag 2 Card	Lateral Flow, Visual Read, Non-prescription Teelling, Serial Screening	H, M, W	HCP, Patients, IFU
01/05/2022	SD Biosensor, Inc.	COVID-19 At-Home Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, IFU, IFU (Home Test)
12/29/2021	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, IFU, IFU (Home Test)
12/22/2021	iHealth Labs, Inc.	iHealth COVID-19 Antigen Rapid Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, IFU, IFU (Home Test)
12/21/2021	Quanterix Corporation	Simoa SARS-CoV-2 N Protein Antigen Test	Paramagnetic Microbead-based Immunoassay, Serial Screening, Saliva	H, M	HCP, Patients, IFU
12/17/2021	Salofa Oy	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette	Lateral Flow, Visual Read	H, M, W	HCP, Patients, IFU
12/10/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening	H, M, W	HCP, Patients, IFU
12/06/2021	Nano-Ditech Corp.	Nano-Check COVID-19 Antigen Test	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP, Patients, IFU
12/02/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP, Patients, IFU
12/01/2021	Access Bio, Inc.	CareStart COVID-19 Antigen Home Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, IFU, IFU (Home Test)
11/23/2021	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test	Lateral Flow, Digital Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)
11/22/2021	InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, IFU, IFU (Home Test)
11/17/2021	GenBody Inc.	GenBody COVID-19 Ag	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP, Patients, IFU
11/16/2021	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack	Chemiluminescence Immunoassay, Instrument Read	H, M	HCP, Patients, IFU
11/15/2021	PHASE Scientific International, Ltd.	INDICAID COVID-19 Rapid Antigen Test	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP, Patients, IFU
11/09/2021	Quidel Corporation	QuickVue SARS Antigen Test	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP, Patients, IFU
11/01/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)
10/29/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test	Microfluidic Immunofluorescence Assay, Instrument Read, Screening	H, M, W	HCP, Patients, IFU
10/27/2021	Princeton BioMeditech Corp.	Status COVID-19/Flu A&B	Lateral Flow, Visual Read, Multi-analyte	H, M, W	HCP, Patients, IFU
10/21/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, IFU, IFU (Home Test)
10/21/2021	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)
10/19/2021	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP, IFU, IFU (Home Test)
10/12/2021	Xtrava Health	SPERA COVID-19 Ag Test	Lateral Flow, Visual Read	H, M, W	HCP, Patients, IFU
09/24/2021	ANP Technologies, Inc	NIDS COVID-19 Antigen Rapid Test Kit 09/24/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP, Patients, IFU
09/03/2021	InBios International, Inc.	SCoV-2 Ag Detect Rapid Test 05/06/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP, Patients, IFU
09/01/2021	Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Rapid Test 04/16/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP, Patients, IFU
08/05/2021	QIAGEN GmbH	QIAreach SARS-CoV-2 Antigen 08/05/2021	Digital Lateral Flow, Fluorescence, Instrument Read	H, M	HCP, Patients, IFU
07/12/2021	DiaSorin, Inc.	LIAISON SARS-CoV-2 Ag 03/26/2021	CLIA	H, M	HCP, Patients, IFU
07/08/2021	Ellume Limited	ellume.lab COVID Antigen Test 07/06/2021	Lateral Flow, Fluorescence, Instrument Read	H, M, W	HCP, Patients, IFU
06/11/2021	Quidel Corporation	Sofia SARS Antigen FIA 05/08/2020	Lateral Flow, Fluorescence, Instrument Read, Serial Screening	H, M, W	HCP, Patients, IFU
06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx 06/04/2021	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP, IFU, IFU (Home Test)
06/04/2021	OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Pro 06/04/2021	Lateral Flow, Visual Read, Serial Screening	H, M, W	HCP, Patients, IFU
04/13/2021	Qorvo Biotechnologies, LLC.	Omnia SARS-CoV-2 Antigen Test 04/13/2021	Bulk Acoustic Wave (BAW) Biosensor, Instrument Read	H, M	HCP, Patients, IFU
03/24/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B 03/24/2021	Chromatographic Digital Immunoassay, Instrument Read, Multi-analyte	H, M, W	HCP, Patients, IFU Viral Mutation Revision Letter - September 23, 2021
03/01/2021	Quidel Corporation	QuickVue At-Home COVID-19 Test 03/01/2021	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP, Patients, IFU, IFU (Home Test)
02/11/2021	Ellume Limited	Ellume COVID-19 Home Test 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP, IFU, IFU (Home Test), FAQ
12/07/2020	Luminostics, Inc.	Clip COVID Rapid Antigen Test 12/07/2020	Lateral flow immunoluminescent assay, instrument read	H, M, W	HCP, Patients, IFU
10/23/2020	Celltrion USA, Inc.	Sampinute COVID-19 Antigen MIA 10/23/2020	Magnetic Force-assisted Electrochemical Sandwich Immunoassay (MESIA)	H, M	HCP, Patients, IFU
10/02/2020	Quidel Corporation	Sofia 2 Flu + SARS Antigen FIA 10/02/2020	Lateral Flow, Fluorescence, Instrument Read, Multi-Analyte	H, M, W	HCP, Patients, IFU


2
TESTS
EASY Sample Collection
15
mins
Results in 15 Minutes
IVD OTC
Celltrion DiaTrust™
COVID-19 Ag
Home Test
CELLTRION


Celltrion DiaTrust™
COVID-19 Ag
Home Test
Test Device
1 test


Celltrion DiaTrust™
COVID-19 Ag
Home Test
Test Tube (Extraction Buffer) and Filter Cap

WORKSPACE FACILITIES by Office Depot

QUOTATION

Account Name:

Account Number:

Date: January 12, 2022

Address:

Attn:

QUOTATION

Quantity	ODS SKU	Description	EACH PRICE	Total Price
7,560	7090695	iHealth COVID Antigen Rapid Test - 1 pallet	$ 19.49	$ 147,344.40
		2 test per kit, 90 kits per case, 84 cases to a pallet		$ -
				$ -
				$ -
				$ -
				$ -
				$ -
				$ -
				$ -
				$ -
				$ -
				$ -
				$ -
				$ -
				$ -
				$ -
				$ -
				$ -
				$ -
		Sub-Total		$ 147,344.40
		Tax %		
		Grand Total		$ 147,344.40

MEMORANDUM

Date:	January 20, 2022
To:	Magnolia Educational & Research Foundation dba Magnolia Public Schools ("**MPS**") Board of Directors
From:	Alfredo Rubalcava, CEO & Superintendent
RE:	Procurement of Antigen Rapid Test Kits for MSA Sites and Home Office

I. CEO Determination

I, Alfredo Rubalcava, MPS CEO and Superintendent, with MPS Staff have determined after careful evaluation from multiple vendors that the purchase of 5,000 Antigen COVID-19 rapid test kits from Aotek Inc. is the best option for tests at the most affordable prices at $21.00 per box containing 2 kits.

II. Background

Due to the recent surge in Covid – 19 omnivariant cases and additional requirements mandated by State and local health departments, MPS will need to procure the rapid test kits in a timely manner in order to ensure the safety of all students and staff members.

Alfredo Rubalcava
Chief Executive Officer and Superintendent