COVID-19 Antigen Testing Using iHealth COVID-19, Emergency Use Authorization, Procedure

Location (includes Employee Health, Custody Health, hospital and all inpatient and outpatient locations and subacute facilities of the hospital, unless otherwise indicated)	
Enterprise Wide, Includes Employee Health and Custody Health	X
O'Connor Hospital	
Santa Clara Valley Medical Center	
St. Louise Regional Hospital	

Who May Perform This Procedure			
RN	X	MUC	
LVN	X	HSR	
HSA		Techs	
MA		MD, APPs, Residents	X
Other (specify) Clinical Lab Scientist	X		

REFERENCES:

iHealth COVID-19 Antigen Rapid Test, Healthcare Provider Instructions for Use, Model: ICO-3000/ICO-3001/ICO-3002., Accessed 01.10.2022 from: https://www.fda.gov/media/153923/download

iHealth COVID-19 Antigen Rapid Test, Fact Sheet for Healthcare Providers, Updated December 22, 2021. Accessed 01.10.2022 from: https://www.fda.gov/media/153922/download

FDA Approval Letter for iHealth COVID-19 Antigen Rapid Test, EUA Number EUA210470, Dated December 22, 2021 Accessed 01.10.2022 from: https://www.fda.gov/media/153925/download

SARS-CoV-2 Testing Procedure for Asymptomatic and Symptomatic Patients and Healthcare Workers (HCWs). SARS-CoV-2 Testing Procedure

SARS-CoV-2 Nasal Swab Collection Procedure for Asymptomatic Healthcare Workers in the County of Santa Clara Health System. SARS-CoV-2 Nasal Swab Collection Procedure

PURPOSE:

To outline the indication(s) and process for use of the iHealth COVID-19 Antigen Rapid Test.

BACKGROUND: Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus is the cause of the COVID-19 pandemic that has spread over 190 countries, across all continents.

iHealth COVID-19 Antigen Rapid Test is a lateral flow immunoassay intended for the qualitative detection of the 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 FDA Emergency Use Authorization also allows use of this product as a point-of-care test in settings that operate under a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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, 2 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 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

POLICY: This test is to be performed on anterior nasal (nares) swab specimens according to current hospital policy for testing of symptomatic and asymptomatic individuals.

PRINCIPLE: 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 with 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.

SPECIMEN REQUIREMENTS:

1. Accepted specimen types: Anterior nasal (nares)
2. Accepted swabs: swab provided with the test kit ONLY.

REAGENTS AND EQUIPMENT (obtained by e-mailing EquipmentHCC):

1. The iHealth COVID-19 Antigen Rapid Test may come in boxes that include one test/box, two tests/box, 5 tests/box, or 40 tests/box. Regardless of which box is used, to perform the test, you will remove from the iHealth COVID-19 Antigen Rapid Test kit:
    a. One COVID-19 Test Card in a pouch
    b. One sealed Nasal Swab
    c. One Tube which has a large orange cap, and a smaller white/clear cap
2. Other materials needed:
    a. Clock, timer, or stopwatch
    b. Cleaning Agents

        1. 70% ethanol - available in commercial wipes or on a damp, lint free cloth or
        2. 70% isopropanol - available in commercial wipes or on a damp, lint free cloth or
        3. 10% bleach - on a damp, lint free cloth only

    c. Personal Protective Equipment
        - Gloves
        - Eye protection (goggles or face shield)
        - Surgical mask (if testing asymptomatic individual), N95 (if testing symptomatic individual or in mass testing setting)

    d. Hand sanitizer or hand washing station
    e.Red biohazard bags and trash can

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.

Procedural Controls:

1. The red line at the "Control" position is an internal procedural control. If the test flows and the reagents work, this line will always appear.

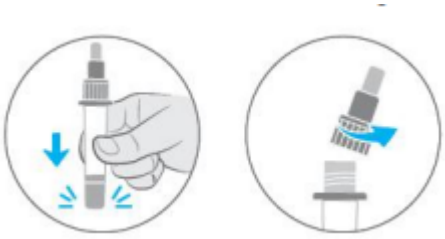
2. The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white within 15 minutes. Background color should not hinder reading of the test.

External Positive and Negative Controls:

There are no external controls required for this test.

SPECIMEN COLLECTION AND TESTING PROCEDURE

1.	Done PPE (face mask, face shield/goggles, gloves)	1.1	If already wearing PPE, change gloves
2.	Identify individual using two (2) patient identifiers.		
3.	Instruct individual to continue to wear face mask.		
4.	Explain procedure to individual		
5.	Open the package and take out one COVID-19 Test Card in pouch, one tube (orange top) with extraction reagent, and one swab.. Remove the swab from its package, being careful not to touch the tips of the swab. Keep the swab package for later use..	6.1	DO NOT use any other swabs
6.	Instruct individual to move mask down so that the nose is exposed but covering the mouth.		
7.	Ask the individual to tilt head back slightly to straighten the nasal passage.		
8.	Insert the entire absorbent tip of the swab (about 1.5-2 cm) into the nostril. Firmly and slowly brush the swab 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 procedure in the other nostril	9.1	Failure to swab properly may cause false negative results.
9.	Tap the tube vertically on the table and twist the large orange cap to open the tube.		

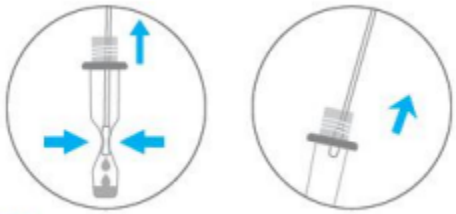


10.	Insert the swab into the tube, touch the bottom		

of the tube with the swab tip, and stir at least 15 times.

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

12.1 If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly, leading to a possible false negative result.



12. Screw back the large orange cap, put the swab back into the package. Safely dispose of the swab and package into red bag waste.

13. Open the COVID-19 Test Card pouch.

14.1 Test card must be used within one (1) hour of opening the pouch.

14. 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.

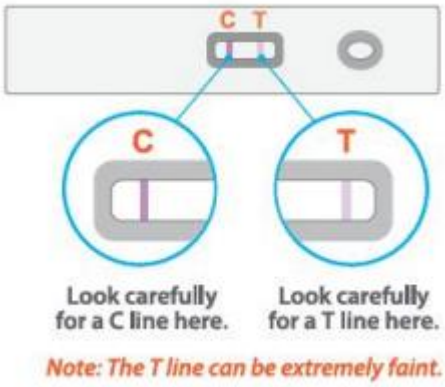
15.1 A false negative of invalid result may occur if too little solution is added to the test card.

15. Wait 15 minutes. Set a timer to ensure correct

16.1 DO NOT interpret your test result until

timing.

16. Read Result. Results should not be read after 30 minutes.



17. Document all results.
EMPLOYEES: Use the reporting form and SCCSECURE e-mail form to O365-HHS-EHCOVIDAG@sccconnect.onmicrosoft.com for proper documentation of results for Employee Health, as well as reporting to regulatory agencies.

PATIENTS: Report results and control results in HealthLink as Point-of-Care CoVid Antigen.

18. Clean work area after each test. Dispose of the Test Card in the red bag biohazard waste after documenting the results.

after your 15-minute timer has completed, as the T line may take as long as 15 minutes to appear (even though the C line takes less time).

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

18.1 Employees: Fill in all blanks on the form, including your name, and test manufacturer.

Patients: Fill in all blanks in HealthLink.

RESULT INTERPRETATION

Negative
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.

Positive
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.

Invalid
If no lines are seen, or it there is a T line but no C line, the assay is invalid. Invalid tests should be repeated with a new test kit.

REFERENCE RANGE

- Normal Range: COVID-19 Negative
- Abnormal Value: COVID-19 Positive

RESULT REPORTING

1. Results of all tests performed must be reported, including documentation of internal control results, and manufacturer name of test kit.
2. Patient results are reported through the nursing Point-of-Care Test pathway in HealthLink.
3. Employee (including physician) results are reported manually on the CoVid Antigen Results form, filling in all blanks. And then SCCSECURE e-mail to O365-HHS-EHCOVIDAG@sccconnect.onmicrosoft.com

COMPETENCY ASSESSMENT

All operators must read the procedure manual and complete the iHealth COVID-19 Antigen Rapid Test Competency Assessment during initial training.

Competency is assessed at orientation and annually using at least two of the following methods:

1. Performing a test on a blind specimen.
2. Unit Expert observes performance of routine work.
3. Each user's quality control performance is monitored.
4. Written testing specific to the method.

The name and operator ID of newly documented operators must be provided to the POCT program. Only approved operators are allowed to run the test.

Expired Operators: Operators who fail to meet competency requirements within 365 days will be required to undergo retraining and competency assessment according to above.

CONTACTS

The Point of Care Coordinators are accessible by phone or email and may be contacted with any questions and concerns regarding Point of Care testing and/or equipment. Support can be obtained after hours by contacting the main laboratory and requesting assistance. If out of the office, emails are encouraged. All calls will be returned as soon as possible.

Santa Clara Valley Medical Center and Custody Health:
Open Hours: M-F 7:30am – 4:00pm
751 S. Bascom Ave San Jose CA 95128 |
Office: 408-885-6321
Fax: 408-885-6366
Email: HHSLabPOCT@hhs.sccgov.org

O'Connor Hospital:

2105 Forest Ave, San Jose, CA 95128
Office: 408-947-2965
Email: luke.wang@hhs.sccgov.org

St. Louise Regional Hospital:
9400 No Name Uno, Gilroy, CA 95020
Office: 408-848-8630
Email: thomas.mendall@hhs.sccgov.org

Attachments:

None

Policies replaced (if applicable): None

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