

RAPID COVID-19 TEST KITS





QuickVue[®]
SARS Antigen TEST

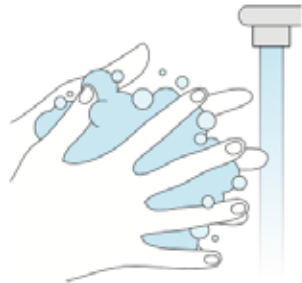




Wash Your Hands

Before you start testing, wash your hands or use hand sanitizer.

Make sure your hands are dry before starting.



STEP 1

Check Your Test Kit

Locate the kit components:

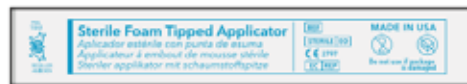
It is recommended gloves (not provided) also be used during testing.



Tubes



Tube Holder



Swabs



Watch or Timer
(not included)



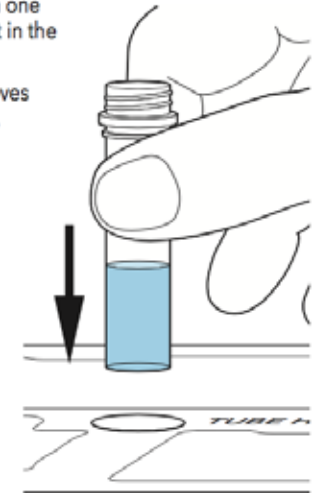
Test Strips

STEP 2

Place Tube in the Tube Holder

Remove cap from one **TUBE** and place it in the **TUBE HOLDER**.

NOTE: Use of gloves is recommended.



STEP 3

Swab the Nostrils

A Remove the **SWAB** from its wrapper, being careful not to touch the **SWAB** head.

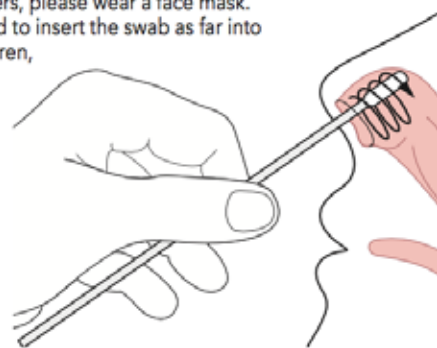


B Gently insert the **SWAB** $\frac{1}{2}$ to $\frac{3}{4}$ of an inch into the nostril, depending on the size of the person's nose. Firmly rub the **SWAB** in a circular motion around the inside wall of **EACH NOSTRIL** at least 4 times.

Be sure to rub BOTH nostrils with the SAME SWAB.

NOTE: If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

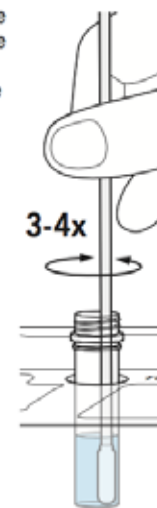
NOTE: Failure to swab properly may cause false negative results.



STEP 4

Place Swab in the Tube

A Immediately place the **SWAB** into the liquid inside the **TUBE**, and ensure it is touching the bottom. Stir 3-4 times.

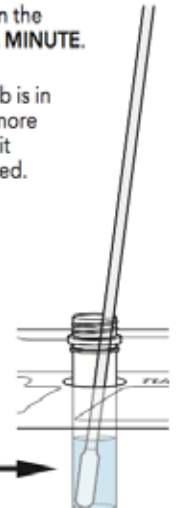


B Leave the swab in the solution for **ONE MINUTE**.

NOTE: If the swab is in the solution for more than 10-minutes it should not be used.



Leave swab in at least 1 minute!

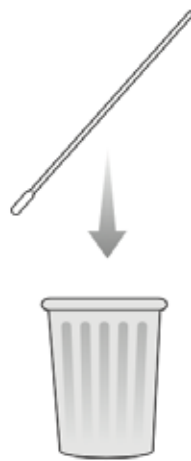
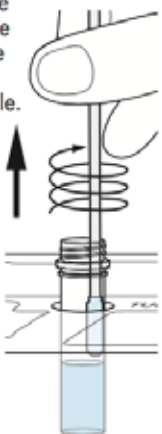


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STEP 5

Remove Swab from the Tube

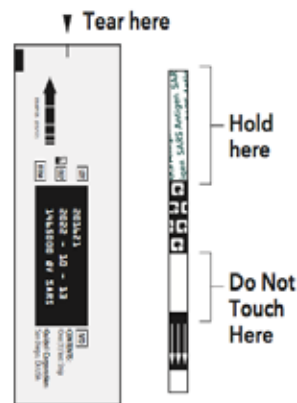
- A** After **ONE MINUTE**, remove the swab from the **TUBE** by rubbing the swab head against the inside wall of the tube to squeeze out as much liquid as possible.
- B** Dispose of swab in the trash.



STEP 6

Open the Test Strip

Open the **TEST STRIP** pouch carefully at the slit and hold the **TEST STRIP** as indicated.



STEP 7

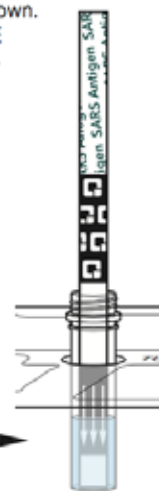
Place Test Strip in the Tube

Place the **TEST STRIP** into the **TUBE** with the arrows pointing down. Leave the strip in the **TUBE** for a **FULL TEN MINUTES** - do not handle or remove.



Leave strip in at least 10 minutes!

Arrows pointing down

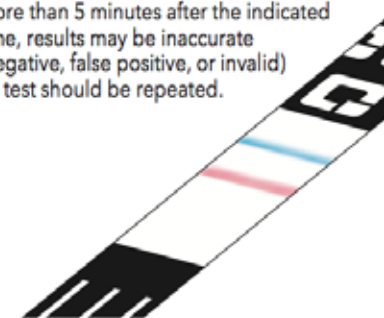


STEP 8

Remove Test Strip from the Tube

At **TEN MINUTES**, remove the **TEST STRIP** from the **TUBE** and place on the test strip outline in Steps 10-12. Ensure the **TEST STRIP** is on a flat surface in good lighting.

NOTE: The test is intended to be read at 10 minutes. If the test is read before this or is read more than 5 minutes after the indicated read time, results may be inaccurate (false negative, false positive, or invalid) and the test should be repeated.



STEP 9

Check Your Results

There are three type of results possible.

1. Check for a Positive Result
2. Check for a Negative Result
3. Check for an Invalid Result

STEP 10

Check for a Positive COVID-19 Result

Place the **TEST STRIP** on the test strip outline below and compare with test result examples shown.



Positive Result

A **POSITIVE** result must show **BOTH** a **BLUE** line and a **PINK** line near the **BLUE** line.

Look closely! Even a very faint, pink Test Line and a blue Control Line is a **POSITIVE** result. The intensity of the lines may vary.



Results shown at 2x.



Positive COVID-19 Result

A positive test result means that proteins from the virus that causes COVID-19 were found in your sample and it is very likely you have COVID-19 and it is important to be under the care of your healthcare provider. It is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give you a positive test result that is wrong (false positive.) If you test positive with the QuickVue At-Home COVID-19 Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test result along with your medical history, and your symptoms.



QUIDEL

Safentri creates a *process* for getting together again.

Accessible tools that introduce **individual accountability** while providing **data and tools** to enterprises. **Administered** to organizations to create **responsible policies** and **manage**



Safentri – how it works



The User signs up for access

The user presents their profile check-in badge, healthcare provider scans for photo Id verification and check-in.

User selects test type and scans product code to attach to user and administers test.

When test result is ready user scans product code, updates result and attaches image to record.

User receives alert that their secure Health Passport is updated and available for sharing via QR code.

Safentri – how it works

COVID-19 Screening Questionnaire

In accordance with the ACH and CDC Visitor Guidelines, we are screening our staff and visitors for everyone's safety. We appreciate your patience while we help keep all medical parties safe.

Facility Access Rules

- Must complete and pass Screening Questionnaire
- Must provide all additional required resources
- Must provide contact information
- Must show photo ID and provide signature

Screening Questionnaire

Question	Yes	No	NA
1. Do you currently have COVID-19?			
2. Are you currently experiencing any symptoms of COVID-19?			
3. Fever (≥100°F/38.3°C)			
4. Cough			
5. Sore throat			
6. Loss of taste and smell			
7. Difficulty breathing or shortness of breath			

Signature: *John Doe*

The User completes a COVID-19 questionnaire.

Locations Directory

Resources Location Entry

ACHS, Residency, ACHS, Care

Quick glance shows the user if the criteria to enter that facility has been met or requires more information.

The User selects a location to visit.

Common Passports

Entity Resource Name Type

- COVID-19 Screening Test/Document
- Social Engineering Policy Policy
- Security Agency Agreement Information
- COVID-19 Vaccination Tracking Tracking

Users can view and manage their individual screening documents.

The User can review and manage the facility's access requirements.

Location Check-In

John Doe
john.doe@gmail.com
(404) 555-4577

Select Location

Select Passports for visit

Yes to the test?

Authorization: By signing below, I certify that all information and resources submitted on my Covid-19 Screening Questionnaire and additionally uploaded documents, are complete, accurate and truthful to the best of my knowledge.

Signature: *John Doe*

The User answers from a pull-down menu and initiates a check-in.

The User answers from a pull-down menu and initiates a check-in.

Location Check-In

John Doe
john.doe@gmail.com
(404) 555-4577

ACHS, Residency

Select Location

Select Passports for visit

Yes to the test?

Authorization: By signing below, I certify that all information and resources submitted on my Covid-19 Screening Questionnaire and additionally uploaded documents, are complete, accurate and truthful to the best of my knowledge.

Signature: *John Doe*

The User chooses a check-in location and signs.

The User chooses a check-in location and signs.

Safentri – how it works

Health Passport

John Doe
john.doe@gmail.com
(404) 555-4577

COVID-19 Test Information

COVID-19 Test Result: Negative

Signature: *John Doe*

Health Passport contains latest test results complete with witness/provider signature.

Health Passport contains latest test results complete with witness/provider signature.

Health Passport

COVID-19 Test Result: Negative

Signature: *John Doe*

Health Passport also contains test result image that can be viewed full screen.

Health Passport also contains test result image that can be viewed full screen.

Health Passport

COVID-19 Vaccination Information

Signature: *John Doe*

Health Passport contains COVID-19 Vaccination information and verification card.

Health Passport contains COVID-19 Vaccination information and verification card.

Health Passport

QR Code

User generates check-in pass to access workplace or venue controlled by Safentri.

User generates check-in pass to access workplace or venue controlled by Safentri.

Health Passport

CLEARED FOR ENTRY

The User's check-in pass is scanned and cleared for entry (or set for review or failed).

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BinaxNOW™ COVID-19 Ag CARD AND NAVICA™ APP

Abbott's BinaxNOW COVID-19 Ag Card is a rapid, highly portable, reliable and affordable tool administered by a healthcare provider for detecting active coronavirus infections on a massive scale, helping slow the spread of the virus. BinaxNOW, combined with the NAVICA app, was designed to help people feel more confident in their daily lives.

PORTABLE AND EASY TO USE

Size of a credit card
Use with a nasal swab
No equipment required



COVID-19 TEST
NAVICA MOBILE APP



FAST

15 minutes for result



RELIABLE

Demonstrated sensitivity of 97.1% and specificity of 98.5% in clinical study



CONNECTIVITY

Complementary NAVICA mobile app stores and displays test results to help facilitate safer access to organizations where people gather, such as workplaces and schools





Part 1 - Sample Test Procedure

Patient Samples require 6 drops of Extraction Reagent.

1 Correct

Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.

Wrong

2

Insert sample or control swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.

3

Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab.

4

Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.

Used test cards should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.

Part 2 - Result Interpretation

A **negative specimen** will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.

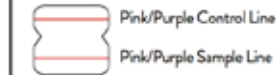
Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

Negative Result



A **positive specimen** will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink/purple colored line is positive.

Positive Result



If no lines are seen, or if just the Sample Line is seen, the assay is invalid. Invalid tests should be repeated.

Invalid Result



Procedure for External Quality Control Testing

External Controls require 8 drops of Extraction Reagent

1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **8 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.

2. Follow Steps 2 – 4 of the Test Procedure shown.





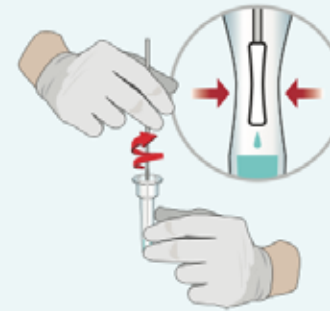
TEST PROCEDURES



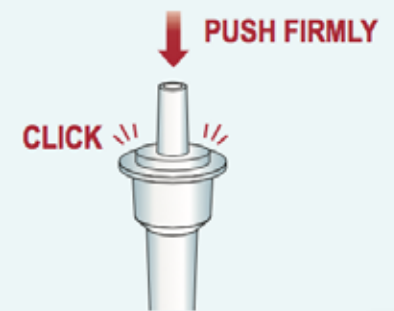
- 1 Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.



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



- 3 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.



- 4 Close the vial by pushing the cap firmly onto the vial.



- 5 Mix thoroughly by flicking the bottom of the tube.



- 6 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.

NOTE: Refer to the Package Insert for the cautions.

Result Interpretation

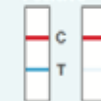
Start the timer



Read the result at 10 minutes. The test result should not be read after 15 minutes.

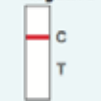


Positive



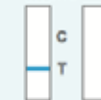
SARS-CoV-2 antigen present; does not rule out co-infection with other pathogens. The color intensity in the test region will vary depending on the amount of SARS-CoV-2 antigen present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.

Negative



Negative results are presumptive. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary for patient management.

Invalid



If the red-colored line in the control region "C" is not visible, the result is invalid. Re-run the test one time using the remaining specimen in the extraction vial if an invalid result is obtained during initial testing.

External Control Swab Test

It is recommended that positive and negative external control swabs are run once with every new lot, shipment, and each new user. External positive and negative control swabs are provided in the kit. The external control should be tested using the nasopharyngeal swab test procedure provided in this package insert or the quick reference instruction card.



AccessBio