

STORAGE SPECIFICATIONS

be.well™ COVID-19 Test Kit
Store be.well™ COVID-19 Test Kit components at 2-30 °C.

Do not use nasal samples stored in Universal Transport Medium (UTM) or other transport media. Mid-turbinate Nasal Swab samples may be stored in a dry, sterile transport tube at -20 °C for up to 5 days.

be.well™ Analyzer
Store be.well™ Analyzer at 15-30 °C.

OPERATING CONDITIONS

For best performance, fresh mid-turbinate Nasal Swab samples should be inserted directly into be.well™ Assay Buffer and tested as soon as possible after collection.

The be.well™ Analyzer and be.well™ Test Kit can operate at room temperature and in uncontrolled relative humidity, non-condensing.

TEMPERATURE DEFINITIONS

Room temperature: 15-30 °C

Note: Do not touch soft end of Nasal Swab. Avoid touching be.well™ COVID-19 Cartridge's electrical contacts. Keep be.well™ Analyzer flat on a level surface while inserting be.well™ COVID-19 Cartridge, as the test is running, and until the test is complete. Do not use the be.well™ COVID-19 Test Kit past the expiration date.

SET UP WORKSPACE

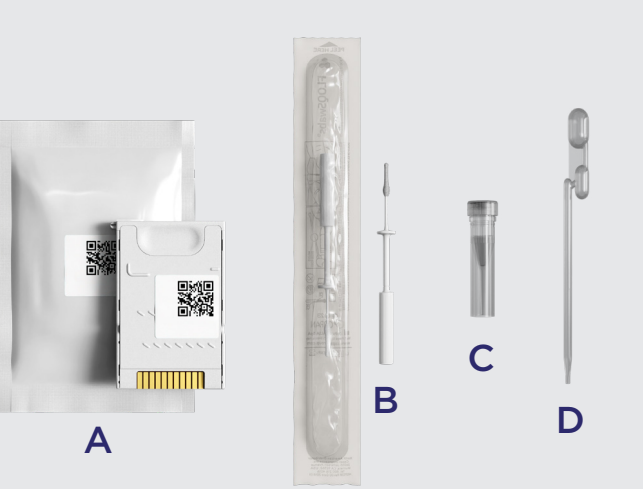
IMPORTANT: Ensure all be.well™ COVID-19 Test Kit components are at room temperature before use.

On a clean, flat surface, place be.well™ Analyzer, mobile device with be.well™ Mobile App installed on it, and ***unopened*** be.well™ COVID-19 Test Kit materials: be.well™ COVID-19 Cartridge, Nasal Swab, be.well™ Assay Buffer, and Transfer Pipette.



Conditions: Ensure the test is run at room temperature in a cool, dry environment. Set up a new workspace for each be.well™ COVID-19 Test. Change gloves between handling samples and setting up a new test.

MATERIALS REQUIRED AND PROVIDED



- A. be.well™ COVID-19 Cartridge
- B. Nasal Swab
- C. be.well™ Assay Buffer
- D. Transfer Pipette

Note: If any parts are missing or damaged, do not use and contact Alveo Support at support@alveotechnologies.com, or call us at +1-833-BE-WELL-0 (+1-833-239-3550)

MATERIALS REQUIRED BUT NOT PROVIDED



be.well™ Analyzer



Apple® iPhone® with be.well™ Mobile App installed

Purchase the be.well™ Analyzer from Alveo Technologies by contacting Alveo Customer Support:

support@alveotechnologies.com, or call us at +1-833-BE-WELL-0 (+1-833-239-3550).

The be.well™ Analyzer comes with one charging cable and one power adapter.

CAUTION



Keep the work area clean to prevent contamination. Wear disposable gloves and appropriate PPE while handling samples and change gloves between testing each specimen.



Follow all local, state, and federal guidelines for disposal of used Nasal Swabs, be.well™ Assay Buffer, Transfer Pipettes, and be.well™ COVID-19 Cartridges.



be.well™ COVID-19 Test

Quick Reference Instructions

For use with the be.well™ Analyzer and be.well™ Mobile App. For the qualitative detection of SARS-CoV-2 nucleic acid. For mid-turbinate Nasal Swab specimens only. For professional use only.

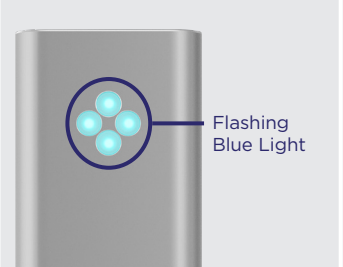


Scan to View Training Video



IMPORTANT: Read the be.well™ COVID-19 Test Instructions For Use (IFU) for complete information.

SET UP SYSTEM

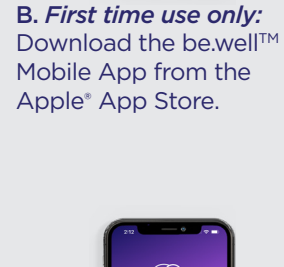


Flashing Blue Light

A. Charge be.well™ Analyzer with power source. The be.well™ Analyzer is ready for use when LED Indicator Lights are flashing blue.
Note: Keep the be.well™ Analyzer plugged in if running multiple tests.



B. First time use only: Download the be.well™ Mobile App from the Apple® App Store.

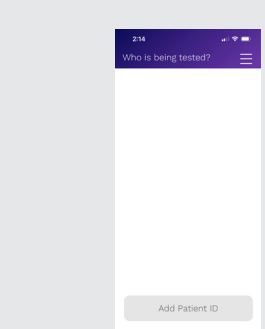


C. First time use only: Follow the on-screen instructions to register an account and agree to the Terms of Use.

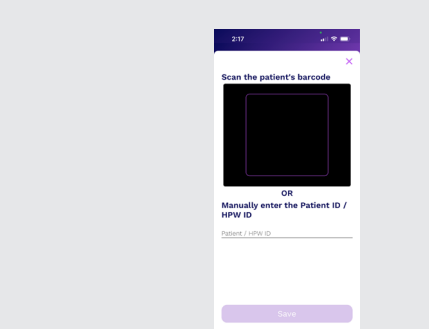


D. Log in to the be.well™ Mobile App. Ensure be.well™ Analyzer is flashing blue lights and “Set up Workspace” was completed.

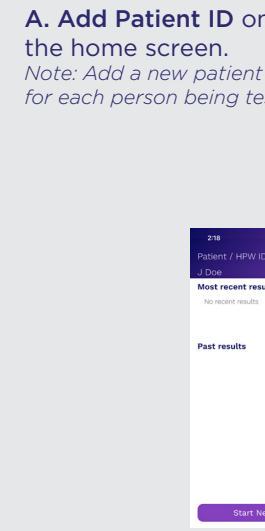
START NEW TEST



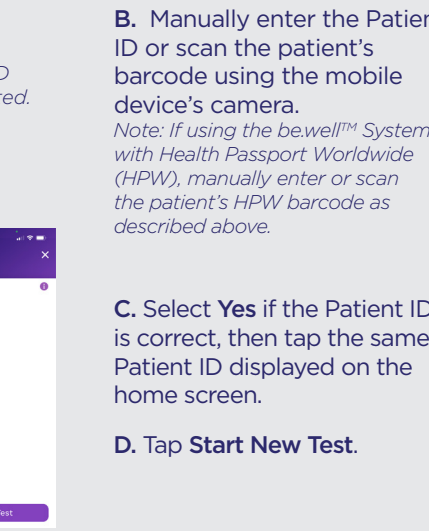
A. Add Patient ID on the home screen.
Note: Add a new patient ID for each person being tested.



B. Manually enter the Patient ID or scan the patient's barcode using the mobile device's camera.
Note: If using the be.well™ System with Health Passport Worldwide (HPW), manually enter or scan the patient's HPW barcode as described above.

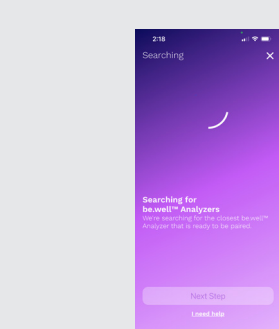


C. Select Yes if the Patient ID is correct, then tap the same Patient ID displayed on the home screen.

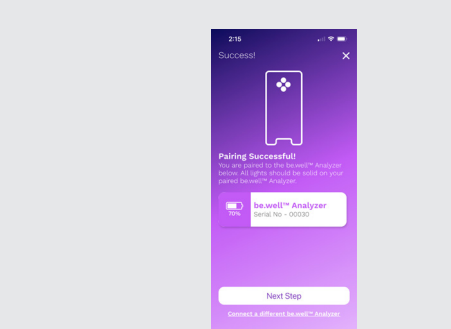


D. Tap Start New Test.

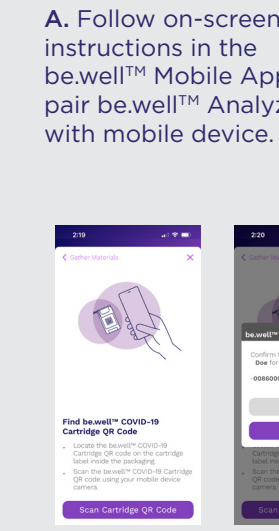
PAIR be.well™ ANALYZER



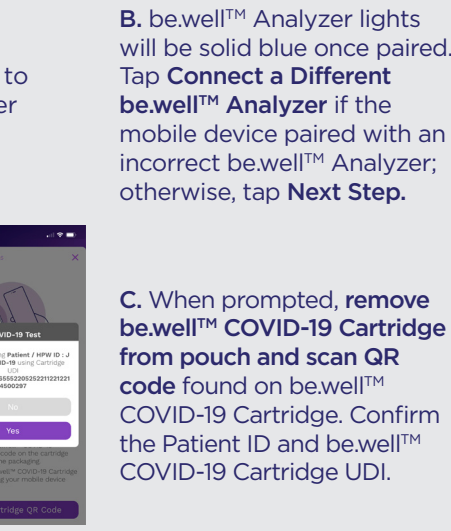
A. Follow on-screen instructions in the be.well™ Mobile App to pair be.well™ Analyzer with mobile device.



B. be.well™ Analyzer lights will be solid blue once paired. Tap Connect a Different be.well™ Analyzer if the mobile device paired with an incorrect be.well™ Analyzer; otherwise, tap Next Step.



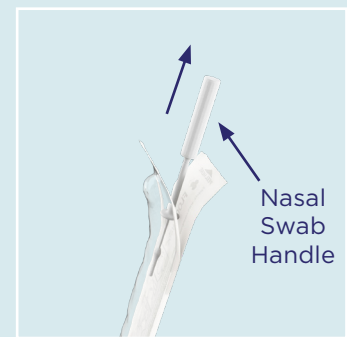
C. When prompted, remove be.well™ COVID-19 Cartridge from pouch and scan QR code found on be.well™ COVID-19 Cartridge. Confirm the Patient ID and be.well™ COVID-19 Cartridge UDI.



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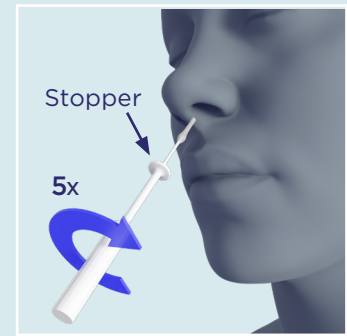
STEP 1. COLLECT NASAL SAMPLE

For best performance, Nasal Swab sample should be tested as soon as possible after collection.



A. Open Nasal Swab packet. Grasp Nasal Swab handle and remove it from the packaging.

Note: The Nasal Swab is sterile. Open just before use.



B. Insert Nasal Swab tip into one nostril (approx. 2-3 cm, or up to the stopper on Nasal Swab). If resistance is felt, do not insert any further.
C. Keep Nasal Swab in contact with the inside wall of the nostril and make 5 large circles.
D. With the same Nasal Swab, repeat steps B and C in the other nostril.

Note: Do not scrape the inside of the nose or try to remove excess mucus. Failure to swab both nostrils properly may result in invalid test results.

STEP 5. INSPECT TRANSFER PIPETTE STEM



A. Inspect Transfer Pipette stem to ensure no fluid remains. If fluid remains, repeat from Step 1 with fresh Nasal Swab and new materials.

Note: If sample was sucked back into the Transfer Pipette stem after filling the be.well™ COVID-19 Cartridge, dispose of the be.well™ COVID-19 Cartridge, collect a new sample, and start test again.

B. Securely close the cap on be.well™ COVID-19 Cartridge.

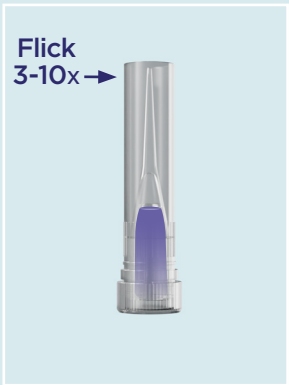
C. Dispose of Transfer Pipette and be.well™ Assay Buffer.

STEP 2. MIX SAMPLE WITH be.well™ ASSAY BUFFER



A. Open be.well™ Assay Buffer and insert Nasal Swab.

B. Stir Nasal Swab against be.well™ Assay Buffer vial wall 10 times.

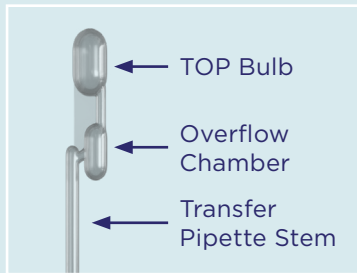


C. Remove Nasal Swab and recap be.well™ Assay Buffer.

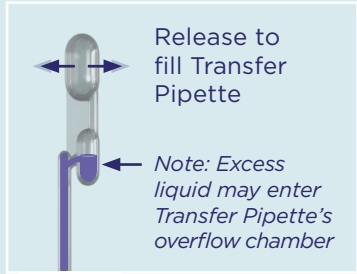
D. Invert sealed be.well™ Assay Buffer vial and flick 3-10 times to mix further.

E. Dispose of Nasal Swab in an appropriate waste container.

STEP 3. COLLECT SAMPLE FROM be.well™ ASSAY BUFFER

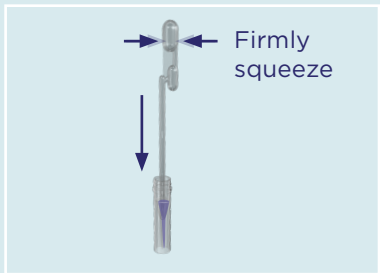


A. Uncap be.well™ Assay Buffer. Pick up Transfer Pipette.

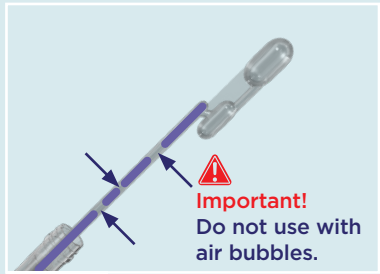


C. Slowly release the TOP bulb while tip is still in the fluid to fill Transfer Pipette stem.

Remove Transfer Pipette from be.well™ Assay Buffer once the stem is fully filled.

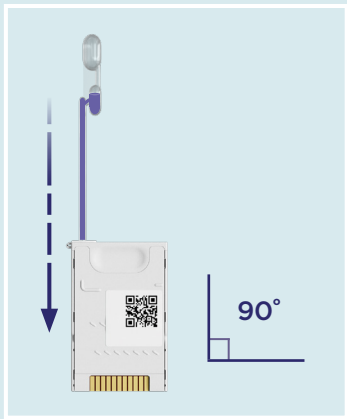


B. Firmly squeeze the TOP bulb of Transfer Pipette and lower the stem into be.well™ Assay Buffer until it touches the bottom of the vial.

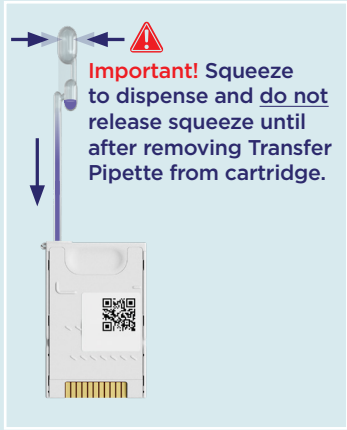


D. If Transfer Pipette stem has air bubbles or gaps, dispense fluid back into be.well™ Assay Buffer vial by squeezing the TOP bulb and repeat from step 3B.

STEP 4. FILL be.well™ COVID-19 CARTRIDGE WITH SAMPLE

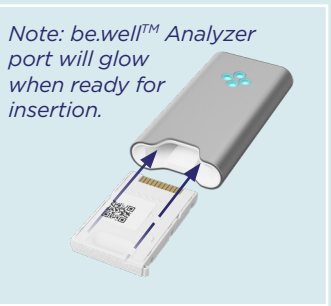


A. Hold be.well™ COVID-19 Cartridge upright and firmly insert Transfer Pipette into sample port.

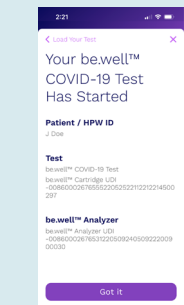


B. Slowly squeeze the TOP bulb to dispense all the fluid into the be.well™ COVID-19 Cartridge and, without letting go of the squeeze, remove the Transfer Pipette.

STEP 6. TEST SAMPLE



A. When directed by the be.well™ Mobile App, insert be.well™ COVID-19 Cartridge fully into be.well™ Analyzer port.



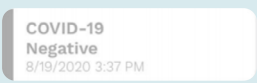
C. Press Got it on the be.well™ Mobile App. Enter symptoms.

WAIT! DO NOT touch or move be.well™ Analyzer while testing is in process.

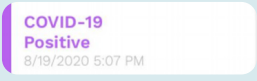
D. When Test Complete appears in the be.well™ Mobile App, remove and discard be.well™ COVID-19 Cartridge.

STEP 7. INTERPRET be.well™ COVID-19 TEST RESULT

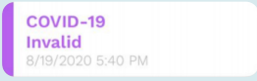
Read and record the results. Refer to Instructions For Use (IFU) for more guidance on reading the results.



A. Negative: No SARS-CoV-2 virus was detected in sample. If inconsistent with symptoms or exposure history, test again with a different authorized test.



B. Positive: SARS-CoV-2 virus was detected in sample.



C. Invalid: The presence of SARS-CoV-2 virus could not be determined in sample. Repeat testing using new test components and new nasal sample. If results are again invalid, test with a different commercial test.

Note: Results do not rule out other viral or bacterial infections.

3.7 Vdc Powered by Battery, 120 Vac from Power Adaptor
BLE: 2402-2480 MHz
PCB Antenna 0 dBi

Email Us: support@alveotechnologies.com
Call Us: +1-833-BE-WELL-0 (+1-833-239-3550)
Website: www.alveotechnologies.com

IMPORTANT: These are not the complete Instructions For Use (IFU). Read the be.well™ COVID-19 Test Instructions For Use (IFU) for complete information.

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