

VOILÀ!

By Precision Biomonitoring Inc.

Quick Start Guide

Voilà!™ Rapid Digital SARS-CoV-2 Antigen Test for Saliva



Read all the instructions carefully before using this device.



Test Purpose: To detect the SARS-CoV-2 antigen from a saliva sample.



Test Administration: This is a point-of-care (POC) test and can be administered by any healthcare professional in near patient settings.



Test Results: Will be available on your smartphone on the Voilà!™ application.

Materials provided in this kit



1 Voilà! antigen testing device



1 Reagent tube



1 Specimen container



1 Disposable graduated transfer pipette



1 Exact volume 100µl transfer pipette

Materials required but not provided:



Smartphone with a Bluetooth connection and Voilà! mobile application available through Google Play or the Apple App Store

IMPORTANT

Guidelines

- Dispose of all used materials and biohazard waste according to the appropriate local and federal regulations.
- Open the battery door using a coin. Remove the battery after use and dispose electronic waste according to local regulations.



Safety Precautions



Wash your hands immediately after removing gloves.



The reagent tube contains mild skin and eye irritants, wash affected area immediately if contact occurs.

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Before Starting the Test

- Rinse mouth with water, do not eat, drink (including water), smoke, or chew gum for 30 minutes before providing saliva sample.
- Ensure the smartphone is charged and Bluetooth is turned on. The mobile app should be downloaded and ready to run.

How to Conduct the Test



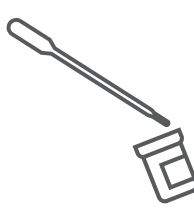
Step 1:

Remove the battery tab and connect to Voilà! mobile app. Ensure the Bluetooth on your phone is turned ON. Add a new test by scanning the QR code.



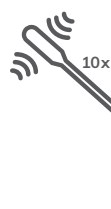
Step 2:

Allow saliva to pool in mouth, then collect in **SPECIMEN CONTAINER**. Repeat until there is at least 1 mL.



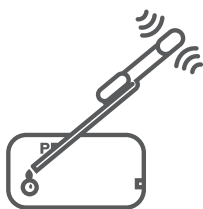
Step 3:

Pool saliva by tilting the **SPECIMEN CONTAINER** and use the disposable graduated transfer pipette to transfer 1 mL of saliva to the **REAGENT TUBE**.



Step 4:

Mix the saliva-reagent mixture by squeezing and releasing the bulb of the graduated transfer pipette 10 times slowly inside the reagent tube. Wait 5 minutes before proceeding to Step 5.



Step 5:

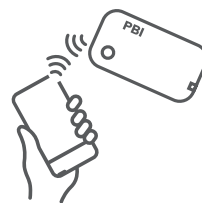
Place the Voilà! testing device on a flat surface. Select "start test" on the app.

Draw 100µl of the saliva-reagent mixture with the exact volume transfer pipette and dispense into the sample well of the Voilà! testing device.



Step 6:

Let the sample mixture run undisturbed for 17 minutes at room temperature.



Step 7:

The results will display automatically after 17 minutes on the Voilà! app.

The result will appear on the screen as positive, negative, or inconclusive. If the result is inconclusive, conduct another test with a new testing device.

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Investigational Device. To be Used by Qualified Investigators Only. Performance specifications of the device have not been established.

Instrument de recherche. Réserve uniquement à l'usage de chercheurs compétents. Les spécifications de rendement de l'instrument n'ont pas été établies.