ABSTRACT
This procedure outlines the protocol for testing for SARS-CoV-2 using a saliva sample collected from an individual. The purpose of this test is to detect low levels of SARS-CoV-2 antigen at a higher sensitivity. Precision Biomonitoring Inc. developed an ultra-rapid digital, disposable, highly-sensitive and inexpensive testing device used for screening purposes. The mobile app complementary to this medical device is connected through Bluetooth. Using this innovation, the user can be tested at point-of-care (POC) by a health care professional, and obtain qualitative results.

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WHAT'S NEW
Proper timing

KEYWORDS
Lateral Flow, Covid-19, SARS-Cov-2, Antigen Testing, Pandemic, Global Pandemic, Virus

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GUIDELINES
- The digital device kits should be stored at room temperature and should never be exposed to extreme temperatures.
- The digital device kits are for single use. Do not reuse the kits. Dispose of all used materials in a biohazard waste container.
- Positive test results should be confirmed by RT-PCR by a health professional.

MATERIALS TEXT
MATERIALS
- **SALIVA Lysis Tube** Precision Biomonitoring Inc. Catalog #SALT202001
- **Disposable Graduated Transfer Pipette** Fisher Scientific Catalog #13-711-9AM
- **Specimen Container** Canadawide Scientific Inc. Catalog #324-765-04
- **LFIA Testing Device** Precision Biomonitoring Inc. Catalog #N/A
- **Samco™ Exact Volume Transfer Pipettes, 100µL, Non-sterile** Thermo Fisher Catalog #787TS

SAFETY WARNINGS
When working with human saliva and other human bodily fluids, there may pathogens present. Wear the correct personal protection equipment (ie. gloves) and wash your hands immediately after removing the gloves.

BEFORE STARTING
Refrain from consuming food or beverage (including water) for 30 minutes before providing a saliva sample.

Setting up the test 20s

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Refrain from consuming food or beverage (including water) for 30 minutes before providing a saliva sample.

Ensure the smartphone is fully charged and Bluetooth on the smartphone is turned on. The mobile app should be downloaded and ready to run.

⚠️ When working with human saliva and other human bodily fluids, pathogens may be present. Wear gloves and wash your hands immediately after removing the gloves.

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Prepping ingredients

2 Collect saliva in

Specimen Container
Canadawide Scientific 324-765-04

3 Transfer 1 mL of saliva into the

SALIVA Lysis Tube
Precision Biomonitor SALLT202001

using the

Disposable Graduated Transfer Pipette
Fisherbrand™ 13-711-9AM

4 Mix the saliva-buffer mixture using the

Disposable Graduated Transfer Pipette
Fisherbrand™ 13-711-9AM

by squeezing the bulb of the pipette 10 times slowly in the Saliva Lysis Tube from Step 3.

5 Let saliva-buffer mixture sit at Room temperature for 00:05:00 before transferring mixture to LFA Device.

Using the Testing device

6 Using the

100μL Exact Volume Transfer Pipette
Thermofisher 787TS also known as Scientific 787
Apply 100 µl of the saliva-buffer mixture into the sample port of the

**LFIA Device**

**Precision Biomonitoring Inc.** N/A

7. Place the device on a flat surface. Let the sample mixture run undisturbed for **00:17:00** at **Room temperature**.

8. Ensure the smartphone is connected to the testing device through Bluetooth and read the results using the mobile phone app.

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