Detailed product description

Product or trade name:

Find® COVID-19

General Description:

Find® COVID-19 is a rapid point of care immunoassay for screening and triage testing of patients with suspected COVID-19. This test uses whole blood samples to detect as biomarkers antibodies against SARS-CoV-2 antigens present in the infection phase (NC and S proteins). This test was designed as a triage or screening test to be used within the diagnostic algorithm to rule out the disease in patients with signs and symptoms or asymptomatic. Patients with a positive result should be selected for the authorized confirmatory test.

The test is based on an agglutination reaction of the patient's blood that is carried out on a cellulose membrane (the "test card") previously covered with recombinant proteins that generate agglutination when the antibodies against the three selected markers (NC and S viral proteins) are present in a whole blood sample. These proteins bind to antibodies against three antigens related to the acute phase of the COVID-19 infection. The result of the test is evaluated by capturing a photograph of the test card with a smartphone application developed by Unima (Xplora®) which is part of this diagnostic kit. This application is capable of generating qualitative results by means of image analysis and neural network algorithms, which are executed locally in the software without the need of an internet connection or a cellphone network. Samples from positive patients generate an agglutination reaction that in turn generates certain specific visual patterns that are recognized and measured by the application while samples from negative patients do not generate these patterns. The final result of the test appears on the screen of the smartphone and is sent to a server in the cloud for result reporting when Internet connectivity is available.

Intended use

This test is used for point of care screening and triage testing of patients with characteristic symptoms related to a suspected infection by the SARS-CoV-2 virus. All patients with positive results must be selected for further confirmatory testing. This test can be used for ruling out COVID-19 on patients.

This test should be used only with whole blood samples without any level of hemolysis. The use of fresh whole blood specimens is recommended. Refrigerated specimens should be used before 72 h and after being allowed to recover to room temperature. If the sample specimen is to be stored in refrigeration, a 3.2% citrate tube must be used. EDTA could affect the results of this test. Frozen samples should never be used with this test.

This test is intended to be used by healthcare professionals and trained healthcare workers and should be used only on patients over 18 years of age.

List of Devices

This description applies to the following products:

1105 Find™ COVID-19 box with 25 tests

Product content list

Each box of product contains the following materials:

1105 Find™ COVID-19 box with 25 tests

25 Test cards

30 Capillary pipettes

30 Micropipette tips

30 Microtubes with buffer solution

1 Fixed volume micropipette

1 Plastic casing for test cards

1 Instructions for use

1 Smartphone validation instructions

The following additional materials are required to perform the test, but not provided with the test kit:

- smartphone with a fully functioning camera (at least 3 MP)
- Xplora™ application installed in the smartphone
- lancets
- alcohol pads
- disposable gloves

For evaluation of the test result, the Xplora™ app needs to be downloaded into a smartphone that has at least a 3 MP digital camera. After the picture of the paper device is taken, an image analysis process and neural network algorithms is run in the app to return a final result.

Test procedure

Finger prick collection

1. Rub the finger to stimulate blood flow and clean the patient figure with an alcohol swab to disinfect the sampling area (figure 1). Allow the cleaned area to dry in the air.

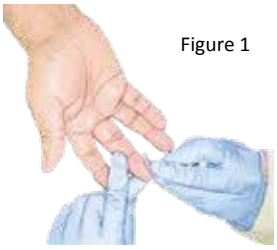


Figure 1

2. Prick the skin of the fingertip side with a safety lancet according to the manufacturer's instructions and keep the fingertip face down lightly pressing the bleeding point (figure 2). Allow for a drop of blood to be formed in the site. Discard the lancet in the biohazard waste bin.

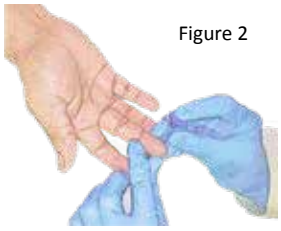


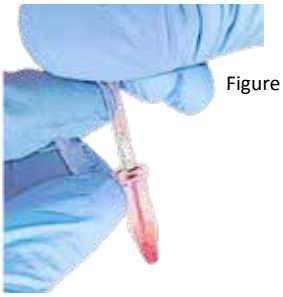
Figure 2

3. Collect the blood specimen with the capillary tube provided. This tube will collect the amount of blood required for the test (40 microl) and it must not be pressed or bent during the sample collection to prevent bubbles or an incorrect volume of sample to be taken (figure 3). If the blood on the prick was not enough to fill the tube, press the area around to extract more.

Figure 3

4. Open the buffer diluent tube provided and gently squeeze the tip of the capillary tube to pour the blood sample specimen in the buffer. To avoid generating foam in the suspension the tip of the tube should be inserted below the buffer level (figure 4). Without taking out the tube to avoid injecting air and foam, mix the suspension by gently pressing the capillary tip inside the suspension five times.

Figure 4



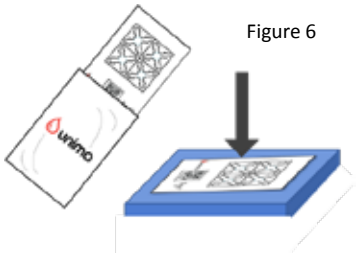
Paper device reaction

5. Leave all materials and specimens to reach room temperature if they were stored in refrigeration.

Figure 5

6. Take out the paper device from the aluminum foil pouch and put it on the plastic casing and close the lid immediately after placing the card (figure 6). If the foil pouch has any tears or is damaged in a way that compromises the integrity of the seal, discard the device.

Figure 6



7. Put a micropipette tip on the fixed volume pipette. Press the plunger to the first stop to take out the air and insert the tip on the blood suspension below the volume level to prevent the formation of foam in the suspension. Release the plunger to fill the tip then press again to expel the suspension (figure 7). This will generate a resuspension of the sample without generating foam. Repeat again four times without taking out the tip from the suspension to achieve an even mix.

Figure 7

8. Press one last time the plunger and release to get a suspension sample into the tip and add this sample into the first testing site of the paper device (figure 8). The sample must be added to the testing site by pushing the plunger to the second stop taking care of not touching the card with the pipette tip. Press the plunger slowly to prevent the blood sample to spill out the sample reservoir in the testing site.

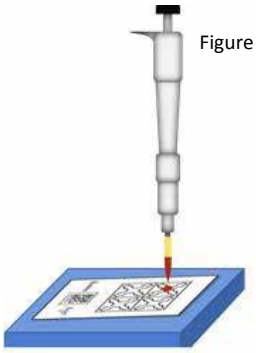


Figure 8

9. Repeat steps 3 and 4 until the four testing sites on the paper device have been filled. Start by filling the testing site in the upper left side marked with a number 1 in figure 9 and end with site marked as 4. After all sites have been filled, close by using a plastic casing lid over the paper divide. Wait 15 minutes for the reaction to occur.

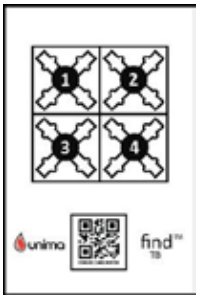


Figure 9

Result evaluation and interpretation

10. After 15 minutes open the lid of the plastic casing. Open the Xplora application in the smartphone (figure 10).
11. Scan the QR code in the paper device centering the scan icon in the smartphone screen with the QR code on the paper device (figures 11 and 12).
12. Next center the paper device inside the square icon on the screen of the smartphone. When the device is correctly centered inside of the square press the screen on the smartphone to take a photograph (figure 13).

13. Fill the age and gender input spaces when prompted by the smartphone application (figure 14).
14. The result of the test will appear on the screen of the smartphone application (figure 15).

Figure 10


Figure 11


Figure 12


Figure 13


Figure 14


Figure 15

Limitations and Contraindications of use

- Only whole blood samples without any level of hemolysis can be used with this test
- The use of fresh whole blood specimens is recommended. Refrigerated specimens should be used before 72 h and after being allowed to recover to room temperature. If the sample specimen is to be stored in refrigeration, a 3.2% citrate tube must be used. EDTA could affect the results of this test. Frozen samples should never be used with this test
- This test was designed as a triage or screening test in the COVID-19 diagnostic algorithm for ruling out disease in patients with typical signs and symptoms of the COVID-19 disease. All patients with positive results must be selected for further confirmatory testing
- This test is intended to be used only by healthcare professionals and trained healthcare workers
- This test may generate false negative results in case of very low antibody concentrations.
- This test should be used only in patients over 18 years of age.
- This test should not be used in patients with severe cases of anemia

- This test should not be used in patients with intravenous infusion

Images and description of the device and its accessories

The following is a list and description from each of the parts of the testing kit, images do not reflect actual scale and colors may vary and are only intended as a visual description:

Testing card: Paper microfluidic card device for the qualitative detection of antibodies against target viral proteins

Capillary pipet: Fixed volume pipette used to draw a whole blood 40 µl sample from a finger prick

Buffer Tube: Plastic conical tube with 160 µl buffer solution used to dilute and suspend the patient's blood sample previously to being dosed to the testing device

Micropipette and tip: Fixed volume micropipette used to dose 30 µl of buffer + blood suspension to the paper device testing sites

Plastic protective case: Plastic base and cover used to protect the paper testing device from the environmental conditions preventing dampening of the paper surface or evaporation of the blood sample during testing process

Analytical validation of sensitivity and specificity of FIND™ COVID-19 in whole blood

Study Protocol
CSPFind 20-01 Find COVID-19 Internal Validation Study

Study dates:
March 20 to April 3

Study site:
Unima Inc R&D Department

Specimen source
Volunteers positive to COVID-19 confirmed by RT-PCR, Volunteers negative to COVID-19 antibodies confirmed by ELISA testing, Serum specimens from patients sampled in 2018 and 2019 (previously to COVID-19 pandemic).

Acceptance criteria:
the product must have Sensitivity and Specificity over 90%, comparable with current rapid tests CE marked for COVID-19.

Study design
A single-blind prospective study collecting specimens from patients diagnosed with the COVID-19 infection and volunteers not presenting symptoms suggestive of COVID-19.

Study population:
For specimen collection, three groups were selected. The first group included volunteer patients that were previously diagnosed with the COVID-19 infection by RT-PCR with no more than 10 days after being sampled for the diagnostic. A second group included asymptomatic volunteers selected with no current symptoms suggestive of the COVID-19 infection (fever, cough shortness of breath) whose specimens were subsequently confirmed as positive or negative to COVID-19 antibodies by ELISA testing. A third group included sera samples from a specimen bank collected for a previous Tuberculosis validation protocol before December 2019 and therefore from patients never exposed to the disease, which were also confirmed as negative to COVID-19 antibodies by ELISA testing. All volunteers were invited to participate in the study and signed their informed consent.

Inclusion criteria:

Positive specimens: volunteer patients that were previously diagnosed with the COVID-19 infection by RT-PCR with no more than 10 days after being sampled for the diagnostic or volunteers who were positive reactive to presence of antibodies by the ELISA test, 18 years of age or older, not under COVID-19 treatment and able and willing to provide informed consent for participation in the study.

Negative specimens: volunteers selected with no current symptoms suggestive of the COVID-19 infection (fever, cough shortness of breath) whose specimens were subsequently confirmed as negative to COVID-19 antibodies by ELISA testing. Additionally, it was included a group of sera samples from a specimen bank collected for a previous Tuberculosis validation protocol before December 2019 and therefore from patients never exposed to the disease, which were also confirmed as negative to COVID-19 antibodies by ELISA testing.

Exclusion criteria:

Positive specimens: volunteer patients who were not confirmed as positives by RT-PCR testing or were negative to antibody presence by ELISA testing, with less than 18 years of age and/or unable to provide informed consent.

Negative specimens: volunteers who tested positive to anti-COVID-19 antibodies in the ELISA test, with less than 18 years of age and/or unable to provide informed consent.

Test Methods:

For fresh blood specimens from volunteers and patients: a blood sample (two drops or approximately 40 µl) is taken from a patient using a finger prick and drawn using a capillary pipette. The specimen is then mixed with 190 µl dilution buffer provided in a tube with the testing kit. After the blood sample has been mixed with the buffer, it is important to run the test as soon as possible. The mixed sample (30 µl) is then deposited on the c enter of the first test site of the test card. This process is repeated until the four test sites of the diagnostic card have been filled. It is estimated that 45 seconds is an adequate period for filling all the test sites of the card.

For sera specimens from sample bank: 16 µl of the sera specimen is added to 24 µl of washed erythrocytes and the suspension is mixed until homogeneous. Then the suspension is mixed with 190 µl dilution buffer provided in a tube with the testing kit. After the blood sample has been mixed with the buffer, it is important to run the test as soon as possible. The mixed sample (30 microliters) is then deposited on the c enter of the first test site of the test card. This process is repeated until the four test sites of the diagnostic card have been filled. It is estimated that 45 seconds is an adequate period for filling all the test sites of the card.

Once the test sites in the card have been filled, a cover is placed over the test card, and after 10 minutes a photograph of the test card is taken with the Xplora™ smartphone application, and the result can be read on the screen as negative or positive. In case of an indeterminate result, the test

should be repeated using a new test card and blood sample. Find™ COVID-19 test result for COVID-19 is for research purposes use only.

Cohort sample profle:
A total of 193 samples were tested, including 108 positive samples and 85 negative samples.

Data management and statistical analysis:
Testing results were captured electronically in an Excel file. Reference results were blinded for personnel executing the testing protocol. Testers registered results in the appropriate format and then the study director registered the reference result for each sample.

Data segmentation:
According to the testing results, these were segmented in the following way:

		Reference test		
		Positive	Negative	
Find™ COVID-19 test	Positive	A	B	A + B
	Negative	C	D	C + D
		A + C	B + D	N

Sensitivity and specificity were calculated for the total results of the protocol using the following formulas:

Sensitivity = A / (A + C)
Specificity = D / (B + D)

Results:
Results from tests are summarized as follows:

Find™ COVID-19	Reference result	
	Positive	Negative
Positive	100	7
Negative	8	78
	108	85

$$\text{Sensitivity} = \frac{Positive}{Positive + False\ Negative} = 92.6\%$$

$$\text{Specificity} = \frac{Negative}{Negative + False\ positive} = 91.8\%$$

Conclusion
This validation represented an initial estimation of the Sensibility and Specificity Find™ COVID-19 and the reference COVID-19 diagnostic test to evaluate the Sensibility and Specificity of the test. In the analyzed cohort, the results shown a Sensibility of 92.6% and a Specificity of 91.8%.