CerTest BIOTEC

CerTest Rapid Test

CerTest *SARS-CoV-2* card test

Test for antigen detection

Now available!

Rapid mass diagnosis

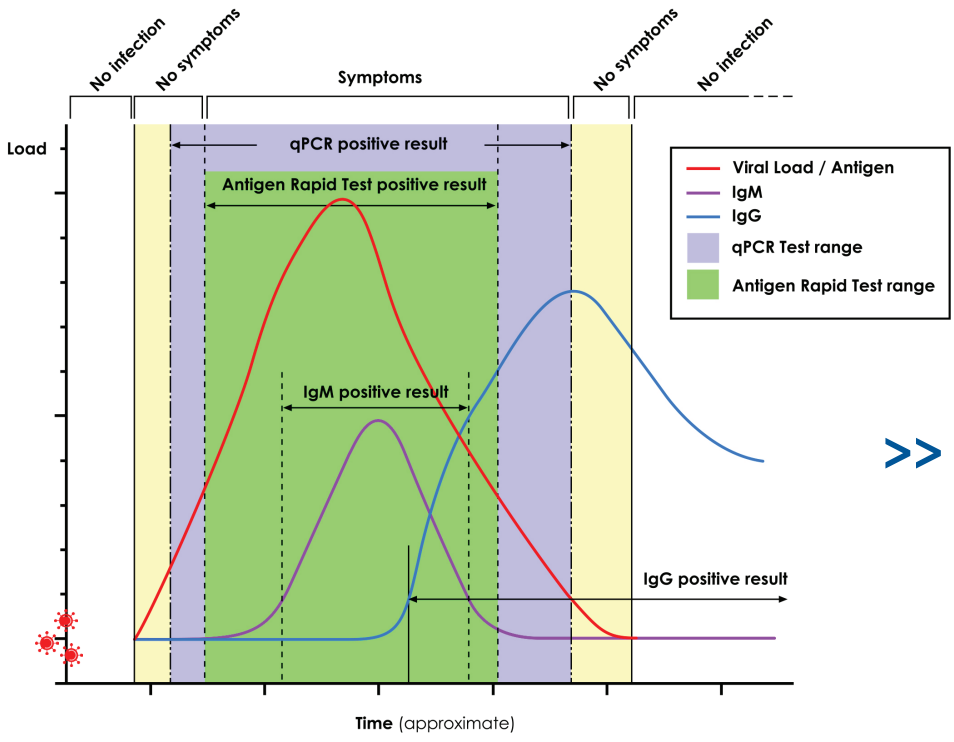
The ***One Step* SARS-CoV-2 *Antigen Test Device*** is a rapid chromatographic immunoassay for the **qualitative detection of Coronavirus (SARS-CoV-2) antigens** in human nasopharyngeal swab specimens to aid in the diagnosis of Coronavirus (SARS-CoV-2) respiratory infection.

This rapid test represents a valuable alternative in the context of a global shortage of diagnostic tests and allows to obtain results quickly and reliably, in a wide population group.

Clinically, patients with SARS-CoV-2 infection tend to suffer symptoms such as olfactory and gustatory dysfunction, fever, dry cough, anosmia, fatigue, dyspnoea, headache, diarrhoea and sore throat, followed by vascular and systemic complications. COVID-19 commonly results in pneumonia, which can evolve into acute respiratory distress syndrome, leading to respiratory or multiorgan failure.

On March 11, 2020, the WHO declared the disease a pandemic, due to the high number of infected people and the rapidity of its spread worldwide.

The following graph shows the evolution of disease:



Non-invasive diagnosis.
Nasopharyngeal swab sample.

No need for additional equipment.
All components included in the kit.

Low cost throughout the process, reaching less developed populations.

Immediate results.
Result in 10 minutes

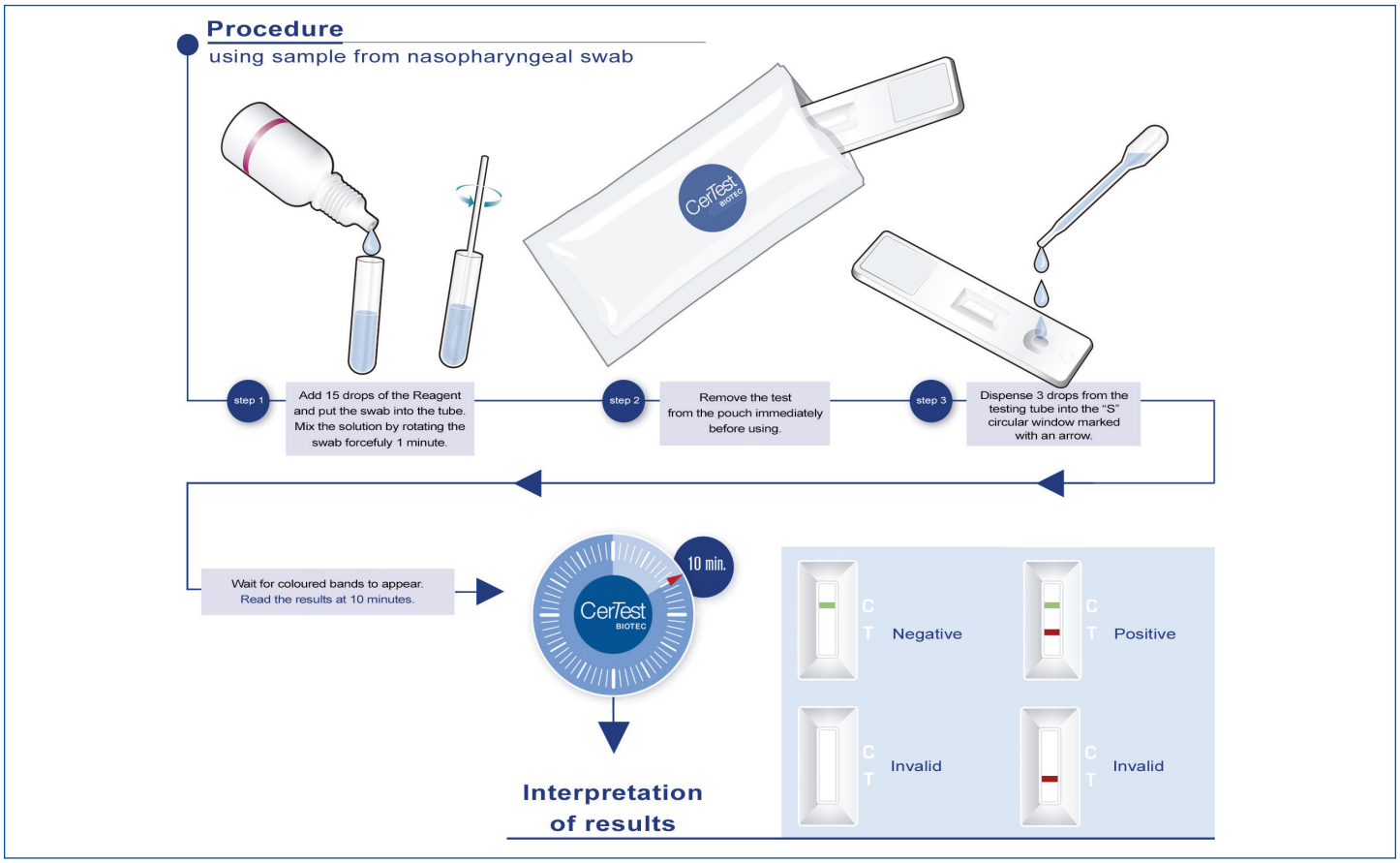
Very simple use and interpretation.
More amount of analysis in the same time.

>> **Comparing antigen detection with antibody detection, detection period is longer for antigens, and the diagnosis is earlier.**

CerTest *SARS-CoV-2* card test

Procedure.

Although it is a very simple test to use, the handling of the samples is considered potentially dangerous, so they must be treated in the same way as an infectious agent, and by trained and qualified personnel.



Sensitivity & Specificity

CerTest SARS-CoV-2 vs. qPCR Technique		
	Mean Value	**95% Confidence interval**
Sensitivity (*)	92.9%	76.5 - 99.1%
Specificity	99.6%	97.6 - 100.0%
PPV	96.3%	81.0 - 99.9%
NPV	99.1%	97.0 - 99.9%

(*) Taking into account the recommendations for *Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays (11 September 2020)* from the WHO, the sensitivity of the test was calculated with nasopharyngeal samples with high viral load (high viral loads is expected in early symptomatic phases of the illness (with the first 5-7 days of illness) in the range of Ag-RDT test detection).

Detection of the viral antigen implies the presence of the virus, **so a positive test result is indicative of current SARS-CoV-2 infection**. High specificity implies high reliability of the positive result. On the other hand, **at the discretion of the prescriber, a negative result may require confirmation by another technique.**

CerTest BIOTEC

For more information and procedure for use, read the instructions for use included in this product.

CE IVD CSQ MED ISO 13485

RapidTest/SARS-CoV-2/0920EN

Proflow™ SARS-CoV-2 Antigen Test

(for In Vitro Diagnostic use only)

PRODUCT CODE PL.3034 20 Tests

CE

INTENDED USE

The Proflow™ SARS-CoV-2 test is a rapid chromatographic immunoassay for the qualitative detection of Coronavirus (SARS-CoV-2) antigens in human nasopharyngeal swab specimens to aid in the diagnosis of Coronavirus (SARS-CoV-2) infection. For Professional In Vitro Diagnostic Use.

SUMMARY AND EXPLANATION

Recently, SARS-CoV-2 (Severe Acute Respiratory Syndrome Corona Virus 2) emerged as a new species able to infect humans and currently causing the COVID-19 (Coronavirus disease-19) pandemic, with an overwhelming hospitalization of infected patients. Clinically, patients with SAR-CoV-2 infection tend to suffer symptoms such as olfactory and gustatory dysfunction, fever, dry cough, anosmia, fatigue, dyspnoea, headache, diarrhoea and sore throat, followed by vascular and systemic complications, such as leukocyte infiltration of the lungs. COVID-19 commonly results in pneumonia, which can evolve into acute respiratory distress syndrome, leading to respiratory or multiorgan failure.

Coronaviruses (CoVs) belongs to the order of Nidovirales, identified by its envelope characteristics and positive-sense RNA as genetic material. CoVs consist of four structural proteins: spike (S), membrane (M), envelope (E) and nucleocapsid (N) proteins.

The M and E proteins are essential for virus assembly, while the S protein, on the surface of the viral particles, is crucial for affinity and attachment to host cells. The S protein, responsible for viral entry, determines the host tropism and virus transmission. The N protein, the main structural protein of SARS-CoV-2 is responsible for the transcription and replication of viral RNA, the packaging of the encapsulated genome into virions and interactions with the cell cycle of host cells. In addition, the N protein, which has a substantial immunogenic ability, is abundantly expressed during viral infection.

It is believed that the high transmissibility of COVID-19 is related to its high viral loads in the upper respiratory tract and the fact that many individuals remain asymptomatic, shedding and transmitting the virus. The COVID-19 virus transmission occurs via droplets of saliva or discharge from the nose of infected individuals, therefore following proper hygiene practices when coughing and sneezing are keys to deplete transmission.

PRINCIPLE OF THE TEST

The Proflow™ SARS-CoV-2 test is a qualitative lateral flow immunoassay for the detection of Coronavirus (SARS-CoV-2) antigen in human nasopharyngeal samples. The membrane is pre-coated with monoclonal antibodies against SARS-CoV-2 antigens on the test line region. During testing, the sample reacts with the particle coated with anti-SARS-CoV-2 antibodies which was pre-dried on the test strip. The mixture moves upwards on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate a coloured line. A green coloured line always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

MATERIALS PROVIDED

- PL.3134 Proflow™ SARS-CoV-2 Test Device: 20 devices
- PL.3234 Proflow™ SARS-CoV-2 Diluent
- Proflow™ test tubes: 20
- Proflow™ pastettes: 40
- Proflow™ swabs: 20
- Proflow™ laboratory rack
- Package insert
- Proflow™ positive control swab

MATERIALS REQUIRED BUT NOT PROVIDED

- Sample collection container
- Timer or stopwatch
- Biohazard disposal container
- Disposable gloves

STABILITY AND STORAGE

- Store all components at 2-30°C.
- **Do not freeze or overheat.**
- Do not use beyond the expiration date printed on the outer package label.

PRECAUTIONS

- For Professional In Vitro Diagnostic use only.
- Directions should be read and followed carefully.
- Tests are for single use only. Do not reuse.
- Do not dilute reagents.
- Do not interchange reagents between kits with different lot numbers.
- Do not use kits or reagents beyond the stated expiration dates.
- Microbial contamination of reagents may decrease the accuracy of the assay.
- Treat all materials as if they were infectious and dispose of all material in accordance with local regulation.
- The test must be carried out within 2 hours of opening the sealed pouch.
- Do not use if the pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposable gloves, do not eat, drink or smoke in the area.
- The test should be discarded in a proper biohazard container after testing.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. Please, take note that the COVID-19 infection is very dangerous, please take appropriate precautions.
- The presence of yellow lines in the results window, in the region of the control and test line zones, visible before using the test are normal. The test is still valid and suitable for use.
- Sterile swabs provided in the kits should be only used for taking the nasopharyngeal sample. They cannot be reused.
- Do not touch the head of the sterile swabs provided when opining their primary packaging to avoid contamination.

SAMPLE STORAGE AND COLLECTION

NASOPHARYNGEAL SWAB METHOD

- Bend shaft to follow curve of nasopharynx.
- Insert swab through nostril to posterior nasopharynx.
- Rotate swab a few times to obtain infected cells.
- For an optimal sample, repeat procedure using other nostril.

Test sample as soon as possible as testing sensitivity decreases over time.Cool specimen to 2-8°C (36-46.4°F) during storage and transport for 8 hours prior to testing.

QUALITY CONTROL PROCEDURE

Internal procedural controls are included in the test. A green line appearing in the control line region (C) confirms sufficient specimen volume and correct procedural technique

TEST PROCEDURE

Allow the tests, samples, controls and buffer to reach room temperature (15-30°C/59-86°F) prior to testing. Do not open pouches until ready to perform the assay.

NASOPHARYNGEAL SWAB METHOD

1. Remove the test from its pack just before use. Place the test on a clean flat surface.
2. Label each test with appropriate patient information.
3. Use a separate pastette and test for each sample or control.
4. Add 15 drops (or 500µL) of diluent into the test vial.
5. Add the swab, mix to remove cells from swab and extract as much liquid from the swab as possible by squeezing against the side of the vial.
6. Dispense 3 drops (or 150µL) of the sample mix into specimen well (S).
7. Read the result at 10 minutes. Do not read the results after 10 minutes as they may be inaccurate.

INTERPRETATION OF RESULTS

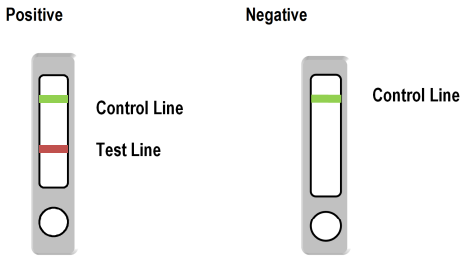
The intensity of the red coloured test line in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

Positive

Two lines appear across the central window, a red test line marked with the letter T and a green control line marked with the letter C.

Negative

Only one green line appears across the control line region marked with the letter C (control line).



Invalid

No line appears in the test window at the control line position. This is an invalid result and cannot be interpreted. This is irrespective of whether or not a coloured line appears in the test window at the test line position. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test.

Proflow™ SARS-CoV-2 Antigen Test

(for In Vitro Diagnostic use only)

PRODUCT CODE PL.3034 20 Tests

INTERPRETATION NOTES

The intensity of the red coloured test line in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

LIMITATIONS OF THE PROCEDURE

1. The Proflow™ SARS-CoV-2 Test will only indicate the presence of Coronavirus (SARS-CoV-2) in the specimen (qualitative detection) and should be used for the detection of Coronavirus (SARS-CoV-2) antigens in nasopharyngeal specimens only (from swab). Neither the quantitative value nor the rate of increase in Coronavirus (SARS-CoV-2) antigens concentration can be determined by this test.
2. VTM, UTM and Saline Buffer are the transport media validated for use with this device. Following always proportion 1:1 (transport media and sample diluent provided with the device). When using transport media the sensitivity of the device can be reduce due to excessive dilution of sample. The preference is to use the sample immediately after taking it.
3. Positive results do not rule out co-infections with other pathogens.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Coronavirus (SARS-CoV-2) infection.
5. This test provides a presumptive diagnosis of Coronavirus (SARS-CoV-2) respiratory infection. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES

On March 11, 2020 the World Health Organization (WHO) declared COVID-19 a pandemic. COVID-19 has led to an emerging, rapidly evolving situation: reaching more than 200 countries, areas, or territories, to date, and causing thousands of deaths, with an overall mortality around 3%. Emerging data from patients afflicted by COVID-19 indicate that genetic immunologic, metabolic and environmental factors are involved in the pathogenesis of COVID-19. It was found that certain infected people were asymptomatic. These individuals are an important reservoir for spread of the infection.

PERFORMANCE CHARACTERISTICS

LIMIT OF DETECTION

The detection limit value (typical value) is: 1 ng/mL of SARS-CoV-2 Recombinant Nucleoprotein or $1x10^3 TCID_{50}$/mL of 2019nCoV/USA-WA1/2020.

SENSITIVITY AND SPECIFICITY

An evaluation was performed on 262 nasopharyngeal samples from people suspected of infection by SARS-CoV-2. The evaluation was performed using Proflow™ SARS-CoV-2 versus qPCR.

		qPCR technique		
		+	-	Total
IC test: Proflow™ SARS-CoV-2	+	26	1	27
	-	2	233	235
	Total	28	234	262

Proflow™ SARS-CoV-2 vs qPCR technique		
		95% CI (Confidence interval)
Sensitivity	92.9%	76.5-99.1%
Specificity	99.6%	97.6-100,0%
PPV	96.3%	81.0-99.9%
NPV	99.1%	97.0-99.9%

Recommendations of the WHO: "Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays (11 september 2020)" were considered. Sensitivity of the test was calculated with nasopharyngeal samples with high viral load in the range of Ag-RDT detection. High viral loads are expected in early symptomatic phases of the illness (first 5-7 days of illness).

HOOK-EFFECT

The device does not show hook effect at the concentration of SARS-CoV-2 protein tested (202500.0 ng/mL).

CROSS-REACTIVITY

An evaluation was performed to determine the cross-reactivity of the Proflow™ SARS-CoV-2 Test. There was no cross reactivity with common respiratory pathogens, other organisms and substances that could cause infections:

Yersinia enterocolitica O:3/O:9	*Coronavirus strain OC43*
Hemoglobin (human/bovine/pig)	*Entamoeba histolytica*
Calprotectin (human)	*Escherichia coli O157:H7*
Campylobacter jejuni	*Giardia*
Clostridium difficile GDH/Toxin A /Toxin B	*Helicobacter pylori*
Coronavirus strain 229E	*Astrovirus*
Coronavirus strain NL63	*Influenza A/Influenza B*
Salmonella enteritidis/paratyphi A/typhi/typhimurium	*Lactoferrin (human)*
Shigella boydii/dysenteriae/ flexneri/ sonnei	*Legionella*
Listeria monocytogenes	*Rotavirus*
Norovirus GI/Norovirus GII	*Streptococcus pyogenes*
Streptococcus pneumococcal	*Transferrin (human)*
Respiratory syncytial virus	*Adenovirus*

Proflow™ SARS-CoV-2 Test has some cross reaction with SARS and very low cross reaction with MERS.

INTERFERENCES

An evaluation was performed to determine interfering substances with Proflow™ SARS-CoV-2 Test. No interference was found with the following substances:

Aceltylcysteine (*Fluimucil*)	Cloperastine (*Flutox*)	Loratadine
Dexchloropheniramine (*Polaramine*)	Ebastine (*Ebastel*)	Prednisone
Ambroxol hydrochloride (*Mucosan*)	Metamizole (*Nolotil*)	Lorazepam
Lysine Carbocysteinate (*Pectox*)	Almagato (*Almax*)	Omeprazole
Phenoxymethylpenicillin potassium	Ibuprofen (*Espidifen*)	Ciprofloxacin
Dexketoprofen trometamol (*Enantyum*)	Mercaptopurine	Amoxicillin
Loperamide hydrochloride (*Fortasec*)	Oseltamivir	Ampicillin
Carbocisteine (*Iniston mucolítico*)	Paracetamol (*Dolocatil*)	Amantadine
Hydroxyzine dihydrochloride	Benzocaine(*Angileptol*)	Levofloxacin
Fosfamycin (*Monurol*)	Heparin *(Hibor)*	Metronidazole
Macrogol 3350 (*Movicol*)	Rifampicin (*Rifaldin*)	Ribavirin
Acetyl Salicylic (*Adiro*)	Codeine (*Toseina*)	

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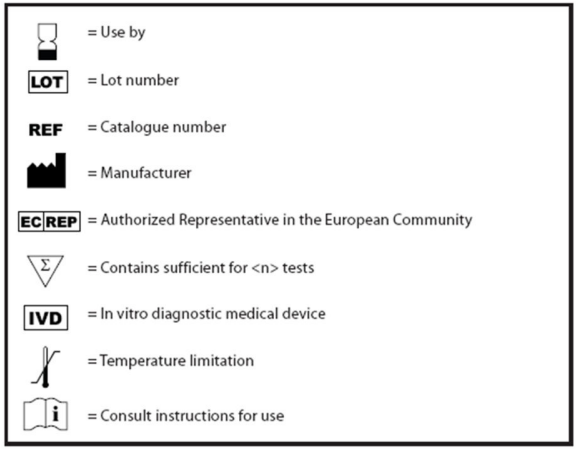
2. Abiodun Iwalokun, B.; Olalekan, A.; Adenipekun, E.; Ojo, O.; Senapon Iwalokun, O.; Mutiu, B.; Orija, O.; Adegbola, R.; Salako, B. and Akinloye, O. Improving the Understanding of Immunopathogenesis of Lymphopenia as a Correlate of SARS-COV-2 Infection Risk and Disease Progression in African Patients: UGLY SARS-COV-2 Study Protocol. Journal of Medical Internet Research. https://preprints.jmir.org/preprint/21242. Jun. 2020.
3. Giménez, E.; Albert, E.; Torres, I.; Remigia, M. J.; Alcaraz, M. J.; Galindo, M. J.; Blasco, M. L.; Solano, C.; Forner, M. J.; Redón, J.; Signes-Costa, J. and Navarro, D. SARS-CoV-2-reactive interferon-γ-producing CD8+T cells in patients hospitalized with Coronavirus Disease 2019. Journal of Medical Virology. https://doi.org/10.1002/jmv.26213. Jun. 2020.
4. Word Health Organization, Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Interim guidance. 11 september.



Proflow™ SARS-CoV-2 ANTIGEN TEST

NOW CE MARKED!

The Proflow™ SARS-CoV-2 Antigen Test is designed for the rapid identification of SARS-CoV-2 antigens in human nasopharyngeal swab samples and will provide results in only 10 minutes!

PRINCIPLE OF THE TEST: The Proflow™ SARS-CoV-2 test is a qualitative lateral flow immunoassay for the detection of Coronavirus (SARS-CoV-2) antigen in human nasopharyngeal samples. The membrane is pre-coated with monoclonal antibodies against SARS-CoV-2 antigens on the test line region. During testing, the sample reacts with the particle coated with anti-SARS-CoV-2 antibodies which was pre-dried on the test strip. The mixture moves upwards on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate a coloured line. A green coloured line always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

SAMPLE STORAGE AND COLLECTION (NASOPHARYNGEAL SWAB METHOD)

- Bend shaft to follow curve of nasopharynx.
- Insert swab through nostril to posterior nasopharynx.
- Rotate swab a few times to obtain infected cells.
- For an optimal sample, repeat procedure using other nostril.

Test sample as soon as possible as testing sensitivity decreases over time. Cool specimen to 2-8ºC (36-46.4ºF) during storage and transport for 8 hours prior to testing.

TEST PROCEDURE: Allow the tests, samples, controls and buffer to reach room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until ready to perform the assay.

NASOPHARYNGEAL SWAB METHOD

- Remove the test from its pack just before use. Place the test on a clean flat surface.
- Label each test with appropriate patient information.
- Use a separate pastette and test for each sample or control.
- Add 15 drops (or 500µL) of diluent into the test vial.
- Add the swab, mix to remove cells from swab and extract as much liquid from the swab as possible by squeezing against the side of the vial.
- Dispense 3 drops (or 120µL) of the sample mix into specimen well (S).
- Read the result at 10 minutes. Do not read the results after 10 minutes as they may be inaccurate.

PERFORMANCE CHARACTERISTICS

Proflow™ SARS-CoV-2 vs qPCR technique		
		95% CI (Confidence interval)
Sensitivity	92.9%	76.5-99.1%
Specificity	99.6%	97.6-100,0%
PPV	96.3%	81.0-99.9%
NPV	99.1%	97.0-99.9%

Please refer to current instructions for use for full details.