COVID-19 Self-Test

Rapid antigen self-test for the detection of SARS-nCoV-2 N-protein from anterior nasal swabs.

Please carefully read all instructions. Failure to follow instructions may lead to incorrect results.

medi-tech.co.za/app/

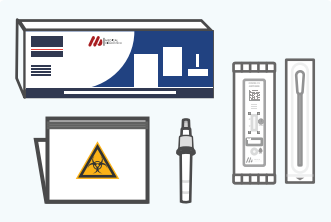
Scan[1] the code or search for HealthPulse TestNow in the Google Play Store or Apple App Store to download the HealthPulse TestNow app.

GET IT ON Google Play | Download on the App Store

MEDICAL DIAGNOSTECH

Ref: MDCOVIDAS, ver: 220608

Kit Contents



- Kit box with tube holder
- Lower nasal swab
- Test cassette
- Tube (with liquid) and nozzle
- Biohazard waste bag
- Instructions for use

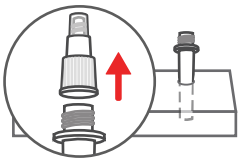
Kit Instructions

1 Clean hands

- Anyone touching supplies must clean their hands.
- Use sanitizer or wash hands with soap and warm water for 20 seconds and dry them.

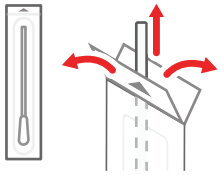
2 Prepare to test

- **Tap tube a few times** until liquid pools at the bottom.
- Stand up tube in the small hole of the kit box.
- Unscrew the large purple cap from the tube so no liquid spills.



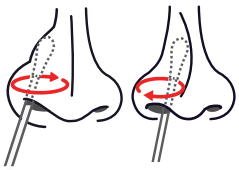
3 Open nasal swab

- Remove the nasal swab from the wrapper by pulling the two ends of the wrapper apart.
- Touch only the swab handle, not the tip.



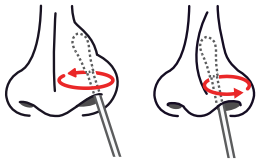
4 Swab first nostril

- Gently insert the entire soft tip of the swab into one nostril until you feel a bit of resistance (**less than 2,5cm**).
- Using medium pressure, rub the swab slowly in a circular motion around the inside wall of the nostril **5 times.**



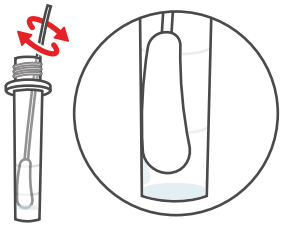
5 Swab other nostril

Repeat the process with the same swab in the other nostril.



6 Put swab in tube

- Insert the swab tip first into the tube.
- Stir for **10 seconds** in a clockwise direction and **10 seconds** in an anti-clockwise direction.
- Press the swab tip against the side of the tube through each rotation.

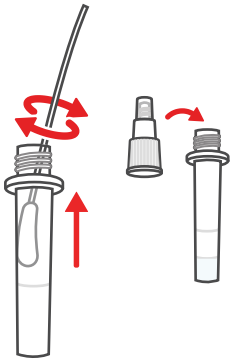


7 Wait for one minute

Leave swab in tube for **1 minute**.

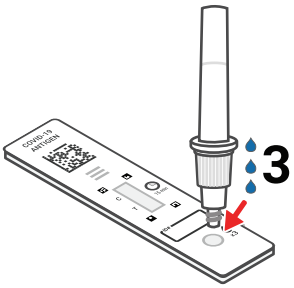
8 Remove swab from tube

- Pick up the tube from the kit box.
- Rub the tip of the swab against the wall of the tube as you pull it out. Squeeze as much liquid out of the swab as possible.
- Screw the large purple cap tightly onto the tube.



9 Activate test

- Open the test cassette and lay flat.
- Remove the small clear cap from the tube.
- Ensure tube is vertical and gently squeeze 3 drops into the sample well on the test cassette.



10 Wait for test to process

Wait 15 minutes for the test to process.

1 Scanning capabilities can vary by phone and may require a third-party application. You can also download the app by searching for HealthPulse TestNow in the Google Play store and Apple App Store.

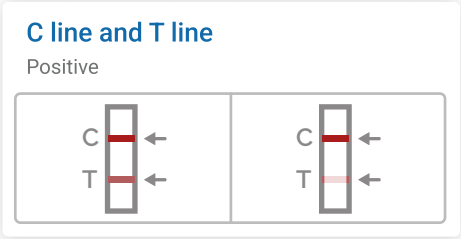
Medical Diagnostech (PTY) LTD, Unit 3 on London, London Circle, Brackengate Business Park, Brackenfell, Cape Town, South Africa, 7560.
Phone: +27 (0) 982 0673 Fax: +27(0) 86 657 2335 Email: info@medi-tech.co.za

Continue to page 2 →

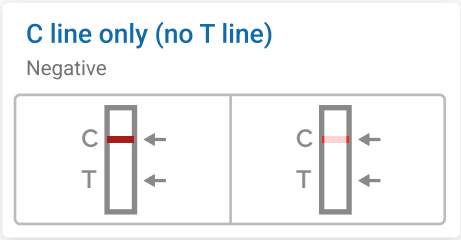
11 Read result

Read the test cassette using the images below as a guide.

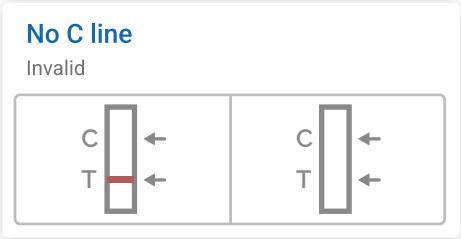
Positive:
The top C line (control line) and T line (test line) can both be seen.



Negative:
The C line is present but there is no T line. This demonstrates that the test was performed correctly but no COVID-19 antigens were detected.



Invalid:
Either no lines are observed or a T line without a C line is present. A result cannot be determined and retaking a test is recommended.



Note: Discard the test cassette, nasal swab, and buffer tube in the provided biohazard waste bag after use.

PLEASE READ:
Seek immediate medical care from a healthcare professional if seriously ill. Call your nearest healthcare center if having a medical emergency. Signs of a serious medical condition include, but are not limited to: severe shortness of breath or difficulty breathing, coughing up blood, chest pain, irregular heartbeat, persistent vomiting or diarrhea.

Storage conditions and shelf life:

- Store kits at room temperature between 4 and 40°C.
- Store in a dry place, humidity can affect test performance.
- The test devices must remain pouched until usage.
- The kits have a shelf-life of 24 months after manufacturing.
- The expiration date printed on the kits and pouches must be verified prior to use.
- Kits should not undergo freezing conditions.

Intended Use:
The MD SARS-nCoV-2 Antigen Device is a rapid visual immunoassay for the qualitative detection of the COVID-19 Nucleocapsid protein (N-protein) antigen from lower nasal swabs. It is intended to accurately diagnose acute infection and informs on whether the patient is currently infected. NOTE: This is different to antibody tests which informs on whether the patient has built up immunity against the virus. Using N-protein technology for the detection of viral proteins, the MD SARS-nCoV-2 Antigen device is highly sensitive and can detect viral antigens down to a concentration of ~ 1 ng/ml.

The MD nCoV-2 Antigen Device is sensitive enough to detect acute infection, but not as sensitive as Reverese Transcription-polymerase reaction (RT-PCR) which is prone to detecting inactive virus. RT-PCR is a molecular assay for the qualitative detection of viral RNA or nucleic acids and is considered the 'gold standard' for the detection of some viruses. This phenomenon has been proven by testing real patients in a clinical setting over a course of their infection cycle. This dramatically lowers the probability of reporting a positive result for non-infectious individuals.

Principle of the test:
The MD SARS-nCoV-2 Antigen device detects COVID-19 through visual interpretation of colour development on the membrane. Capture monoclonal antibodies (anti-COVID N-protein (T)) are immobilized onto nitrocellulose membrane. Virus particles are released which bind selectively to these antibodies as the sample is wicked up the strip. The colloidal gold signal reagent is coated with specific COVID-19 antibodies which bind with the antibody-antigen complexes formed on the membrane, producing a red line. Presence of a coloured line at the T-line region indicates a positive result, while their absence indicates a negative result. The presence of the C-line demonstrates that the test has been performed correctly.

Precautions and warnings:

- For in vitro diagnostic use only.
- All tests are for single use; do not re-use.
- Follow the test procedure, results interpretation, and precautions precisely in order to get accurate results.
- Do not open the sealed pouch, unless ready to conduct the test.
- Do not use expired tests.
- Do not mix reagents and components from different test kits.
- Do not use the test if pouch is damaged or the seal is broken.
- Do not eat, drink or smoke while handling specimens and test devices.
- The MD SARS-nCoV-2 Antigen device does not present any risk to the user if used as recommended.

Limitations of the test:

- The MD SARS-nCoV-2 test is intended to be used for the qualitative detection of COVID-19 antigens only.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods (e.g. RT-PCR) is recommended. A negative result does not at any time rule out the existence of COVID-19 antigens in human nasal swab samples, as the antigens may be absent or below the minimum detection level of the test.

Internal quality control:
The MD SARS-n-CoV-2 antigen test includes a control line which is used as a procedural control. It should always appear confirming the test procedure has been performed accurately.

Symbols

IVD	For in-vitro diagnostic use only	2	For single use only
	Content		Expiry date
LOT	Lot number		Storage temperature

Medical Diagnostech (PTY) LTD, Unit 3 on London, London Circle, Brackengate Business Park, Brackenfell, Cape Town, South Africa, 7560.
Phone: +27 (0) 982 0673 Fax: +27(0) 86 657 2335 Email: info@medi-tech.co.za