MD SARS-nCoV-2 Antigen Test (COVID-19 Acute Infection Test)

Rapid test for the detection of acute infection of SARS-nCoV-2 N-protein from nasopharyngeal swabs

MEDICAL DIAGNOSTECH

Ref: MDCOVID19AG, ver 210819

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 nasopharyngeal swabs. It is intended for professional use 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 RT-PCR which is prone to detecting dead virus (non-infectious individual). 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 test line region indicates a positive result, while their absence indicates a negative result. The presence of an upper red line (the procedural control line (C)) demonstrates that the test has been performed correctly.

Reagents and material provided in the kit

Units	Components
20	Single pouched test cassettes with desiccant
20	Nasopharyngeal swabs
20	Viral extraction tubes with nozzle cap
1	Running buffer
1	Instructions for use

Timer required but not provided.

Storage conditions and shelf life

The following indications must be followed to ensure accurate test performance:

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

Precautions and warnings

1. For in vitro diagnostic use only.
2. All tests are for single use; do not re-use.
3. Follow the test procedure, results interpretation, and precautions precisely in order to get accurate results.
4. Do not open the sealed pouch, unless ready to conduct the test.
5. Do not use expired tests.
6. Do not mix reagents and components from different lots.
7. Do not use the test if pouch is damaged or the seal is broken.
8. Do not eat, drink or smoke while handling specimens and test devices.
9. Wear protective gloves and eye protection while handling specimens.
10. Respect standard procedures to dispose of specimens and potentially contaminated material, in biohazard containers.
11. The MD SARS-nCoV-2 Antigen device does not present any risk to the user if used as recommended.

Specimen collection and test procedure

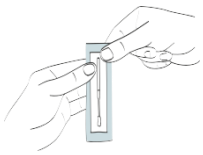
Before use allow the test in the foil bag to reach room temperature. Open the foil bag to be used, only before conducting the test, exposing the cassette.

Step 1
Dispense 8-10 drops of viral extraction buffer into the viral extraction tube provided.

Place the filled tube in an appropriate holder to avoid spilling.

Step 2
Peel open the swab packaging only when ready to conduct the test and gently remove the swab. Do not touch the the soft, fabric tip of the swab with your hands.

Please note: The sample collection may cause gagging and minor discomfort.

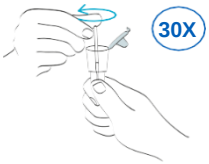


Step 3
Tilt patient's head back 70 degrees. Gently and slowly insert the swab into one of the patient's nostrils until it reaches the posterior nasopharynx; keep inserting until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient.

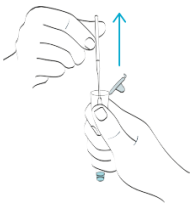
Slowly and gently rotate the swab 5 times.

Step 4
Pick up the extraction tube and place the fabric tip of the swab into the extraction tube so it is in the liquid.

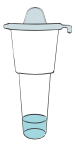
Press the tip against the edge of the extraction tube, while rotating it around the extraction tube for 30 times in a clockwise and anti-clockwise direction. Leave the swab in the vral extraction tube buffer for 1 minute.



Step 5
Press the swab against the sides of the extraction tube as you remove it. Make sure you remove all to most liquid from the soft tip of the swab.

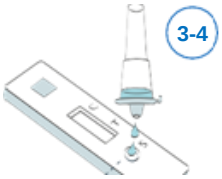


Step 6
Press the nozzle cap tightly on to the extraction tube to avoid any leaks.



Step 7
Gently squeeze the extraction tube to place 3-4 drops (80µL) of the liquid onto the sample well.

Read result at 15 minutes.



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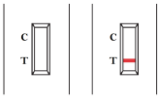
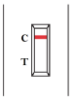
Interpretation of results

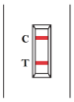
Invalid:
Either no lines are observed or a test line without control line is present. Improper test procedure was carried out or reagents have deteriorated. Re-test.



Negative:
The control line is present but no test line, demonstrating the test was performed correctly but no COVID-19 antigens were detected.



Positive:
The top (C) and bottom (T) lines are evident.



Limitations of the test

1. The MD SARS-nCoV-2 test is for professional in vitro diagnostic use. It is intended to be used for the qualitative detection of COVID-19 antigens only.
2. 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.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. Definitive clinical diagnosis should not be made until the physician has evaluated the result in combination with other clinical and laboratory findings.

Internal quality control

The MD SARS-nCoV-2 antigen test includes a control line which is used as 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
Σ	Content		Expiry date
LOT	Lot number		Storage temperature

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