



Rapid Antigen Testing

Identify COVID-19 patients in minutes.





Product Overview and Specification

The MP Biomedicals Rapid SARS-CoV-2 Antigen Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2 virus antigen in nasopharyngeal swabs or oropharyngeal swabs samples. The diagnostic kit is CE marked for use as a point of care test by TUV in Germany.

CLAIMED PERFORMANCE

Sensitivity	96.08%
Specificity	99.14%
Overall Accuracy	98.59%

KEY PRODUCT FEATURES

- » Provides results in 15 Minutes – simple result interpretation
- » Simple process for healthcare professionals to follow
- » Room temperature storage
- » Internal quality control
- » Sensitivity 96.08% - detects as little as 1ng/ml SARS - CoV-2 recombinant nucleocapsid protein
- » Specificity 99.14% - no cross-reactivity with common respiratory pathogens detected
- » Accuracy 98.59%
- » CE marked

PACKAGING

- » Rapid SARS-CoV-2 Antigen Test Card
- » Sterile swab
- » Extraction Tube
- » Sample extraction buffer
- » Instructions for use
- » Tube Holder

Why Use Antigen Testing?

As stated in the UK NHS test and trace guidelines, up to a third of individuals who test positive for COVID-19 have no symptoms at all, and can therefore spread it unknowingly. Identifying those individuals will save lives.



QUICK

Swabbing and processing of these tests should be conducted at a dedicated testing site in the premises with results available in around 15-20 minutes.



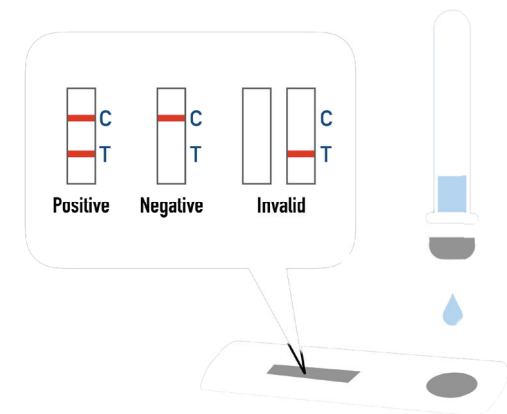
SAFE

These tests work. In validation studies conducted by Centro Diagnostico Delta S.r.l in Italy, they were shown to be almost as accurate in identifying a case as a PCR test (99.14% specificity) . The tests have lower sensitivity, but they are better at picking up cases when a person has higher viral load, hence the need to test frequently. When used in combination with other measures such as Personal Protective Equipment (PPE), washing hands regularly and social distancing, these tests further reduce the risk of transmission. We must not relax any of these measures – this testing programme should be an addition to them.



EASY

Approved for use in Australia, these devices are CE marked for self-test . The devices are designed to be intuitive and require minimal training to operate.

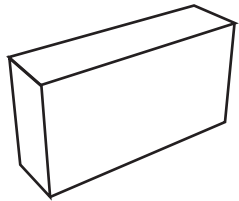


Simple Test Procedure

Specimen Collection and Processing Guide

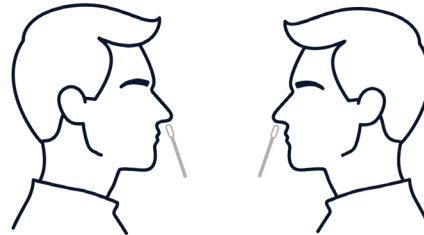
STEP 01

Unpack the antigen test from the box.



STEP 02

Insert the swab into one nostril (it should be inserted up to 2.5cm) from the edge of the nostril. Rotate the swab 5 times along the inside of the nostril to ensure that both mucus and cells are collected. Using the same swab, repeat the same process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.



STEP 03

Twist off the top of the buffer bottle. Slowly dispense all the buffer into the extraction tube.



STEP 04

Insert the swab into the extraction tube and plunge the swab up and down in the fluid for a minimum of 20 seconds. Hold the swab inside the bottom of the tube and rotate 5 times, taking care not to splash the contents.



STEP 05

Remove the swab whilst squeezing the sides of the tube to extract the liquid from the swab.



STEP 06

Insert the nozzle cap firmly in to the extraction tube containing the processed sample. Mix thoroughly by swirling or flicking the bottom of the tube.



STEP 07

Tear off the foil pouch, take out the test strip/cassette and place the strip on a clean and level surface. Always label the strip with participant name to avoid reporting incorrect results.



STEP 08

Gently squeeze the ridged body of the tube, dispensing 3 drops of the processed specimen into the sample well on the test strip.



STEP 09

Read and interpret the test results between 15 and 20 minutes from dispensing the drops onto the test strip. Do not read the results after 20 minutes.



Thank You

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