

RAPID SARS-COV-2 ANTIGEN TEST SPECIFICATION SHEET

IDENTIFY COVID-19 PATIENTS IN MINUTES





SPECIFICATION



SKU	078AL10020
Components	Components per kit for 20 tests: Sterilised Swab, Extraction Tubes, Sample Extraction Buffer, Test Card, Package Insert, Tube Holder
Pack Size	20 tests (includes all required consumable materials including sterile swabs)
Sample Type	Nasal, Nasopharyngeal, Oropharyngeal swabs
Sensitivity	96.08% (nasopharyngeal) 96.23% (oropharyngeal) 96.19% (nasal)
Specificity	99.14% (nasopharyngeal) 99.20% (oropharyngeal) 99.20% (nasal)
Accuracy	98.59% (nasopharyngeal) 97.84% (oropharyngeal) 97.83% (nasal)
Storage	2– 30°C
Usage Statement	The product is included on the ARTG for professional use at the point of care.
Key Applications	COVID-19 Diagnostics
Test Type	Qualitative
Duration	Results after 15 minutes
Countries Tested	Germany, United Kingdom, Netherlands, Denmark, Italy, Switzerland

PRODUCT BENEFITS



High sensitivity & specificity



Effective against the Delta strain with extensive clinical data

The product has been tested against 20 strains



CE Marked for self-test, efficient & simple to use



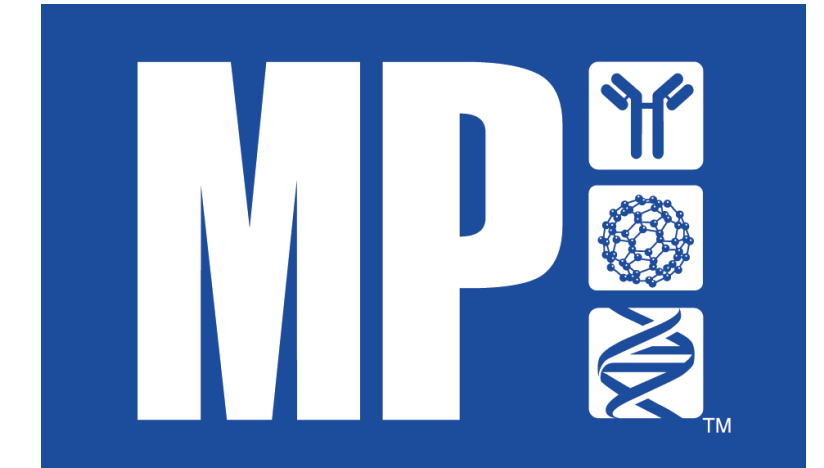
Speeds up the testing process



Patient-friendly nasal sample collection with superior sensitivity



SIMPLE TEST PROCEDURE



SPECIMEN COLLECTION GUIDE

How to use the swab (Steps 1-2)

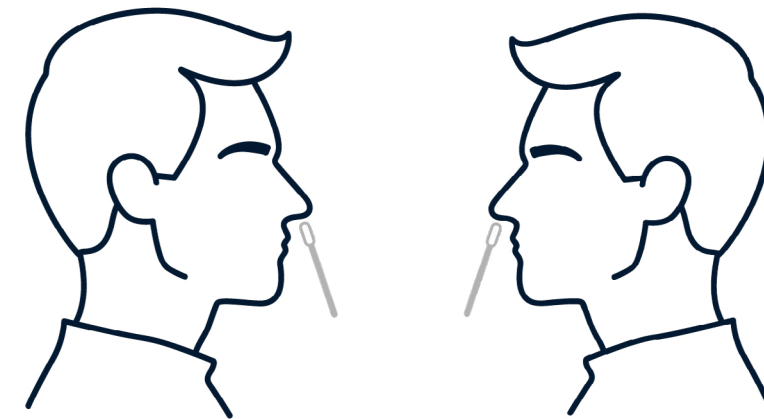
STEP 01

Unpack the antigen test kit from the box.



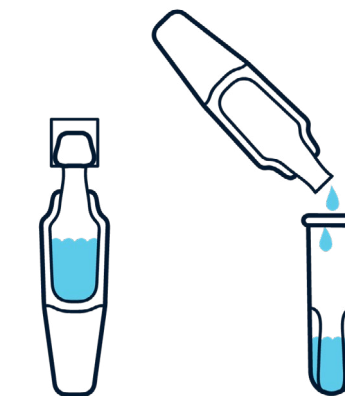
STEP 02

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.



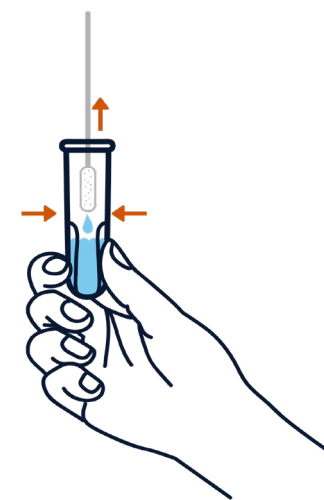
STEP 04

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.



Consult Instructions for Use for full procedure

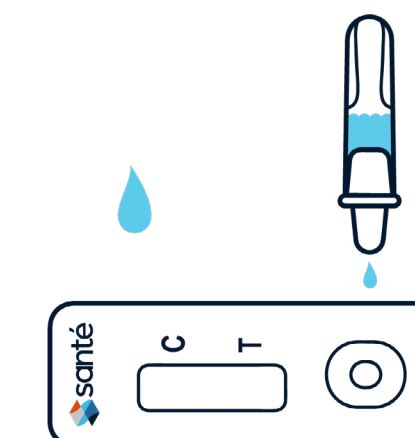
STEP 07

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.



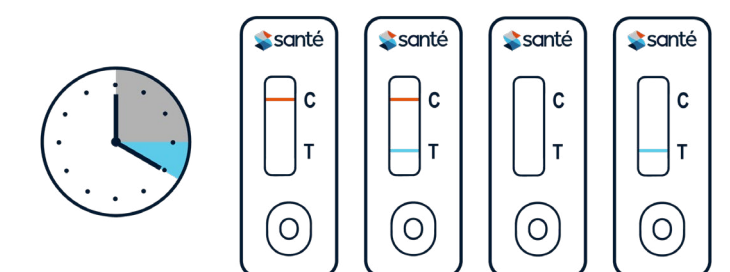
STEP 08

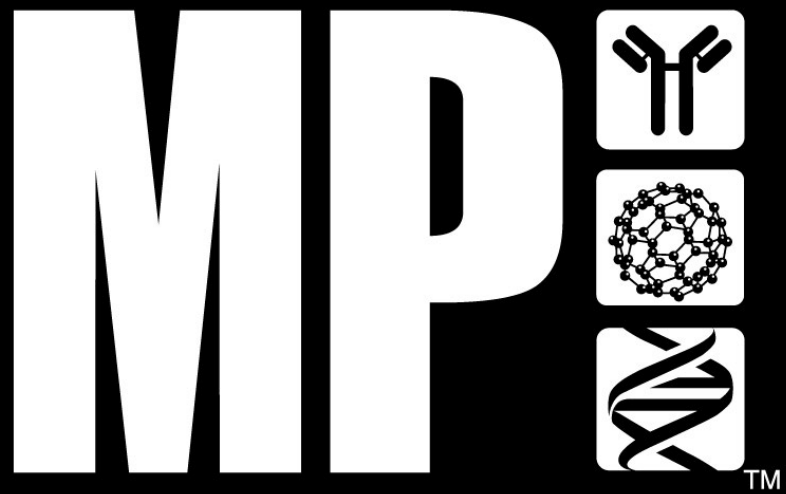
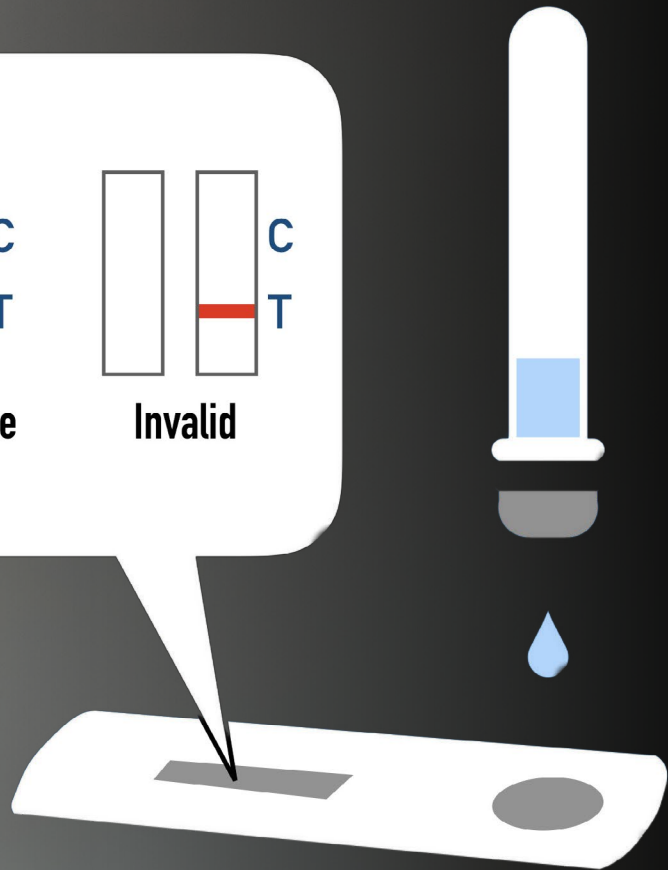
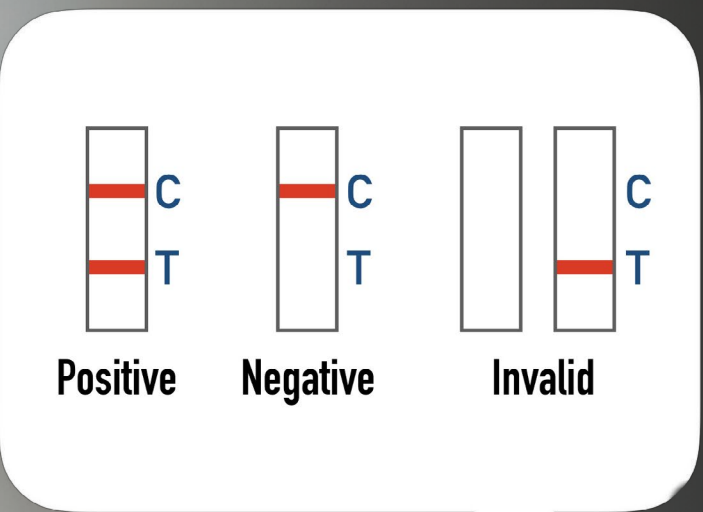
Gently squeeze the ridged body of the tube, dispensing 3 drops of the processed specimen into the sample well on the test strip.



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.





Manufactured in Singapore by MP Biomedicals
Conditions of sale under TGA regulation apply

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