

## **RAPID SARS-COV-2 ANTIGEN TEST SPECIFICATION SHEET**

# IDENTIFY COVID-19 PATIENTS IN MINUTES

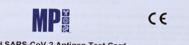


Santé Area Medilogic

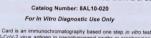


## SPECIFICATION





Rapid SARS-CoV-2 Antigen Test Card FOR THE QUALITATIVE ASSESSMENT OF SARS-CoV-2 VIRUS ANTIGEN IN NASOPHARYNGEAL SWAB OR OROPHARYNGEAL SWAB SPECIMENS



. Based on the curre eriod is 1 to 14 days, nny nose, sore throat,

MATERIALS REQUIRED BUT NOT SUPPLIED Clock or timer, biohazard waste container, personal protection equipment.

ue: The test device at 2 to 30°C in the original sealed pouch. Do Not Freeze. Softents are stable until the expiration date printed on the outer box based on the proper storage conditions. Heat device should remain in its original sealed pouch until ready for use. After opening, the test device should be used ediately. Do not reuse the device.

ECAUTIONS

nal in vitro diagnostic use only. is strictly for medical professional use only and not intended for personal use. he product the pouch is damaged or the seal is broken. he product the pouch is damaged or the seal is broken. her means as potentially infectious. diral laboratory procedure and lossafety guidelines for handling and disposal of potentially infectious material. to rinapropriate specimen collection, storage, and transport may yield maccurate test results. to rinapropriate specimen collection, storage, and transport may yield maccurate test results. to rinapropriate specimen collection, storage, and transport may yield maccurate test results. the start of the storage is recommended if operators are not experienced with specime collection and handling start and evaluate. Pathogenic microorganisms, hubding hepatite and viruse and Hummin Himmunode/lectory Virus, dire and evaluate. Pathogenic microorganisms, nucliding hepatite should always be followed in Herotoxide 2000-0114 kN





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

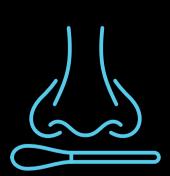
The product has been tested against 20 strains



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.

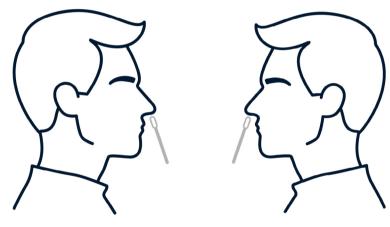


#### **STEP 02**

Insert the swab into one nostril (it should be inserted up to 2.5cm) from the Twist off the top of the buffer edge of the nostril. Rotate the swab 5 times aong the inside of the nostril to bottle. Slowly dispense all the ensure that both mucus and cells are collected. buffer into the extraction tube.

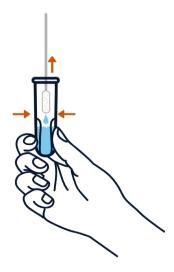
Using the same swab, repeat the same process for the other nostril to ensure that an

adequate sample is collected from both nasal captivities.



#### **STEP 05**

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



Consult Instructions for Use for full procedure

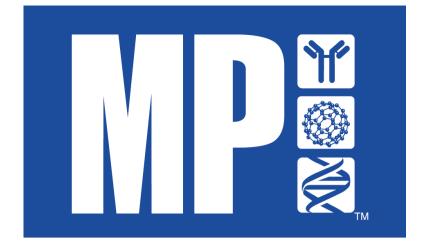
#### **STEP 06**

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.



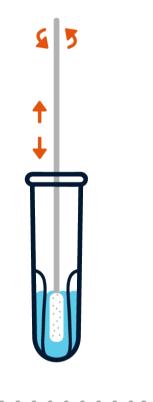
#### **SAMPLE PROCESSING GUIDE**

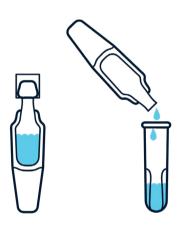
How to process the test (Steps 3-9)

#### **STEP 03**

#### **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.

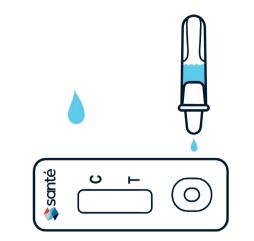






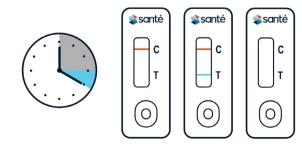
#### **STEP 08**

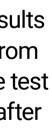
Gently squeeze the ridged body of the tube, dispensing 3 drops of the processed specimen into the sample well on the test strip.



#### **STEP 09**

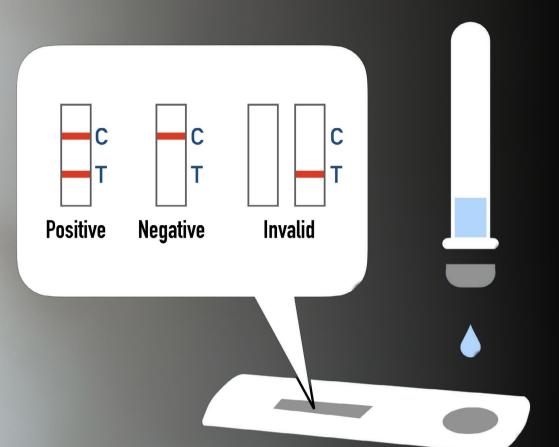
Read and interpret the test results between 15 and 20 minutes from dispensing the drops onto the test strip. Do not read the results after 20 minutes.

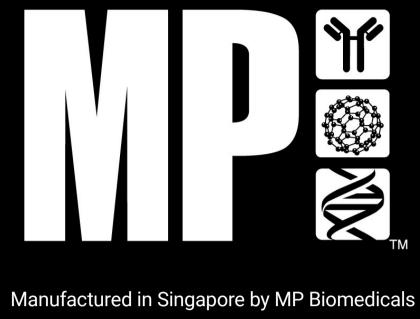












Conditions of sale under TGA regulation apply

#### CONTACT US TODAY

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