



# Fact Sheet

## All-in-One Rapid COVID-19 Antigen Saliva Pen

### WORLD'S FIRST 'NO-SPIT' ORAL SWAB ANTIGEN RAPID TEST

NO SETUP REQUIRED

NO EQUIPMENT

RESULTS AFTER 15 MINS

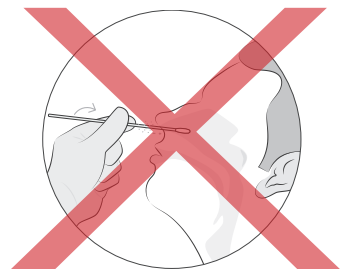
SAMPLE TYPE: SALIVA

SENSITIVITY 90.0%



### *i* Background

*The New Rapid Response™ COVID-19 Saliva Pen is the world's first 'No-Spit' oral swab rapid antigen test. Designed for convenience, the compact test offers results for individuals suspected of COVID-19 in just 15 minutes, without any setup or equipment!*



### *Target* Target Customers

**Essential Businesses:** Production and manufacturing sites, logistics, customer facing employees, residential delivery, public transport employees, private hire companies, border control facilities.

**Health Care:** Physical and occupational health, therapists, GP practices, Residential care homes, visiting nurses.

**Travel:** International and domestic travel.

**Education:** Colleges, universities, private and public schools, boarding schools, school support staff.

**Hospitality and Recreation:** Service and bar staff, hotel staff and guests, airline and airport staff, sports teams.



### *Performance* Performance

**Sensitivity:** 90.0%      **Estimated LOD:** 100 TCID<sub>50</sub>/ml  
**Specificity:** 97.0%      **Storage:** 2-30°C



Distributed by:



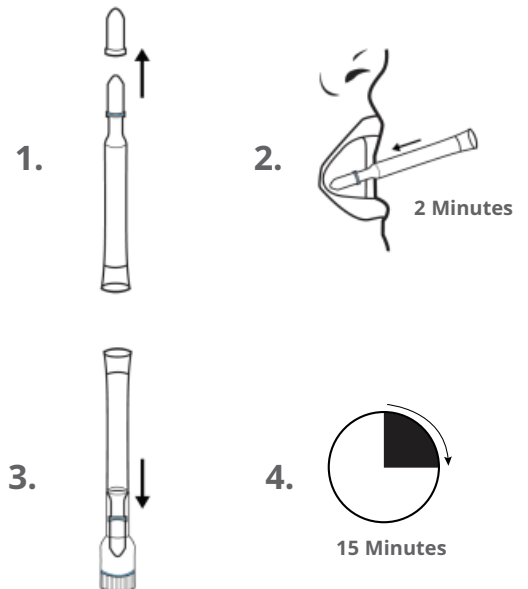
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## All-in-One Rapid COVID-19 Antigen Saliva Pen

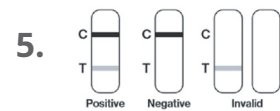


### Test Procedure

1. Open the pouch and remove the Saliva Collection Pen and Extraction Buffer Cap from the packaging. Label the Saliva Collection Pen with patient identification. For best results, the assay should be performed within two hours.
2. Clear throat, then cough deeply four times with mouth closed before collecting the samples.
3. Remove the plastic guard from the tip of the Saliva Collection Pen.
4. Place the Saliva Collection Pen in the mouth above the tongue. Hold in place for 2 minutes.
5. Remove the Saliva Collection Pen from the patient's mouth. Holding the Saliva Collection Pen vertically, place it into the extraction buffer Cap. Press down to break the seal of the Extraction Buffer Cap, which will release the buffer solution.
6. Start the timer immediately after breaking the seal. Read the results at 15 minutes.



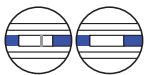
### Result Interpretation



**Positive:** Two coloured bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



**Negative:** Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).



**Invalid:** Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

#### Note:

1. The colour intensity in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour in the test region should be considered positive. Note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

*This test is intended for professional use only.*

**For more information please refer to product insert**

\*NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of SARS-CoV-2 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.