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# SARS-COV-2

ANTIGEN RAPID TEST  
ORO/NASOPHARYNGEAL SWAB



“SARS-CoV-2 Antigen Rapid Swab” is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19.

“SARS-CoV-2 Antigen Rapid Swab” is intended for use by trained clinical laboratory personnel specifically instructed and trained in vitro diagnostic procedures.

## Specimen Collection

Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after five days of symptoms are more likely to produce negative results. Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

### **Nasopharyngeal Swab Sample**

Insert minitip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.

Swab should reach depth equal to distance from nostrils to outer opening of the ear.

Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

### **Oropharyngeal Swab Sample**

Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

## Specimen Preparation

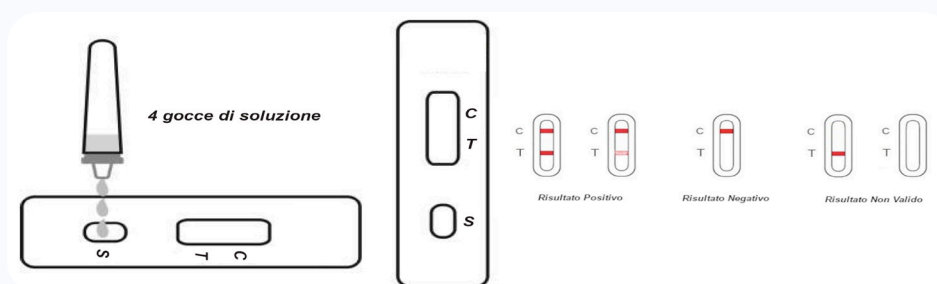
1. Unscrew the lid of an extraction reagent. Add all of the extraction reagent into an extraction tube, and put it on the work station.

2. Insert the swab sample into the extraction tube which contains extraction reagent.  
Roll the swab at least 5 times while pressing the head against the bottom and side of the extraction tube. Leave the swab in the extraction tube for one minute.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. The extracted solution will be used as test specimen.
4. Insert a dropper tip into the extraction tube tightly.

## Test Procedure

Allow the test device and specimens to equilibrate to temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch.
2. Reverse the specimen extraction tube, holding the specimen extraction tube upright, transfer 3 drops (approximately 100µl) to the specimen well(S) of the test cassette.
3. Wait for colored lines to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes.



## Materials Provided

- |                   |                      |                |
|-------------------|----------------------|----------------|
| - Test Cassette   | - Extraction Reagent | - Work Station |
| - Sterilized Swab | - Dropper Tip        |                |
| - Extraction Tube | - Package Insert     |                |

PRODUCT CODE	DESCRIPTION	BOX
COVID-19/HGA	SARS-COV-2 ANTIGEN DETECTION KIT	25

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