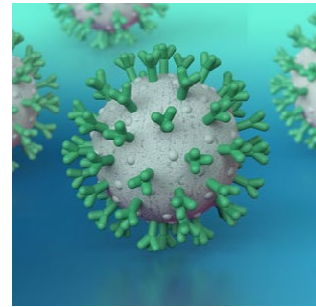


# Coronavirus Ag Rapid Test Cassette



## Product Information

The Coronavirus Ag Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal (NP) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first ten days of symptom onset. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. Negative results from patients with symptom onset beyond ten days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. The Coronavirus Ag Rapid Test Cassette (Swab) does not differentiate between SARS-CoV and SARS-CoV-2.

## Test Procedure & Interpretation

### Specimen collection

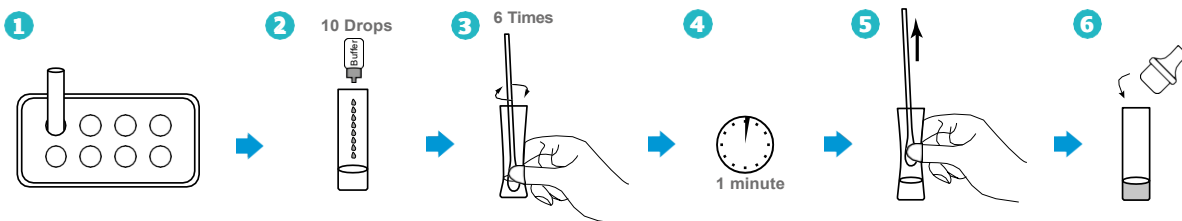
Use the nasopharyngeal swab provided in the kit.

1. Carefully insert the swab in the patient's nostril.
2. Swab over the surface of the posterior nasopharynx and rotate the swab several times.
3. Withdraw the swab from the nasal cavity.

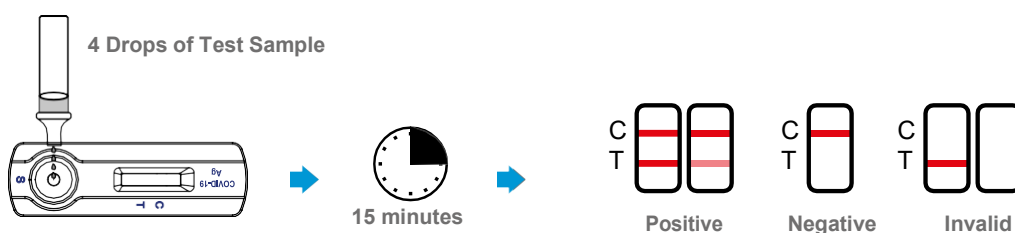


### Sample preparation

1. Insert the test extraction tube into the workstation provided in the kit. Make sure that the tube is standing upright and reaches the bottom of the workstation.
2. Add 300  $\mu$ L (about 10 drops) of the extraction buffer into the extraction tube.
3. Insert the swab into the extraction tube which contains 300  $\mu$ L of the extraction buffer. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
4. Leave the swab in the extraction tube for 1 minute.
5. Squeeze the tube several times from the outside to immerse the swab. Remove the swab.
6. Push the tip which contains the filter onto the extraction tube. Ensure the tip has a tight fit.



### Test procedure & interpretation of results



## Coronavirus Ag Rapid Test Cassette

### Performance Characteristics

Clinical Performance of the Coronavirus Ag Rapid Test Cassette (Swab) was evaluated by being involved in 7 sites within the US, where patients were enrolled and tested. Testing was performed by 24 Health Care Workers that were not familiar with the testing procedure. A total of 317 fresh nasopharyngeal swab samples was collected and tested, which includes 61 positive samples and 256 negative samples. The Coronavirus Ag Rapid Test Cassette (Swab) results were compared to results of USFDA Emergency Use Authorized RT-PCR assays for SARS-CoV-2 in nasopharyngeal swab specimens. Overall study results are shown below.

Method		PCR		Total Results
Coronavirus Ag Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	59	2	61
	Negative	2	254	256
<b>Total</b>		<b>61</b>	<b>256</b>	<b>317</b>

- Relative Sensitivity: 96.72 % (95 % CI\*: 88.65 %-99.60 %)
- Relative Specificity: 99.22 % (95 % CI\*: 97.21 %-99.91 %)
- Accuracy: 98.74 (95 % CI\*: 96.80 %-99.66 %)

\*Confidence Intervals

### Benefits

- Rapid testing for SARS-CoV-2 antigen within the first ten days of symptom onset
- Rapid results within 15 minutes
- Facilitates patient treatment decisions quickly
- Simple, time-saving procedure
- No instrumentation required
- High sensitivity and specificity

### Specification

Information	In Detail
Time to result	15 minutes
Storage	2-30 °C
Shelf life	24 months from date of manufacture
Specimen type	Nasopharyngeal swab

### Contents

- 20 Test cassettes
- 20 Sterile swabs
- 20 Extraction tubes and tips
- 2 Extraction buffer vials
- 1 Workstation
- 1 Package insert

### Ordering Information

Product Description	Specimen	Catalog No.	Kit Size
Coronavirus Ag Rapid Test Cassette	Nasopharyngeal Swab	5501589	20 Tests/Kit

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