

Rapid Test

Flowflex™ SARS-CoV-2 Antigen Rapid Test

The Flowflex SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection the nucleocapsid protein antigen from SARS-CoV-2 in nasal or nasopharyngeal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The SARS-CoV-2 Antigen Rapid Test can also test specimens from asymptomatic individuals.



- Nasal and Nasopharyngeal swab specimens
- Results at 15 min
- Excellent performance compared to molecular methods
- Room temperature storage

Materials Provided

- Test Cassettes
- Extraction Buffer Tubes (Extraction Buffer and Extraction Tubes)
- Nasal Swabs or Nasopharyngeal Swabs
- Negative Control Swab
- Positive Control Swab
- Package Insert
- Specimen Collection Guide



- Nasal swab specimens
- Results at 15 min
- Excellent performance compared to molecular methods
- Room temperature storage

Materials Provided

- Test Cassettes
- Extraction Buffer Tubes
- Nasal Swabs
- Package Insert

Clinical Performance

Nasal Swab Specimens

The performance of SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from individual symptomatic patients who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

Clinical Performance for SARS-CoV-2 Antigen Rapid Test

Method		RT-PCR		Total Results
		Negative	Positive	
SARS-CoV-2 Antigen Rapid Test	Negative	433	5	438
	Positive	2	165	167
Total Results		435	170	605
PPA: 97.1%(93.1%-98.9%)*		NPA: 99.5%(98.2%-99.9%)*		OPA: 98.8%(97.6%-99.5%)*

PPA-Positive Percent Agreement; NPA-Negative Percent Agreement; OPA-Overall Percent Agreement, *95% Confidence Intervals

Stratification of the positive samples post onset of symptoms between 0-3 days has a positive percent agreement (PPA) of 98.8% (n=81) and 4-7 days has a PPA of 96.8% (n=62).

Positive samples with Ct value ≤ 33 has a higher positive percent agreement (PPA) of 98.7% (n=153).

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Nasopharyngeal Swab Specimens

The performance of SARS-CoV-2 Antigen Rapid Test was established with 299 nasopharyngeal swabs collected from individual symptomatic patients who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

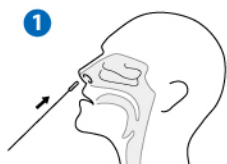
Clinical Performance for SARS-CoV-2 Antigen Rapid Test

Method	Results	RT-PCR		Total Results
		Negative	Positive	
SARS-CoV-2 Antigen Rapid Test	Negative	175	3	178
	Positive	1	120	121
Total Results		176	123	299
PPA: 97.6% (92.8%-99.5%)*		NPA: 99.4% (96.5% - 99.9%)*		OPA: 98.7% (96.5% - 99.6%)*

PPA-Positive Percent Agreement; NPA-Negative Percent Agreement; OPA-Overall Percent Agreement, *95% Confidence Intervals.

Specimen Collection

Nasal Swabs



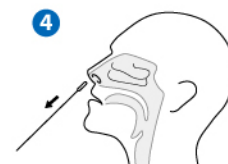
Using gentle rotation, insert the swab into the nostril to less than 2.5 cm (1 inch) from the edge of the nostril.



Rotate the swab 5 times against the mucosa inside the nostril.

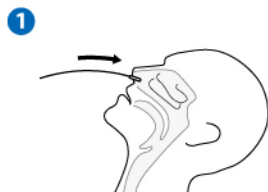


Using the same swab, repeat this process in the other nostril.



Withdraw the swab from the nasal cavity. The sample is now ready for preparation.

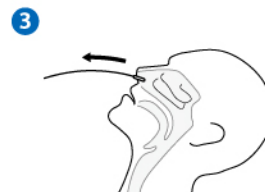
Nasopharyngeal Swabs



Tilt patient's head back 70 degrees. Gently and slowly insert a nasopharyngeal swab, through the nostril parallel to the palate until resistance is encountered.



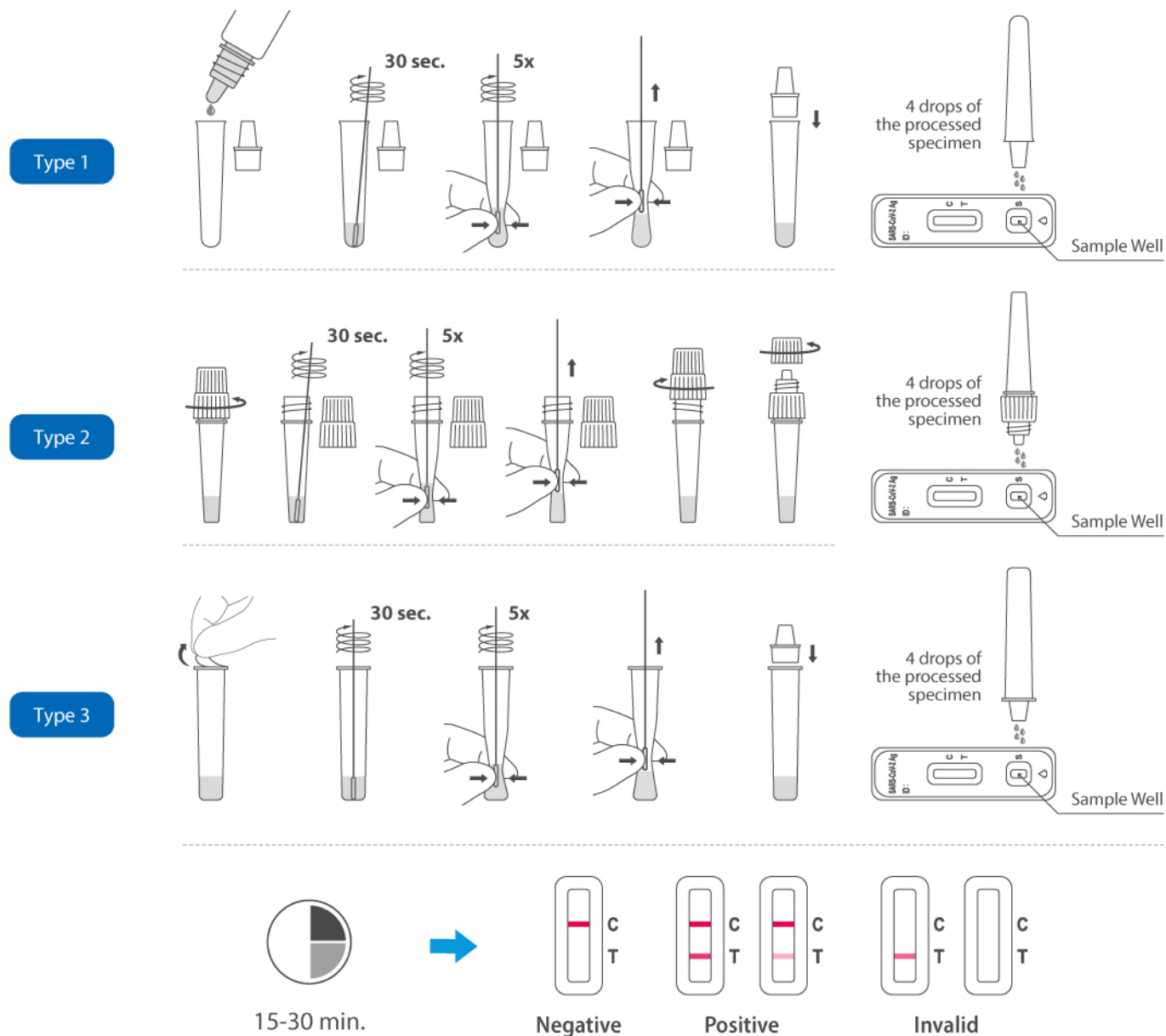
Gently rub and roll the swab, leaving it in place for several seconds to absorb secretions.



Slowly remove swab while rotating it. The specimen is now ready for preparation using the extraction buffer tubes.

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Test Procedure and Interpretation



*Three type of tubes are available, which depends on the package you ordered.

Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
Flowflex SARS-CoV-2 Antigen Rapid Test	L031-11815√	Cassette	Nasal and Nasopharyngeal swabs	25 Tests/Kit
	L031-11825√	Cassette	Nasal and Nasopharyngeal swabs	25 Tests/Kit
	L031-11845√	Cassette	Nasal swabs	1 Test/Kit 20 Kits/Box
	L031-118C5√	Cassette	Nasal swabs	5 Tests/Kit