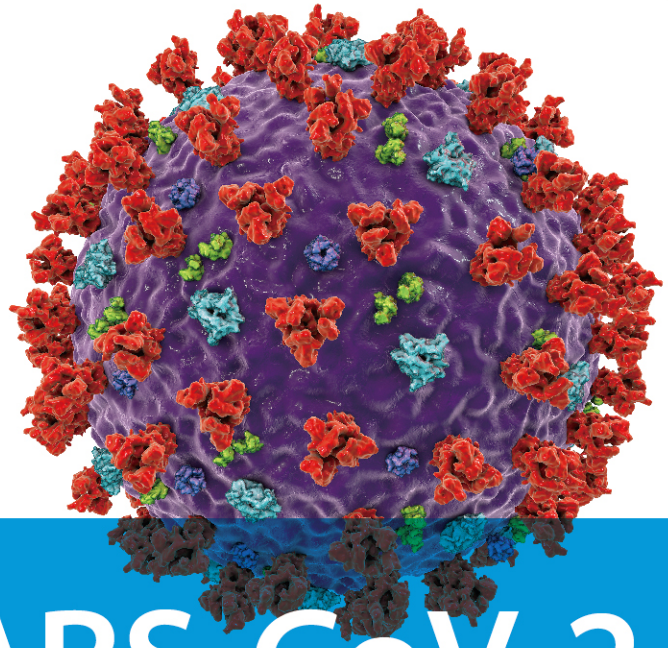
Flowflex™



SARS-CoV-2
Antigen Rapid Test

A rapid, highly reliable and affordable kit, providing an aid in early diagnosis of individuals who are suspected of COVID-19 by their healthcare provider and who are asymptomatic.

Digitally signed by Goreacii Vitalie
Date: 2021.10.15 11:13:15 EEST
Reason: MoldSign Signature
Location: Moldova

The Global Leader of Rapid Test with 26 Years Experience.

Fast | Reliable | Easy to Use | User friendly | CE Marked

ACON®
ACON Biotech (Hangzhou) Co., Ltd.

Flow*flex* SARS-CoV-2 Antigen Rapid Test

The Flow*flex* 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 and 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**

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
SARS-CoV-2 Antigen Rapid Test	Results	Negative	Positive	
	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).

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		RT-PCR		Total Results
SARS-CoV-2 Antigen Rapid Test	Results	Negative	Positive	
	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%)*		

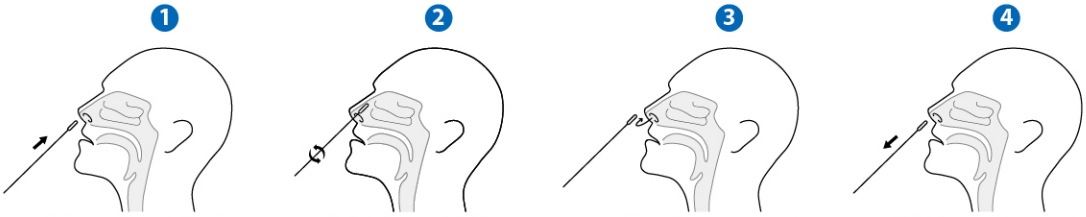
PPA-Positive Percent Agreement; **NPA**-Negative Percent Agreement; **OPA**-Overall Percent Agreement, *95% Confidence Intervals.

Materials Provided

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

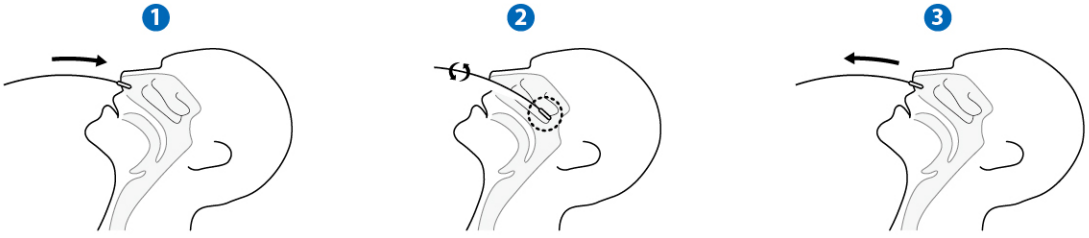
Specimen Collection

Nasal Swabs



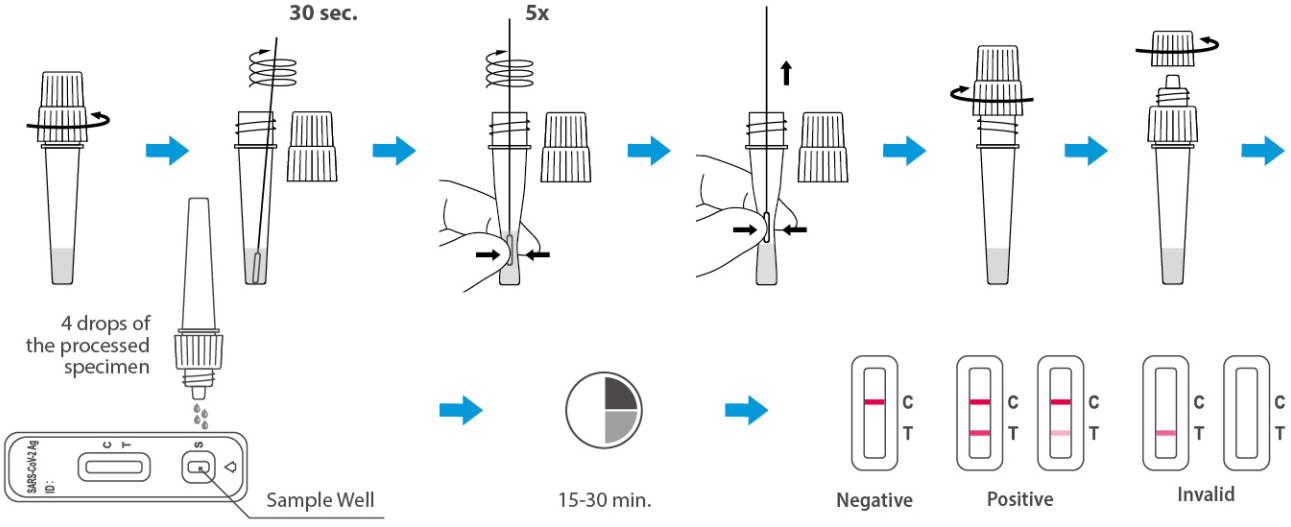
1. Using gentle rotation, insert the swab into the nostril to less than 2.5 cm (1 inch) from the edge of the nostril.
2. Rotate the swab 5 times against the mucosa inside the nostril.
3. Using the same swab, repeat this process in the other nostril.
4. Withdraw the swab from the nasal cavity. The sample is now ready for preparation.

Nasopharyngeal Swabs



1. 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.
2. Gently rub and roll the swab, leaving it in place for several seconds to absorb secretions.
3. Slowly remove swab while rotating it. The specimen is now ready for preparation using the extraction buffer tubes.

Test Procedure and Interpretation



Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
Flow*flex* SARS-CoV-2 Antigen Rapid Test	L031-11815 √	Cassette	Nasal and Nasopharyngeal swabs	25 Tests/Kit

√ CE marked

www.aconbio.com

***ACON* Biotech (Hangzhou) Co., Ltd.**
No.210 Zhenzhong Road, West Lake District,
Hangzhou, P.R.China, 310030
Tel: +86-571-8118 9706
Fax: +86-571-8777 5781
Email: information@aconlab.com.cn