Providing Comprehensive Solutions to SARS-CoV-2

SARS-CoV-2 Antigen Rapid Test
SARS-CoV-2 IgG/IgM Rapid Test
SARS-CoV-2 IgG and IgM EIA Test Kits
NES-32 Nucleic Acid Extraction System
Viral Nucleic Acid Isolation Kits (Spin Column)
960 Real-Time PCR System
SARS-CoV-2 RT-PCR Test Kit
Fluorescent Immunoassay Analyzer
SARS-CoV-2 Antigen FIA

The novel coronavirus belongs to the β genus. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the novel coronavirus are the main source of new infections; asymptomatic carriers can also be a source of infection propagation. Based on the current research, the incubation period is between 2 to 14 days after exposure to the virus. The main manifestations of the disease include fever, fatigue and dry cough. Nasal congestion, loss of smell, sore throat, myalgia and diarrhea as well as other less common symptoms can also be seen in patients.

ACON®

Introduction

For over 25 years, *ACON* has led the way in making high quality diagnostic and medical devices more affordable to people around the world. In fact, the *ACON* name is well recognized in over 150 countries.

Headquartered in San Diego, California, the US office is the center of strategic management, administration, business development, innovative research and development. Our state of the art manufacturing facility is ISO 13485:2016 certified, FDA registered, and has been inspected by US FDA.

Our current product lines include **Diabetes Care, Clinical Chemistry (Urinalysis and Point of Care Tests), Rapid Test, Immunoassay (ELISA and Allergen Test) and Molecular Diagnostics.** As a global enterprise, we also have distributors around the world who contribute to our products development, international sales and technical support.

Disclaimer: Some products in this brochure may not be available in all countries. Please consult with your local *ACON* sales representative for details.

ACON History

1995 — ***ACON* was founded**
Founded in Bethlehem, PA, USA, ACON operated in a 27,000 sq. ft. manufacturing facility.

1999 — **Moved to San Diego, CA, USA**

2001 — **Became a large manufacturer**
ACON increased its manufacturing facility to 150,000 sq. ft. with more than 1,500 employees

2006 — **Launched new product lines**
ACON sold its lateral flow (LF) rapid diagnostic business in the US, Europe, Canada, Israel, Japan, Australia, and New Zealand. ACON began to focus on, and launch, new products lines including Diabetes Care, Clinical Chemistry, and Immunoassay.

2009 — **Expanded product lines**
ACON sold the LF rapid diagnostic business in Asia, the Middle East, Africa and Latin America. ACON continued to expand its business in Diabetes Care, Clinical Chemistry, and Immunoassay.

2015 — **Moved to a much larger facility for manufacture, R&D and business development**
ACON's new facility of 70,000 sq. m (750,000 sq. ft.) includes state-of-the-art manufacturing equipment to supply the growing demand of the global diagnostic market.

2018 — **Centralised and Point of Care Solutions**
The Centralised and Point of Care Solutions were launched to offer better solutions, and the business expanded globally.

Future — **Looking forward**
ACON is looking forward to developing new products to meet the IVD, and Medical Diagnostic markets growing needs by expanding its diagnostic and healthcare offerings.

Rapid Test

Flowflex™ SARS-CoV-2 Antigen Rapid Test (Self-Testing)

The SARS-CoV-2 Antigen Rapid Test is a lateral flow test for the qualitative detection of the nucleocapsid antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals suspected of COVID-19 within the first seven days of the onset of symptoms. The test can also test specimens from individuals without symptoms.

- **Specimen: Anterior nasal swab specimens**
- **Test Time: Results at 15 min.**
- **Shelf life: 24 months**
- **Storage temperature: 2-30°C**
- **Accuracy: 98.8%**
- **Sensitivity: 97.1%**
- **Specificity: 99.5%**

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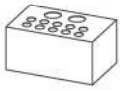
Test Preparation

A. Open your test kit :

B. You should have:

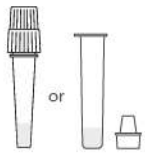
Note: For 1T and 5T, the hole is on the kit box.



Tube Holder (for 25T only)

Disposable Swab

Test cassette



Extraction Buffer Tube

Package Insert

Waste Bag

C. Wash or sanitize your hands.

D. Read the instructions.

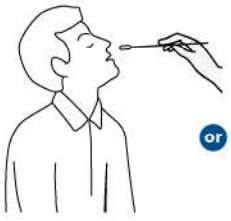
E. Check the expiration date.

F. Open the pouch.

G. Check the cassette

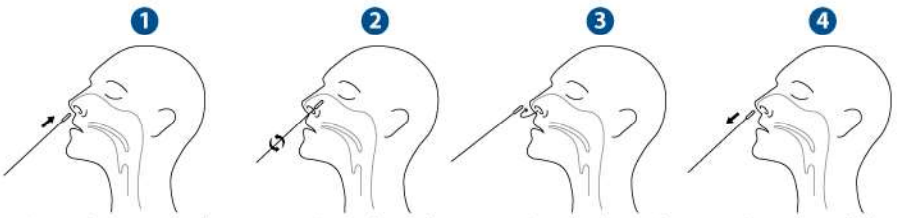
Specimen Collection

COLLECTION BY AN ADULT CAREGIVER



or

SELF COLLECTION

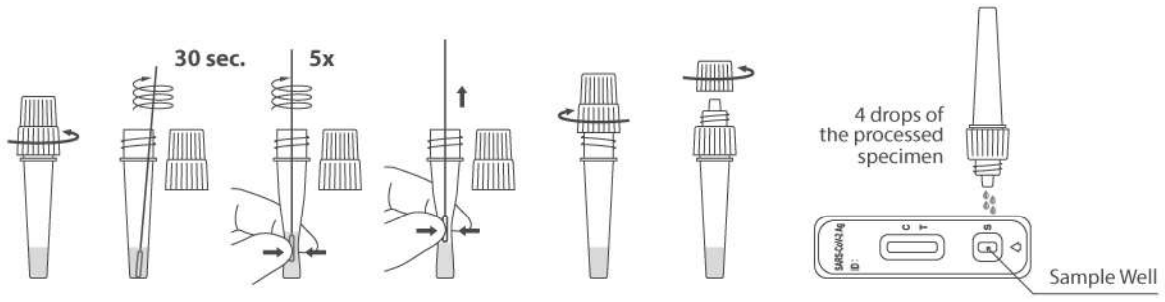


1. Insert the entire absorbent tip of the swab into one nostril. Using gentle rotation, push the swab less than 2.5 cm from the edge of the nostril.
2. Rotate the swab 5 times brushing against the inside of the nostril.
3. Remove the swab and insert it into the other nostril.
4. Remove swab from the nostril.

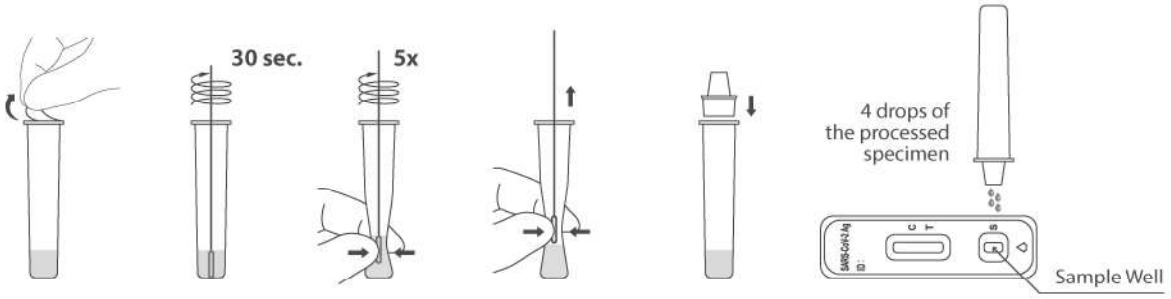
Rapid Test

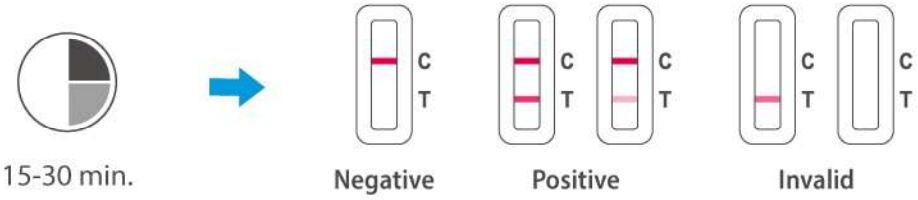
Test Procedure and Interpretation

Type 1



Type 2





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

Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
Flow*flex* SARS-CoV-2 Antigen Rapid Test (Self-Testing)	L031-11855 √	Cassette	Anterior nasal swabs	1 Test/Kit
	L031-118A5 √	Cassette	Anterior nasal swabs	5 Tests/Kit
	L031-118Q5 √	Cassette	Anterior nasal swabs	25 Tests/Kit
	L031-118M5 √	Cassette	Anterior nasal swabs	1 Test/Kit
	L031-118P5 √	Cassette	Anterior nasal swabs	5 Tests/Kit
	L031-118R5 √	Cassette	Anterior nasal swabs	25 Tests/Kit

√ CE marked

Rapid Test

Flowflex™ SARS-CoV-2 Antigen Rapid Test

The Flow*flex* SAS-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.

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- **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

CE

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- **Results at 15 min**
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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
	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).