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THE RIGHT SCREW FOR YOU AND SAFETY TOO!

Flowflex™

COVID-19 Antigen Home Test

A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection.

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ACON®
ACON Laboratories, Inc.

Flowflex COVID-19 Antigen Home Test

Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older or with adult-collected anterior nasal samples directly from individuals aged 2 years or older. **The Flowflex COVID-19 Antigen Home Test does not require serial testing.**

- Anterior nasal swab specimens
- Results in 15 minutes
- 12 Months shelf life
- Store between 36 to 86° F
- Sample self-collection ages 14 and older
- Sample collection by an adult in **children ages 2 to 13**
- Excellent performance when compared to an FDA authorized molecular SARS-CoV-2 test.

Clinical Performance

The performance of Flowflex COVID-19 Antigen Home Test was established in an all-comers clinical study conducted between March 2021 and May 2021 with 172 nasal swabs self-collected or pair-collected by another study participant from 108 individual symptomatic patients (within 7 days of onset) suspected of COVID-19 and 64 asymptomatic patients. The Flowflex COVID-19 Antigen Home Test results were compared to an FDA EUA RT-PCR COVID-19 assay to determine test performance in the table below:

Performance of Flow*flex* COVID-19 Antigen Home Test in ALL subjects

Flow*flex* COVID-19 Antigen Home Test	RT-PCR method		
	Positive	Negative	Total
Positive	39	0	39
Negative	3	130	133
Total	42	130	172
Positive Percent Agreement (PPA)	**93%** (95% CI: 81% - 99%)		
Negative Percent Agreement (NPA)	**100%** (95% CI: 97% - 100%)		

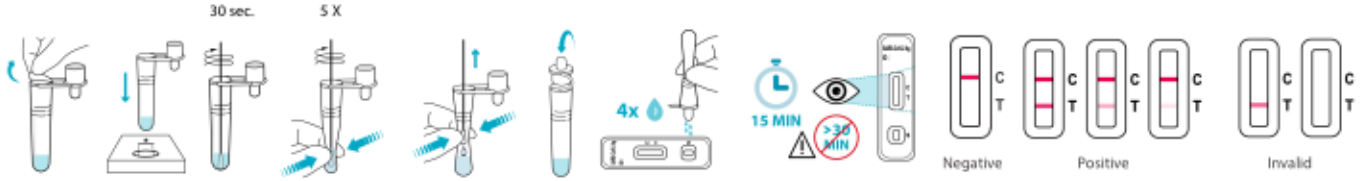
Analytical Sensitivity: Limit of Detection (LoD) :
LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time. Based on this testing, the LoD in nasal matrix was confirmed to be 2.5 x 10^3 $TCID_{50}$/mL

SARS-CoV-2 Concentration in nasal matrix	Number of Positives/Total	% Detected
2.5 x 10^3 $TCID_{50}$/mL	60/60	100%

Materials Provided

- Test Cassette(s)
- Package Insert
- Extraction Buffer Tube(s)
- Nasal Swab(s)
- External Tube Holder - Package of 25 tests

Test Procedure and Interpretation



Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
Flowflex COVID - 19 antigen Home Test	L031-118B5	Cassette	Nasal swabs	1 Test/Kit
Flowflex COVID - 19 antigen Home Test	L031-125M5	Cassette	Nasal Swabs	2 Tests/Kit
Flowflex COVID - 19 antigen Home Test	L031-125N5	Cassette	Nasal swabs	5 Tests/Kit
Flowflex COVID - 19 antigen Home Test	L031-125P5	Cassette	Nasal Swabs	25 Tests/Kit

- This product has not been FDA cleared or approved but has been authorized by FDA under an EUA.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of IVDs for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- For more information on EUAs please visit: https://www.fda.gov/emergency-preparednessand-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19
- For detailed instructions, please visit: www.aconlabs.com

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