



COVID-19 Antigen Home Test

A rapid test for the detection of SARS-CoV-2 Antigens in anterior nasal specimens.



Flowflex COVID-19 Antigen Home Test

A rapid lateral flow immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older or adult-collected anterior nasal swab samples from individuals 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

- Results in 15 minutes
- Free Web Application for results recording and step-by-step instructions.
- 24 Months shelf life
- Store between 36 to 86° F

Clinical Performance

· Small sized packaging makes for easy travel and storage

- Self-collected anterior nasal swab specimens from individuals aged 14 years or 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.

The Flowflex COVID-19 Antigen Home Test was compared to an FDA authorized molecular SARS-CoV-2 test. The Flowflex COVID-19 Antigen Home Test correctly identified 93% of positive specimens and 100% of negative specimens.

Materials Provided

- Test Cassette(s)
- Package Insert (English & Spanish)
- 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

• In the USA, 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; and,

• 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 in vitro diagnostics 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-preparedness-and-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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ACON Laboratories, Inc. 5850 Oberlin Drive, # 340 San Diego, CA 92121, USA Tel: 1.858.875.8000 Fax: 1.858.200.0729 Email: info@aconlabs.com