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

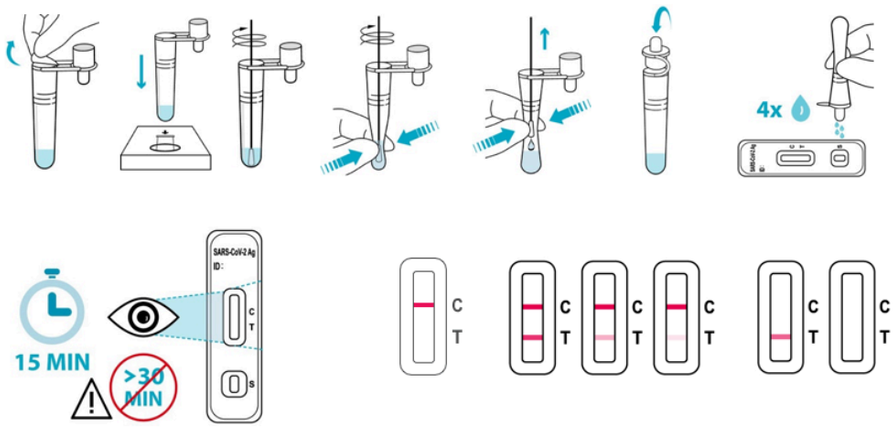
Clinical Performance

The 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
- 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	L031-18B5	Cassette	Nasal swabs	1 Test/Kit
Flowflex COVID - 19 antigen Home Test	L031-125M5	Cassette	Nasal swabs	2 Test/Kit
Flowflex COVID - 19 antigen Home Test	L031-125N5	Cassette	Nasal swabs	5 Test/Kit
Flowflex COVID - 19 antigen Home Test	L031-125P5	Cassette	Nasal swabs	25 Test/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