

# 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.



Fast



Easy to Use



Accurate

# 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.

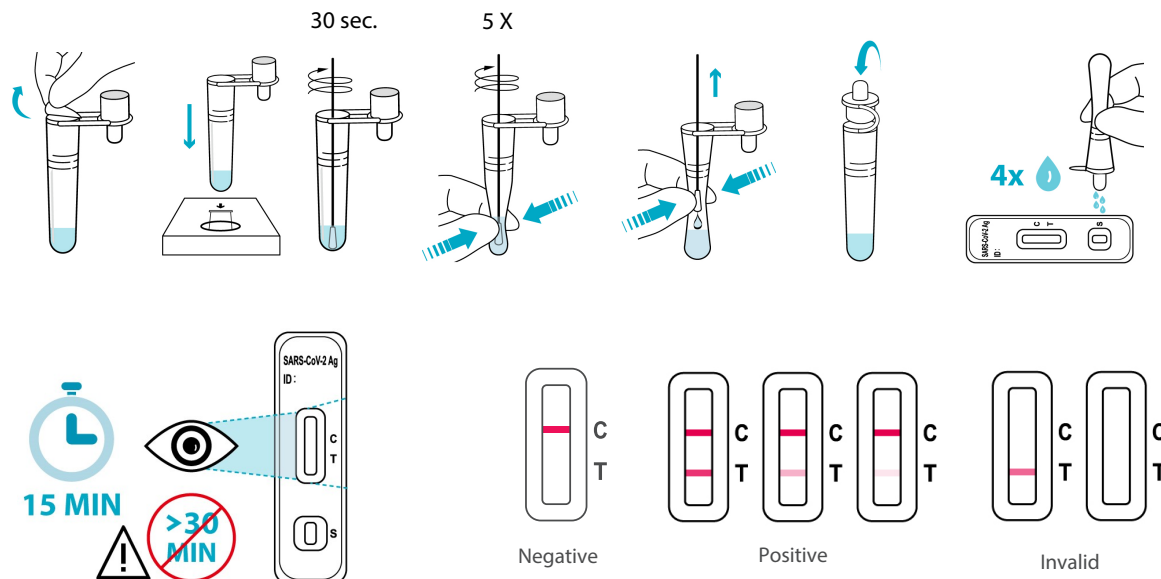
## Clinical Performance

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	L031-118B5	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-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](http://www.cdc.gov/COVID19)
- For detailed instructions, please visit: [www.aconlabs.com](http://www.aconlabs.com)



aconlabs.com

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**Cc:** J; Izzo, Rebecca L; Longenecker, Emmalani H  
**Subject:** COVID Test Kits Distribution  
**Attachments:** Covid Test Kits Distribution signed 2.10.22.pdf; Flowflex -COVID-19-Antigen-Home-Test Kit-Information Sheet.pdf

Good afternoon Principals,

The BIE School Operations is coordinating the distribution of COVID-19 antigen test kits for all BIE students, families, staff, and all BIE employees, including Southwestern Indian Polytechnic Institute (SIPI) and Haskell University. During the period of February 11 through March, 11, 2022, schools will receive a shipment of COVID-19 test kits.

Please find attached **COVID-19 Test Kit memo** from BIE Director Dearman, and test kit information sheet.

**ACTION:** Upon receipt of shipment of COVID-19 test kits at your school sites, please issue **8 test kits** to each student, staff, and BIE employee along with a copy of the attached memo and test kit information sheet.

**QUESTIONS:**

- Test Kit Usage: Contact Donald Dryer, Safety and Occupational Health Manager at [Donald.dryer@bie.edu](mailto:Donald.dryer@bie.edu)
- Test Kit Delivery: Contact Jacqueline Daugomah, Contracting Officer Representative at [Jacqueline.daugomah@bie.edu](mailto:Jacqueline.daugomah@bie.edu)

Thank you for your cooperation and support in this important endeavor!

Respectfully,

***Marcel Felicia, MPH, REHS***

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