Fast COVID Test results Anytime Anywhere

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Flowflex COVID-19 Antigen Home Test

- **Part Number: JANTL031118B5**
- 1 test per box unit
- Anterior nasal swab specimens
- Results in 15 minutes
- 12 Month shelf life
- Store between 36 to 86° F
- Sample self-collection ages 14 and older
- Sample collection by an adult for ages 2 to 13
- Excellent performance when compared to an FDA authorized molecular SARS-CoV-2 test.

Product Description

Flowflex COVID-19 Antigen Home Test is 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. For self-testing use. For use under an Emergency Use Authorization (EUA) only.

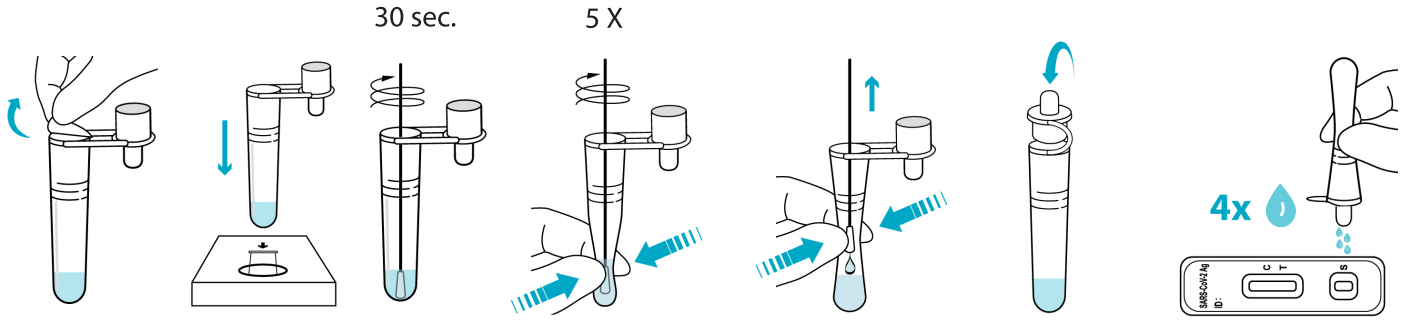
This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older or with adult-collected anterior nasal samples directly from individuals aged 2 years or older. The Flowflex COVID-19 Antigen Home Test does not require serial testing.

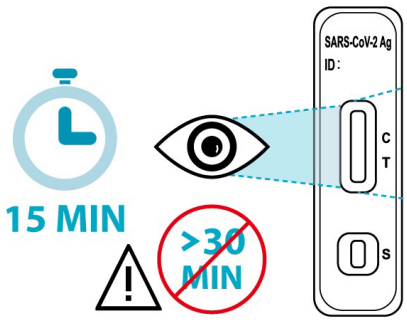
Contents:

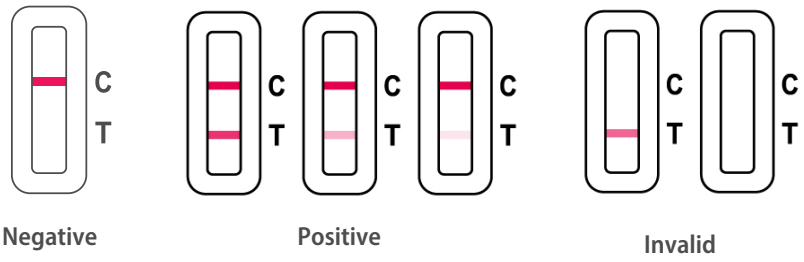
- Test Cassette
- Package Insert
- Extraction Buffer Tube
- Nasal Swab
- External Tube Holder

Use and Performance

Test Procedure and Interpretation







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:

Flowflex 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%)		

- 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