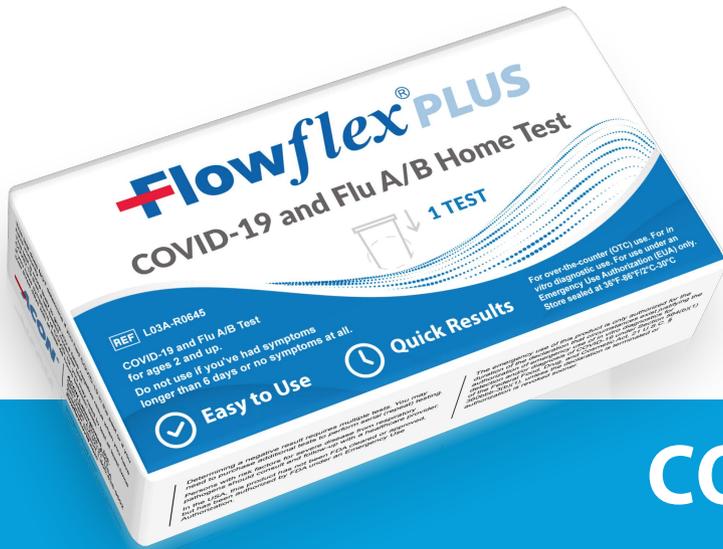


Flowflex[®] PLUS



COVID-19 and Flu A/B Home Test

A rapid test for the detection and differentiation of SARS-CoV-2, Influenza A, and Influenza B protein antigens in anterior nasal swab specimens.



Fast



Easy to Use



Trusted

Flowflex Plus COVID-19 and Flu A/B Home Test

The Flowflex Plus COVID-19 and Flu A/B Home Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens. This test is authorized for non-prescription home use with self-collected anterior nares nasal swab specimens from individuals aged 14 years or older, or with adult-collected anterior nasal swab specimens from individuals two (2) years or older. This test is only authorized for individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first six (6) days of symptom onset when tested at least twice over three days with at least 48 hours between tests. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. The Flowflex Plus COVID-19 and Flu A/B Home Test does not differentiate between SARS-CoV and SARS-CoV-2 viruses and are not intended to detect influenza C antigens. All negative SARS-CoV-2 results are presumptive.

- Results in 15 minutes
- 15 months shelf life
- Store between 36 to 86°F
- 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 a FDA EUA and 510k RT-PCR COVID-19 and Flu A/B assays

Clinical Performance

The Flowflex Plus COVID-19 and Flu A/B Home Test was compared to a FDA EUA and 510k RT-PCR COVID-19 and Flu A/B assays. The Flowflex Plus COVID-19 and Flu A/B Home Test correctly identified 90.6% of positive specimens and 99.3% of negative specimens of COVID-19, 91.7% of positive specimens and 99.8% of negative specimens of Flu A, and 93.6% of positive specimens and 99.7% of negative specimens of Flu B.

Materials Provided

- Test Cassette(s)
- Quick Reference Instructions (English & Spanish)
- Extraction Buffer Tube(s)
- Nasal Swab(s)
- External Tube Holder - Package of 25 tests

Test Procedure and Interpretation

The diagram illustrates the test procedure in 10 steps: 1. Insert the nasal swab into the extraction buffer tube. 2. Rotate the swab 5 times. 3. Repeat step 2. 4. Insert the swab into the extraction buffer tube for 30 seconds. 5. Mix the contents 5 times. 6. Add the mixture to the test cassette. 7. Wait for results. 8. Read the results. 9. Dispose of the swab. 10. Dispose of the cassette.

Below the procedure, a 15-minute timer icon is shown. The interpretation results are shown as test cassettes with the following patterns of lines:

- Negative:** Ctl (red line), B (no line), A (no line), CoV (no line).
- COVID-19 Positive:** Ctl (red line), B (no line), A (red line), CoV (red line).
- Flu A Positive:** Ctl (red line), B (no line), A (red line), CoV (no line).
- Flu B Positive:** Ctl (red line), B (red line), A (no line), CoV (no line).
- COVID-19 + Flu A Positive:** Ctl (red line), B (no line), A (red line), CoV (red line).
- COVID-19 + Flu B Positive:** Ctl (red line), B (red line), A (no line), CoV (red line).
- Flu A + Flu B Positive:** Ctl (red line), B (red line), A (red line), CoV (no line).
- COVID-19, Flu A + Flu B Positive:** Ctl (red line), B (red line), A (red line), CoV (red line).
- Invalid:** Ctl (red line), B (no line), A (no line), CoV (red line).

Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
Flowflex Plus COVID-19 and Flu A/B Home Test	L03A-R0645	Cassette	Nasal Swabs	1 Test/Kit
Flowflex Plus COVID-19 and Flu A/B Home Test	L03A-R0745	Cassette	Nasal Swabs	2 Tests/Kit
Flowflex Plus COVID-19 and Flu A/B Home Test	L03A-R0845	Cassette	Nasal Swabs	5 Tests/Kit
Flowflex Plus COVID-19 and Flu A/B Home Test	L03A-R0945	Cassette	Nasal Swabs	25 Tests/Kit



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- 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 and differentiation of proteins from SARS-CoV-2, influenza A, and influenza B - 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
- For detailed instructions, please visit: www.aconlabs.com



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