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# Get Ready for Respiratory Season!

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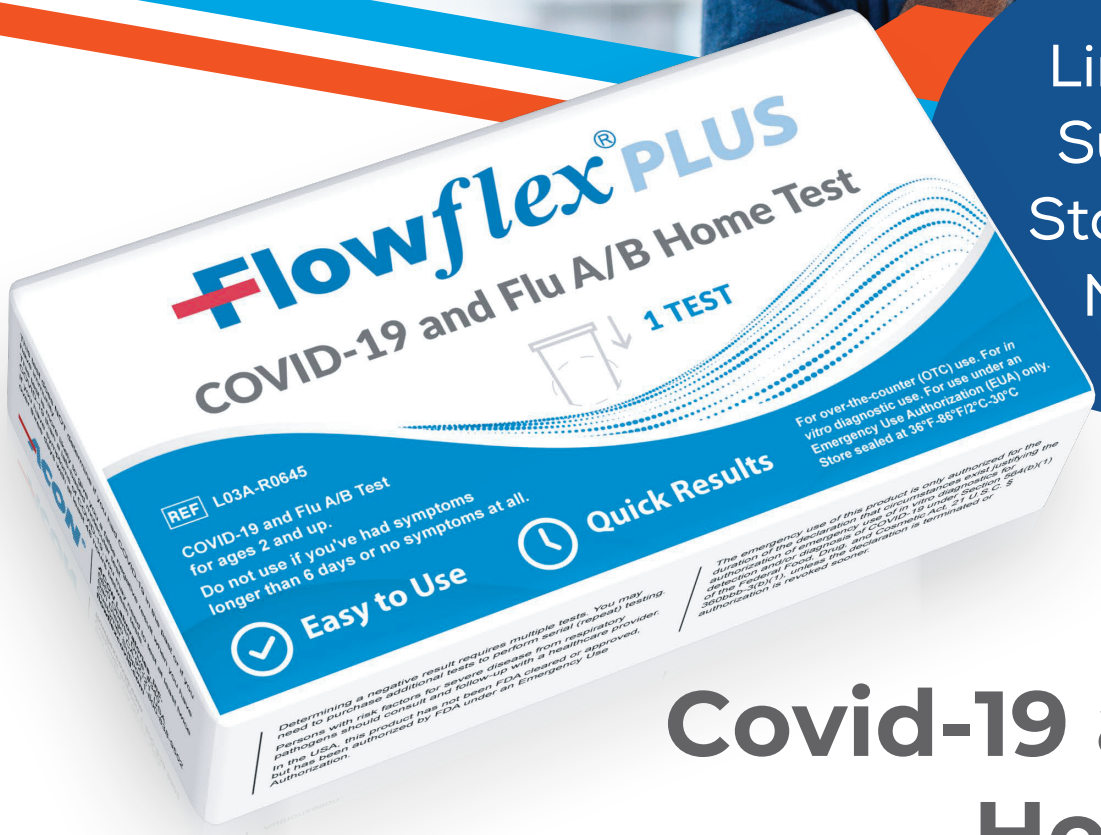


# Covid-19 and FLU Home Test

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

15 Min

Fast | Easy to Use | Trusted

Flowflex® PLUS

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# Flow*flex* Plus COVID-19 and Flu A/B Home Test

The Flow*flex* 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
- Excellent performance when compared to a FDA EUA and 510k PCR-RT COVID-19 and Flu A/B assays.

## Clinical Performance

The performance of Flowflex Plus COVID-19 and Flu A/B Home Test was established in a prospective all-comers clinical study conducted between December 2022 and March 2024. 741 anterior nasal swabs were evaluated in symptomatic individuals with respiratory symptoms within 6 days of symptom onset and were either self-collected and tested by users >14 years of age or collected and tested by an adult from users who were < 14 years of age. The study was conducted in a simulated home setting environment at ten study sites in the U.S. All adults and all minors ≥ 14 years of age performed the test unassisted and interpreted the result, using only the Quick Reference Instructions. The investigational sample was collected after the collection of the nasopharyngeal swab for comparator testing. The Flowflex Plus COVID-19 and Flu A/B Home Test results were compared to FDA EUA and 510(k) RT-PCR COVID-19 molecular assays to determine test performance in the tables below:

**Table 2. COVID-19 result of the Flow*flex* Plus COVID-19 and Flu A/B Home Test compared to reference RT-PCR Assay**

| COVID-19 Result of Flow*flex* Plus COVID-19 and Flu A/B Home Test | RT-PCR for COVID-19 | | |
|---|---|---|---|
| | Positive | Negative | Total |
| COVID-19 Positive | 164 | 4 | 168 |
| COVID-19 Negative | 17 | 551 | 568 |
| Total | 181 | 555 | 736* |
| Positive Percent Agreement (PPA) | 90.6% (164/181) (95%CI: 85.4% - 94.4%) | | |
| Negative Percent Agreement (NPA) | 99.3% (551/555) (95%CI: 98.2% - 99.8%) | | |

* 5 samples excluded due to invalid/inconclusive results with comparator methods.

**Table 4. Flu A results of Flow*flex* Plus COVID-19 and Flu A/B Home Test compared to reference RT-PCR Assay**

| Flu A Result of Flow*flex* Plus COVID-19 and Flu A/B Home Test | RT-PCR for Flu A | | |
|---|---|---|---|
| | Positive | Negative | Total |
| Flu A Positive | 77 | 1 | 78 |
| Flu A Negative | 7 | 656 | 663 |
| Total | 84 | 657 | 741 |
| Positive Percent Agreement (PPA) | 91.7% (77/84) (95%CI: 83.6% - 96.6%) | | |
| Negative Percent Agreement (NPA) | 99.8% (656/657) (95%CI: 99.2% - 100%) | | |

**Table 5. Flu B results of Flow*flex* Plus COVID-19 and Flu A/B Home Test compared to reference RT-PCR Assay**

| Flu B Result of Flow*flex* Plus COVID-19 and Flu A/B Home Test | RT-PCR for Flu B | | |
|---|---|---|---|
| | Positive | Negative | Total |
| Flu B Positive | 44 | 2 | 46 |
| Flu B Negative | 3 | 692 | 695 |
| Total | 47 | 694 | 741 |
| Positive Percent Agreement (PPA) | 93.6% (44/47) (95%CI: 82.5% - 98.7%) | | |
| Negative Percent Agreement (NPA) | 99.7% (692/694) (95%CI: 99.0% - 100%) | | |

**Analytical Sensitivity: Limit of Detection (LoD)** :
LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time. Based on this testing, the LoD in nasal matrix was confirmed to be 1.27 x $10^3$ $TCID_{50}$/mL for COVID-19 (SARS-CoV-2 USA-WA1/2020), 1.51 x $10^3$ $TCID_{50}$/mL for Flu A, and 5.17 x $10^0$ $TCID_{50}$/mL for Flu B.

**Table 6. LoD of Flow*flex* Plus COVID-19 and Flu A/B Home Test**

| Virus | Subtype/ Lineage | LoD concentration ($TCID_{50}$/mL) | LoD concentration ($TCID_{50}$/mL) | # Positive/ # Total | Percent Detected (%) |
|---|---|---|---|---|---|
| Flu A/Brisbane/02/18 | H1N1 | 1.51 x $10^3$ | 7.55 x $10^1$ | 60/60 | 100% |
| Flu A/Perth/16/09 | H3N2 | 1.87 x $10^3$ | 9.35 x $10^1$ | 60/60 | 100% |
| Flu B/Washington/02/19 | Victoria | 5.17 x $10^0$ | 0.259 | 60/60 | 100% |
| Flu B/Phuket/3073/13 | Yamagata | 1.86 x $10^1$ | 0.93 | 60/60 | 100% |
| SARS-COV-2 | USA-WA1/2020 | 1.27 x $10^3$ | 6.35 x $10^1$ | 60/60 | 100% |

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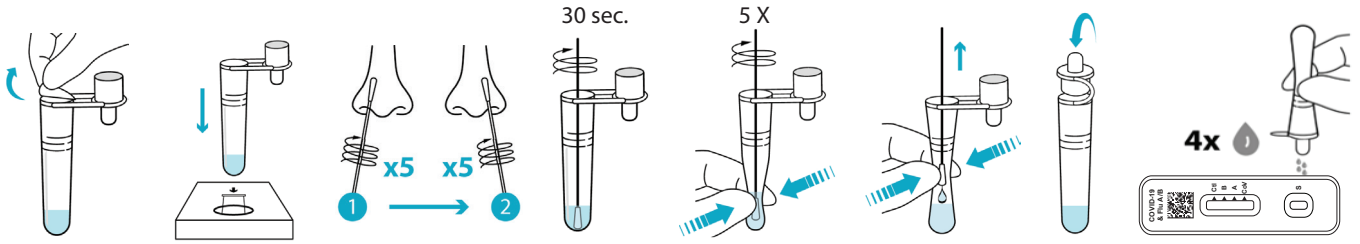
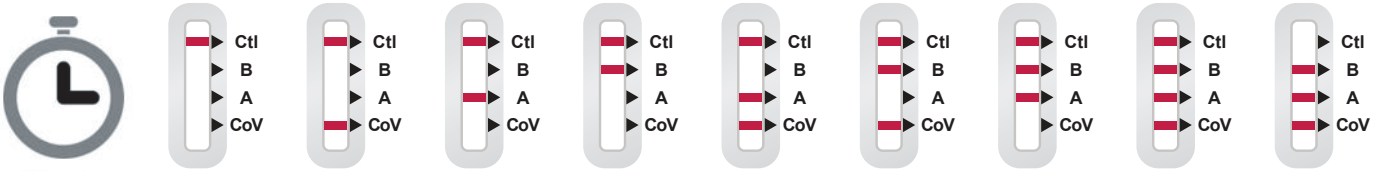
## Materials Provided

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

## Test Procedure and Interpretation




15 min | Negative | COVID-19 Positive | Flu A Positive | Flu B Positive | COVID-19 + Flu A Positive | COVID-19 + Flu B Positive | Flu A + Flu B Positive | COVID-19, Flu A + Flu B Positive | Invalid

## Ordering Information

| Product Name | VAI No. | Catalog No. | Format | Specimen | Package |
|---|---|---|---|---|---|
| Flow*flex* Plus COVID-19 and Flu A/B Home Test | 404554 | L03A-R0645 | Cassette | Nasal Swabs | 1 Test/Kit |
| Flow*flex* Plus COVID-19 and Flu A/B Home Test | 404557 | L03A-R0745 | Cassette | Nasal Swabs | 2 Tests/Kit |
| Flow*flex* Plus COVID-19 and Flu A/B Home Test | 404558 | L03A-R0845 | Cassette | Nasal Swabs | 5 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 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 auuthorization 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-policyframework/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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FOR MORE INFORMATION, PLEASE CONTACT
YOUR CONCORDANCE ACCOUNT MANAGER

SCAN HERE TO VISIT
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10/11/24