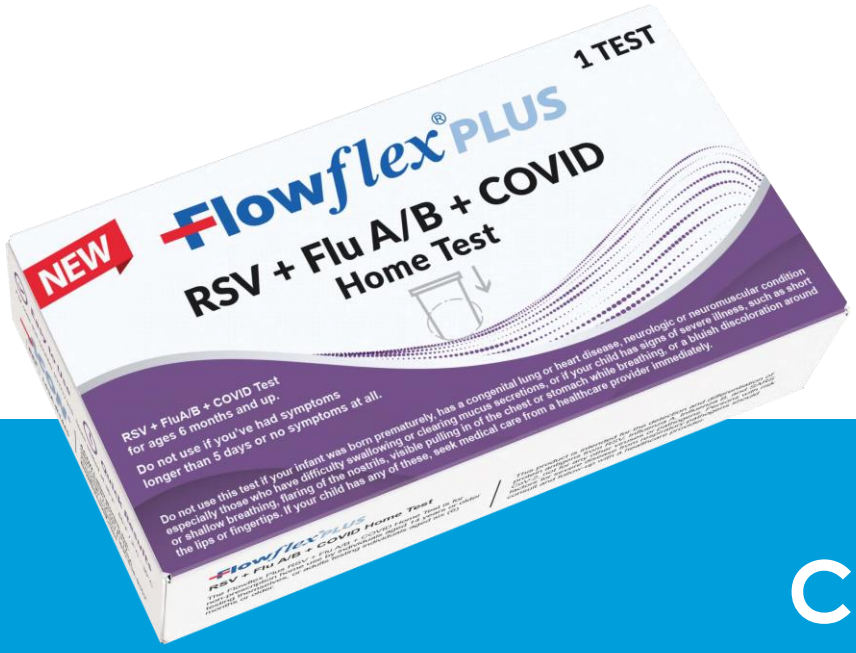
Flowflex® PLUS



RSV + Flu A/B + COVID Home Test

A rapid test for the detection and differentiation of respiratory syncytial virus (RSV), Influenza A, Influenza B, and/or SARS-CoV-2 antigens in anterior nasal swab specimens.

15 Min

Fast

Easy to Use

Trusted

ACON®

ACON Laboratories, Inc.

Flow*flex* Plus RSV + Flu A/B + COVID Home Test

The Flow*flex* Plus RSV + Flu A/B + COVID Home Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of respiratory syncytial virus (RSV), influenza A, influenza B, and SARS-CoV-2 protein antigens directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to RSV, influenza, and SARS-CoV-2 can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged six (6) months or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with RSV, influenza, SARS-CoV-2 or other pathogens. Individuals who test negative and/or experience continued or worsening symptoms, such as fever, cough and/or shortness of breath should therefore seek follow-up care from their healthcare provider.

- Results in 15 minutes
- 24 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 for children ages 2 to 13
- Sample collection by adults with swab guard for children 6 to 23 months
- Excellent performance when compared to highly sensitive PCR tests

Clinical Performance

The performance of Flow*flex* Plus RSV + Flu A/B + COVID Home Test was established in a prospective all-comers clinical study conducted in a simulated home setting environment at ten study sites in United States. A total of 1263 anterior nasal swab samples were collected from symptomatic individuals within 5 days of respiratory symptom onset and met the inclusion criteria for the analysis, of which 1257 samples were evaluable for COVID-19 and 1261 samples evaluable for Flu A/B and RSV respectively. The investigational nasal swab samples were either self-collected by each enrolled subject or by another adult lay user collected from a subject after the collection of the nasopharyngeal swab for comparator testing. Each subject or lay user performed the test and interpreted the result, unassisted by using only the Quick Reference Instructions. The Flow*flex* Plus RSV + Flu A/B + COVID Home Test results were compared to FDA cleared highly sensitive RT-PCR molecular assays to determine test performance in the tables below.

Table 1. SARS-CoV-2 result of the Flow*flex* Plus RSV + Flu A/B + COVID Home Test compared to reference RT-PCR Assay

SARS-CoV-2 Result of Flow*flex* Plus RSV + Flu A/B + COVID Home Test	RT-PCR for SARS-CoV-2		
	Positive	Negative	Total
SARS-CoV-2 Positive	131	1	132
SARS-CoV-2 Negative	12	1113	1125
Total	143	1114	1257*
Positive Percent Agreement (PPA)	91.6% (131/143) (95%CI: 85.9% - 95.1%)		
Negative Percent Agreement (NPA)	99.9% (1113/1114) (95%CI: 99.5% - 100%)		

* 6 samples excluded due to invalid results with comparator methods.

Table 3. Flu A results of Flow*flex* Plus RSV + Flu A/B + COVID Home Test compared to reference RT-PCR Assay

Flu A Result of Flow*flex* Plus RSV + Flu A/B + COVID Home Test	RT-PCR for Flu A		
	Positive	Negative	Total
Flu A Positive	236	2	238
Flu A Negative	18	1005	1023
Total	254	1007	1261*
Positive Percent Agreement (PPA)	92.9 % (236/254) (95%CI: 89.1 % - 95.5 %)		
Negative Percent Agreement (NPA)	99.8% (1005/1007) (95%CI: 99.3 % - 100 %)		

* 2 samples excluded due to invalid results with comparator methods.

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

Flu B Result of Flow*flex* Plus RSV + Flu A/B + COVID Home Test	RT-PCR for Flu B		
	Positive	Negative	Total
Flu B Positive	91	1	92
Flu B Negative	7	1162	1169
Total	98	1163	1261*
Positive Percent Agreement (PPA)	92.9 % (91/98) (95%CI: 86.0 % - 96.5 %)		
Negative Percent Agreement (NPA)	99.9 % (1162/1163) (95%CI: 99.5 % - 100 %)		

* 2 samples excluded due to invalid results with comparator methods.

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

RSV Result of Flow*flex* Plus RSV + Flu A/B + COVID Home Test	RT-PCR for RSV		
	Positive	Negative	Total
RSV Positive	159	2	161
RSV Negative	10	1090	1100
Total	169	1092	1261*
Positive Percent Agreement (PPA)	94.1 % (159/169) (95%CI: 89.5% - 96.8%)		
Negative Percent Agreement (NPA)	99.8 % (1090/1092) (95%CI: 99.3% - 100%)		

*2 samples excluded due to invalid results with comparator methods.

Analytical Sensitivity: Limit of Detection (LoD) :

A limit of detection (LoD) study was conducted to determine the lowest detectable concentration of RSV, influenza A, influenza B, and SARS-CoV-2, (i.e., at least 95% of all true positive replicates are consistently detected as positive). The LoD study was determined using a two-step method: a preliminary range finding study, followed by a confirmatory LoD study. A preliminary LoD was determined by first testing serial ten-fold dilutions of live RSV A and RSV B, influenza A and B, and inactivated SARS-CoV-2 virus stocks diluted into pooled negative swab matrix (PNSM) in 5 replicates per dilution and confirmatory testing was conducted with 20 replicates for 3 lots. The lowest concentration that generated ≥95% positive detection rate was set as the LoD concentration. The results of LoD confirmation testing for each virus are summarized in Table 7.

Table 7. LoD of Flow*flex* Plus RSV + Flu A/B + COVID Home Test

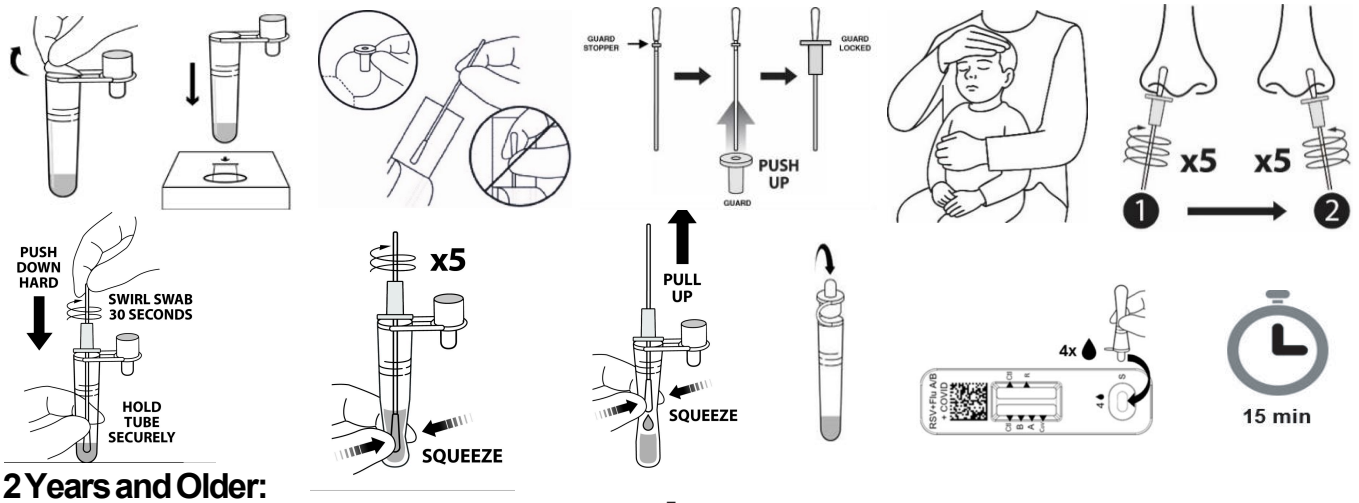
Virus	Subtype /Lineage	Strains	LoD Concentration ($TCID_{50}$/ml)	LoD per swab ($TCID_{50}$/swab)	# Positive /Total	Percent detected (%)
SARS-CoV-2	Omicron XBB	USA/CA-Stanford-109_S21/2022	5.95×10^4	2.98×10^3	60/60	100%
	Wild-type	USA-WA1/2020	1.27×10^3	6.35×10^1	60/60	100%
Flu A	H1N1	A/Guangdong-Maonan/SWL1536/19	3.90×10^3	1.95×10^2	60/60	100%
		A/Victoria/4897/22	3.89×10^1	1.95×10^0	60/60	100%
	H3N2	A/Darwin/6/2021	1.56×10^2	7.80×10^0	60/60	100%
Flu B	Victoria	B/Hong Kong/574/19	5.01×10^2	2.51×10^1	60/60	100%
		B/Alabama/02/17	3.90×10^2	1.95×10^1	60/60	100%
	Yamagata	B/Phuket/3073/13	1.86×10^1	9.30×10^{-1}	60/60	100%
RSV	A	2006 Isolate	1.05×10^3	5.25×10^1	60/60	100%
	B	CH93(18)-18	4.17×10^2	2.09×10^1	59/60	98.3%

Materials Provided

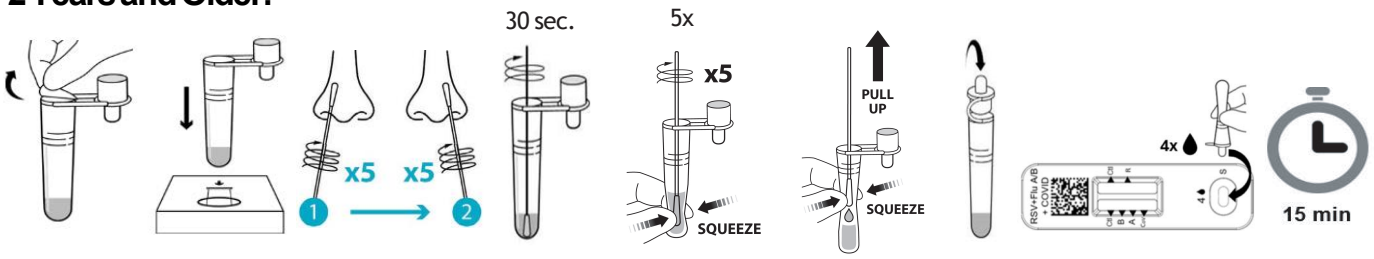
- Test Cassette(s)
- Quick Reference Instructions (English & Spanish)
- Extraction Buffer Tube(s)
- Nasal Swab(s)
- External Tube Holder - Package of 25 tests
- Swab Guard(s)

Test Procedure and Interpretation

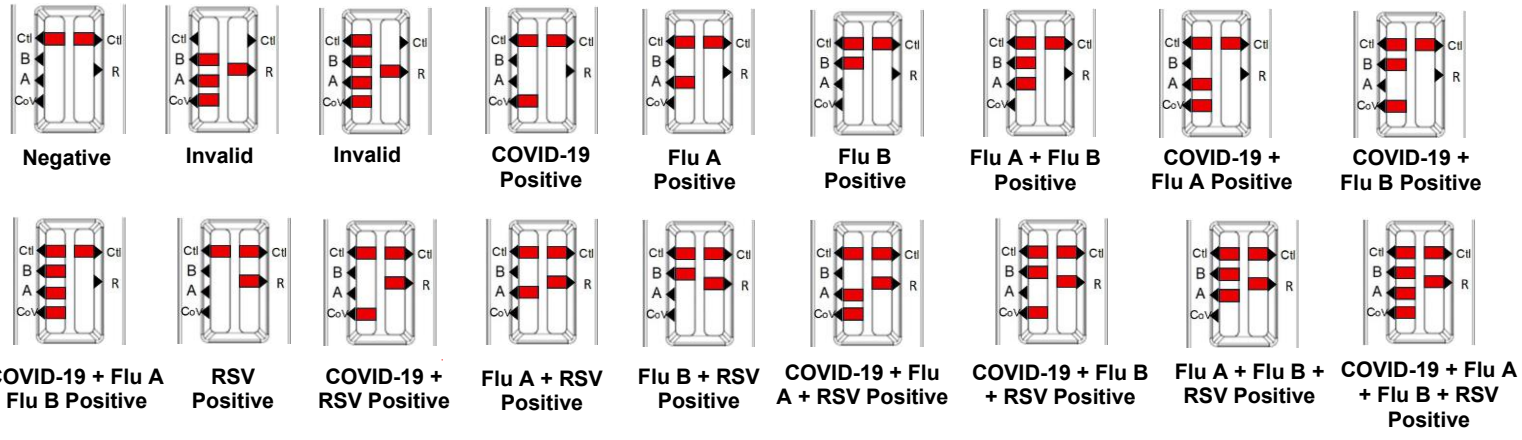
Infants (6 Months - 23 Months):



2 Years and Older:



Results Interpretation:



Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
Flow*flex* Plus RSV + Flu A/B + COVID Home Test	L03A-R1445	Cassette	Nasal Swabs	1 Test/Kit
Flow*flex* Plus RSV + Flu A/B + COVID Home Test	L03A-R1545	Cassette	Nasal Swabs	2 Tests/Kit
Flow*flex* Plus RSV + Flu A/B + COVID Home Test	L03A-R1645	Cassette	Nasal Swabs	5 Tests/Kit
Flow*flex* Plus RSV + Flu A/B + COVID Home Test	L03A-R1745	Cassette	Nasal Swabs	25 Tests/Kit

ACON®

Distributed by

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