



Sofia² Flu+SARS Antigen FIA

AVAILABLE FOR SALE IN THE USA AS EUA

Flu A, Flu B + SARS-CoV-2 at Your Fingertips

One Test, Three Results, 15 Minutes



Accurate, objective and automated results in **15 minutes**



Track via **secure, remote instrument management** with **Virena[®]**



Excellent performance compared to viral culture or molecular methods



Integrated data management automatically stores test and user history



Flexible, dual mode testing for high throughput in variety of laboratory environments

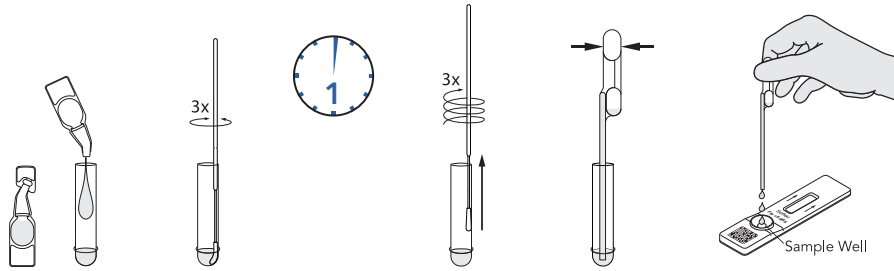


User and patient ID captured with **onboard barcode scanner**



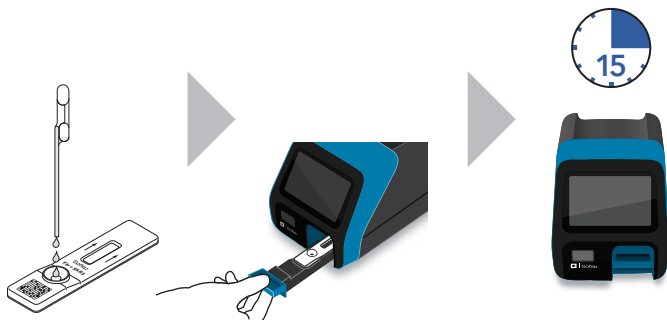
Sofia 2 Flu + SARS Antigen FIA - Procedures

Nasal/Nasopharyngeal Swab Procedure

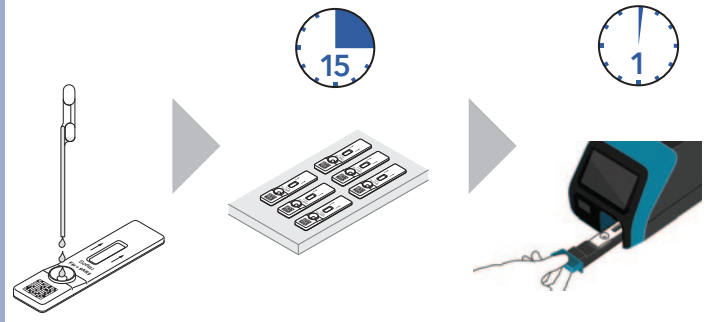


Sofia 2 Development Modes

WALK AWAY Mode – Walk away and multitask



READ NOW Mode – Batch multiple samples per hour



Sofia 2 Flu + SARS Antigen FIA*

- Nasal and nasopharyngeal specimens
- Accurate detection with direct samples
- Results in 15 minutes
- Kit includes 25 sterile nasal or nasopharyngeal swabs and a set of positive and negative control swabs
- Room temperature storage
- 12-month shelf life from date of manufacture



Sofia 2 Flu + SARS Antigen FIA Clinical Performance*

	Sample Type	Sens/PPA*	Spec/NPA*
Influenza A	Nasal	90%	95%
	Nasopharyngeal	97.1%	94.6%
Influenza B	Nasal	89%	96%
	Nasopharyngeal	90%	97%
SARS-CoV-2*	Nasal	95.2%*	100%*

*Results for SARS-CoV-2 are expressed as PPA/NPA and were tested on nasal swabs in the study, however, may also be used with NP swabs.

Refer to the Package Insert for additional performance claims.

The Sofia 2 Flu + SARS Antigen FIA has not been FDA cleared or approved but has been authorized by the FDA under an EUA for use by authorized laboratories for the detection of proteins from SARS-CoV-2, and influenza, not for any other viruses or pathogens. This assay is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics 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 authorization is terminated or revoked sooner.

SL3202 | SS2037701EN00 (04/21)

Sofia 2 Flu + SARS Antigen FIA – 25 Test Kit (nasal swabs): Catalog #20377

25 Test Kit (nasopharyngeal swabs): Catalog #20390

