



# Sofia<sup>®</sup> SARS Antigen FIA

AVAILABLE FOR SALE IN THE USA AS EUA  
FOR BOTH SOFIA 2 AND SOFIA INSTRUMENTS

## Objective SARS-CoV-2 Results at Your Fingertips



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



Track via **secure, remote instrument management** with **Virena<sup>®</sup>**



**Excellent performance** compared to molecular methods



**Integrated data management** automatically stores test and user history



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

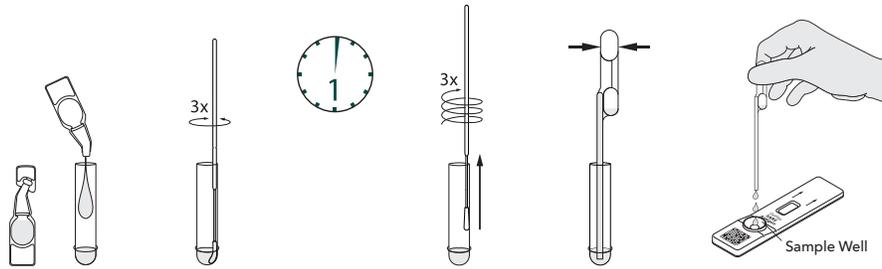


User and patient ID captured with **onboard barcode scanner**



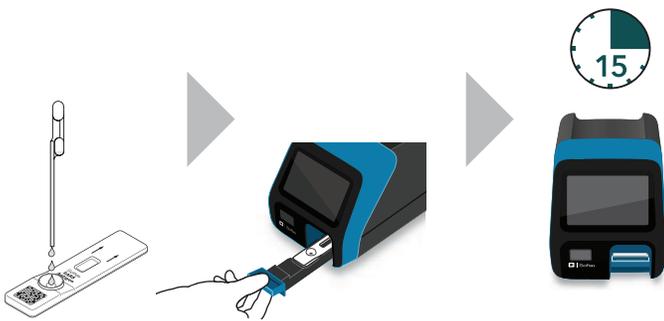
# Sofia SARS Antigen FIA – Procedure

## Anterior Nares Swab Procedure

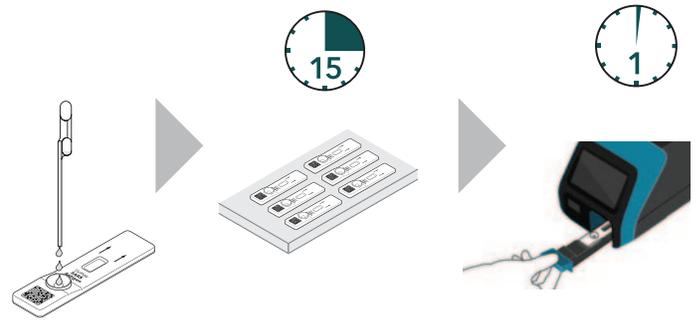


## Sofia Development Modes

### WALK AWAY Mode – Walk away and multitask



### READ NOW Mode – Batch multiple samples per hour



## Sofia SARS Antigen FIA

- Anterior nares swab specimens
- Accurate detection with direct samples
- Results in 15 minutes
- Kit includes 25 sterile nasal swabs and a set of positive and negative control swabs
- Room temperature storage

## Sofia SARS Antigen FIA Clinical Performance\*

	Reference Extracted RT-PCR assay				95% CI			
		POS	NEG	Total	PPA	96.7%	83.3%	99.4%
<b>Sofia SARS Antigen FIA Assay</b>	POS	29	0	29	NPA	100.0%	97.9%	100.0%
	NEG	1	179	180	PPV	100.0%	88.3%	100.0%
	Total	30	179	209	NPV	99.4%	96.9%	99.9%
					Prevalence	14.4%	7.4%	14.3%
					% agreement	99.5%		

\*Please refer to the Package Insert for full study design and explanation.



The Sofia 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, 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 | SS2037406EN00 (04/21)

Sofia SARS Antigen FIA – 25 Test Kit (nasal swabs): Catalog #20374

