



Sofia®
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®



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

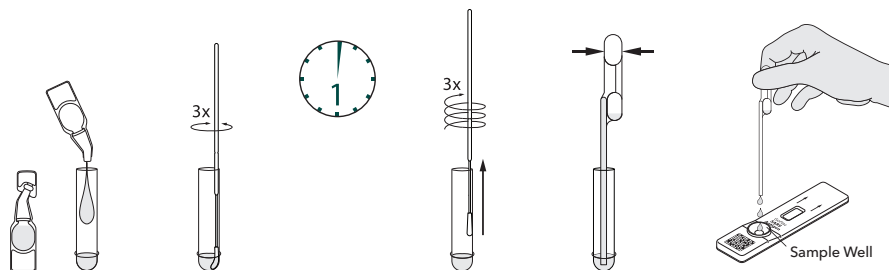


User and patient ID captured
with **onboard barcode scanner**



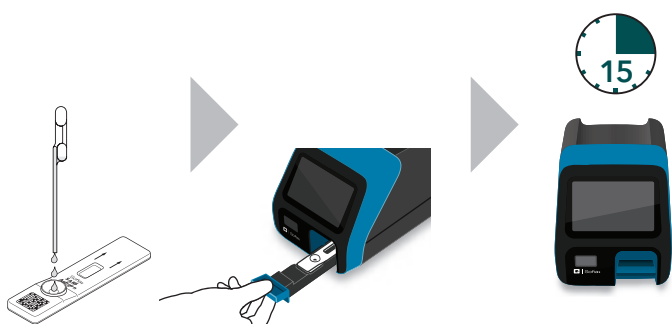
Sofia SARS Antigen FIA – Procedure

Nasal/Nasopharyngeal Swab Procedure

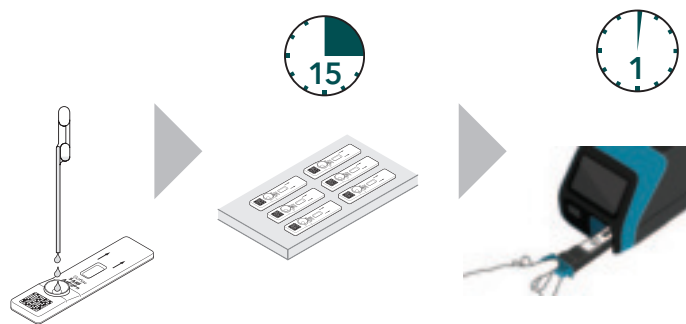


Sofia Development Modes

WALK AWAY Mode – Walk away and multitask



READ NOW Mode – Batch multiple samples per hour



Sofia SARS Antigen FIA

- Nasal and nasopharyngeal 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%
Sofia SARS Antigen FIA Assay	POS	29	0	29	NPA	100.0%	97.9%
	NEG	1	179	180	PPV	100.0%	88.3%
	Total	30	179	209	NPV	99.4%	96.9%
					Prevalence	10.3%	7.4%
					% agreement	99.7%	

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

