







Sofia[®] SARS Antigen FIA

AVAILABLE FOR SALE IN CANADA
UNDER COVID-19 INTERIM ORDER 314994

Objective SARS-CoV-2 Results at Your Fingertips

The first rapid antigen test intended for serial testing
of asymptomatic populations in Canada

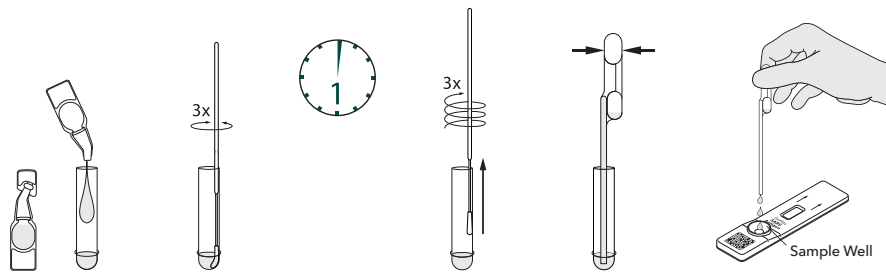
-  Accurate, objective and automated results in **15 minutes**
-  **Serial testing of asymptomatic populations** at a minimum every 3 days/72 hours (91.6% sensitivity)
-  **Gentle nasal collection** with the nasal swab supplied in the kit
-  **Excellent performance** compared to molecular methods (96.7% sensitivity)*
-  Extended shelf life, up to **24 months**
-  **Flexible, dual mode testing** for high throughput in a variety of environments
-  **Integrated data management** plus user and patient ID captured with **onboard barcode scanner**



*For patients within the first 5 days of the onset of symptoms.

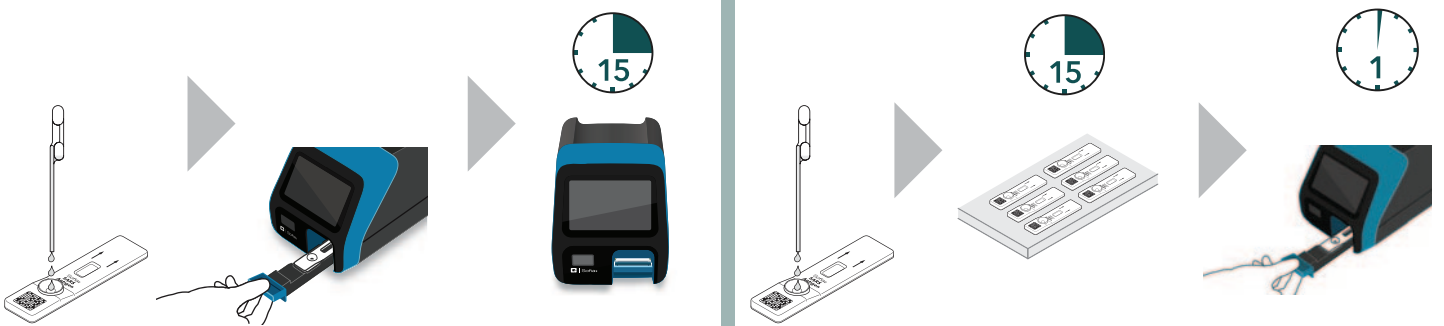
Sofia SARS Antigen FIA – Procedure

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 (nasal) 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
- 24 months shelf life

Sofia SARS Antigen FIA Clinical Performance*

	Reference Extracted RT-PCR assay				95% CI			
	POS	NEG	Total	PPA	96.7%	83.3%	99.4%	
Sofia SARS Antigen FIA Assay	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.

