



Sofia² SARS Antigen FIA

AVAILABLE FOR SALE IN THE USA AS EUA



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

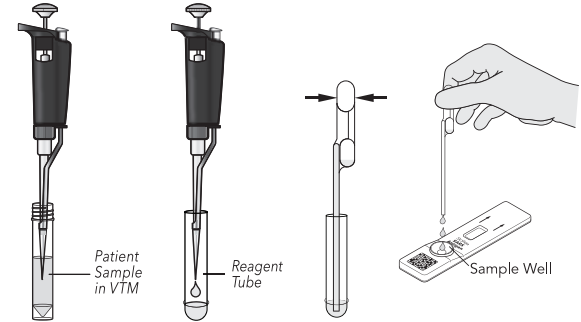
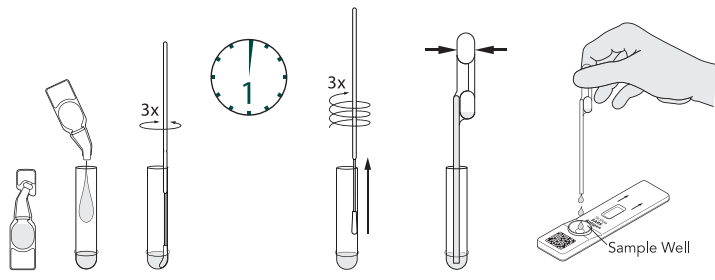


User and patient ID captured with **onboard barcode scanner**



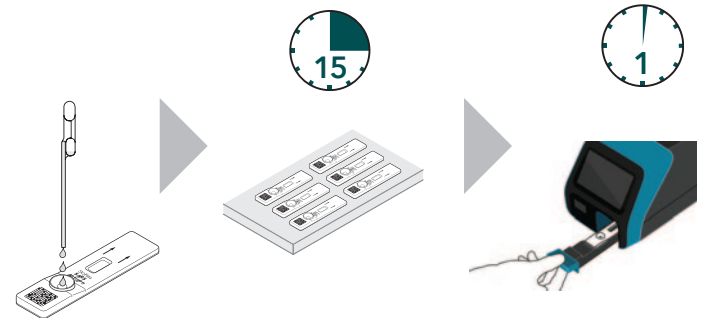
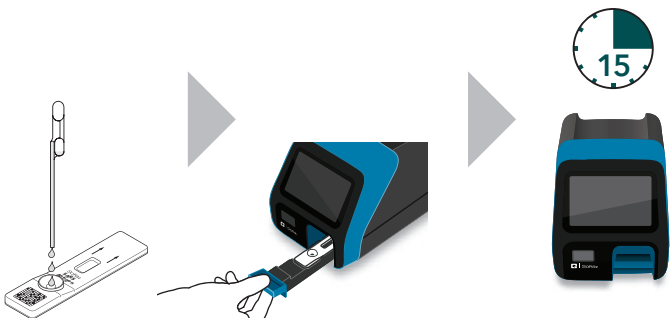
Sofia 2 SARS Antigen FIA – Procedures

Nasal/Nasopharyngeal Swab Procedure OR Liquid Specimens/VTM Test Procedure



Sofia 2 Development Modes

WALK AWAY Mode – Walk away and multitask READ NOW Mode – Batch multiple samples per hour



Sofia 2 SARS Antigen FIA*

- Nasal and nasopharyngeal specimens
- Accurate detection with direct and VTM samples
- Results in 15 minutes
- Positive and negative control swabs included
- Room temperature storage
- 12-month shelf life from date of manufacture

*Refer to the Package Insert.



Sofia 2 SARS Antigen FIA Clinical Performance

Nasopharyngeal in VTM		SARS-CoV-2 Molecular			PPA	80%	95% CI	
		POS	NEG	Total			68%	88%
Sofia 2 SARS Antigen FIA	POS	47	0	47	NPA	100%	96%	100%
	NEG	12	84	96	PPV	100%	92%	100%
	Total	59	84	143	NPV	88%	79%	93%
					Prevalence	41%	34%	49%
					% agreement	92%		

Direct Nasal Swab		Lyra® SARS-CoV-2 Molecular EUA200016/A002			PPA	80.0%	95% CI	
		POS	NEG	Total			37.6%	96.4%
Sofia 2 SARS Antigen FIA	POS	4	0	4	NPA	100.0%	91.8%	100.0%
	NEG	1	43	44	PPV	100.0%	51.0%	100.0%
	Total	5	43	48	NPV	97.7%	88.2%	99.6%
					Prevalence	10.4%	4.5%	22.2%
					% agreement	97.9%		

