



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

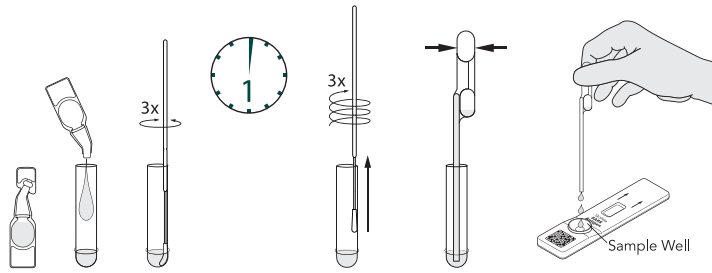


User and patient ID captured with **onboard barcode scanner**

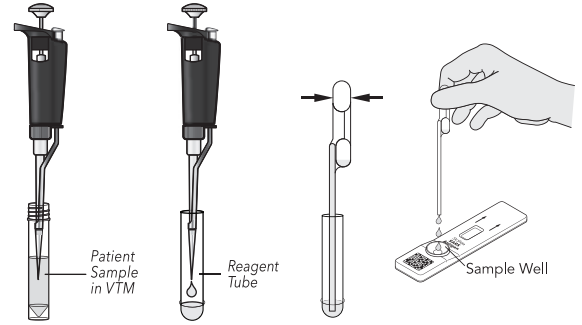


Sofia SARS Antigen FIA – Procedures

Nasal/Nasopharyngeal Swab Procedure

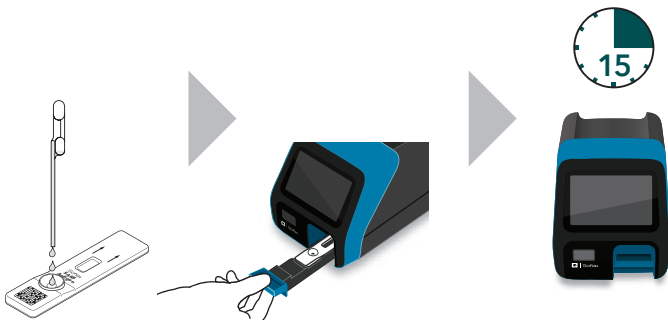


OR CDC Media/VTM Test Procedure

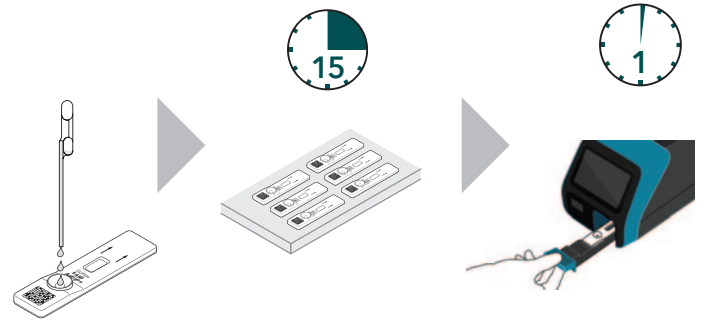


Sofia Development Modes

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 and VTM samples
- Results in 15 minutes
- Kit includes 25 sterile nasal swabs and a set of positive and negative control swabs
- Room temperature storage

*Refer to the Package Insert.



Sofia SARS Antigen FIA Clinical Performance

Nasopharyngeal in VTM		SARS-CoV-2 Molecular			PPA	80%	95% CI	
		POS	NEG	Total			68%	88%
Sofia 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 EUA200016/A002			Sensitivity <th rowspan="2">93.8%</th> <th colspan="2">95% CI</th>	93.8%	95% CI	
		POS	NEG	Total			71.7%	98.9%
Sofia SARS Antigen FIA	POS	15	0	15	Specificity	100.0%	98.1%	100.0%
	NEG	1	200	201	PPV	100.0%	79.6%	100.0%
	Total	16	200	216	NPV	99.5%	97.2%	99.9%
					Prevalence	7.4%	4.6%	11.7%
					% agreement	99.5%		