



Sofia[®]
Strep A+ FIA

Objective Strep A Results at Your Fingertips



Accurate, objective and automated results in **5 minutes**



Secure, remote instrument management through the Virena ecosystem



Excellent performance compared to molecular and bacterial culture methods



Integrated data management automatically stores test and user history



Flexible, dual mode testing and simple, CLIA-waived procedures for a variety of laboratory environments

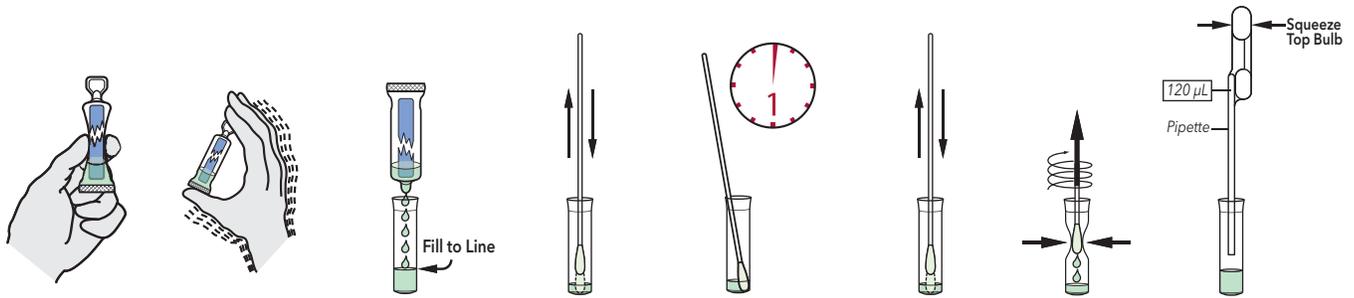


User and patient ID captured with **onboard barcode scanner**



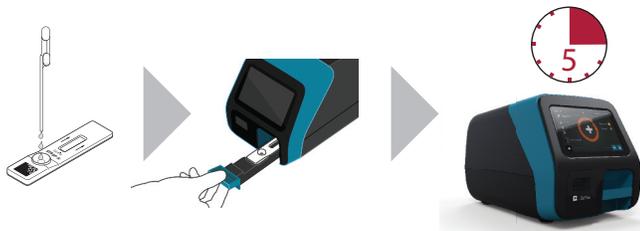
Sofia Strep A+ FIA – Procedures

Throat Swab Procedure

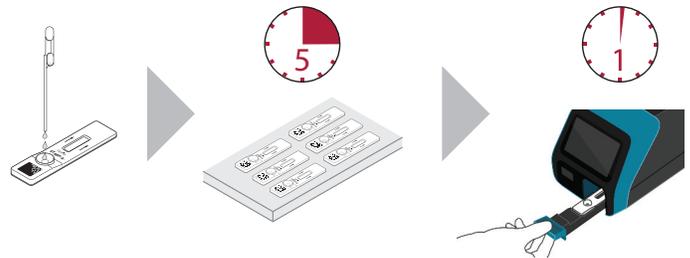


Sofia 2 Development Modes

WALK AWAY Mode – Walk away and multitask



READ NOW Mode – Batch multiple samples per hour



Sofia Strep A+ FIA

- CLIA waived
- Accurate detection with throat swab samples
- Excellent performance demonstrated in a multi-site study*
- Compatible with viral transport media
- Room temperature storage
- 24-month shelf life from date of manufacture

Sofia Strep A+ FIA Results vs. Culture*

	Culture		Sensitivity	93.7% (164/175)
	Pos	Neg		
Sofia Pos	164	38**	Specificity	94.4% (638/676)
Sofia Neg	11***	638		
Total	175	676		

**Of the 38 discordant specimens, 24 of these specimens were positive for GAS when tested with an FDA-cleared molecular device, 14 were negative.

***Of the 11 discordant specimens, 3 were negative when tested with an FDA-cleared molecular device, 8 were positive.

*Refer to the Package Insert for additional performance claims.