

# The **ONLY** instrument providing Antigen (GDH) and Toxin A & B at the Point-of-Care!

Accurate

Automated

Objective

Timely Results

Convenient

Reliable

**GDH + Toxin A & B  
Immunoassay**



## See the **difference**, make the **difference** with the Sofia 2 analyzer and Sofia C. Difficile FIA



**Excellent performance** providing accurate, objective and automated results in **only 15 minutes**



**Integrated data management** automatically stores test and user history



**Fast, easy workflow** reducing hands-on to 4 easy steps, requiring minimal training



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



**Compact footprint** Sofia 2 can be implemented practically anywhere

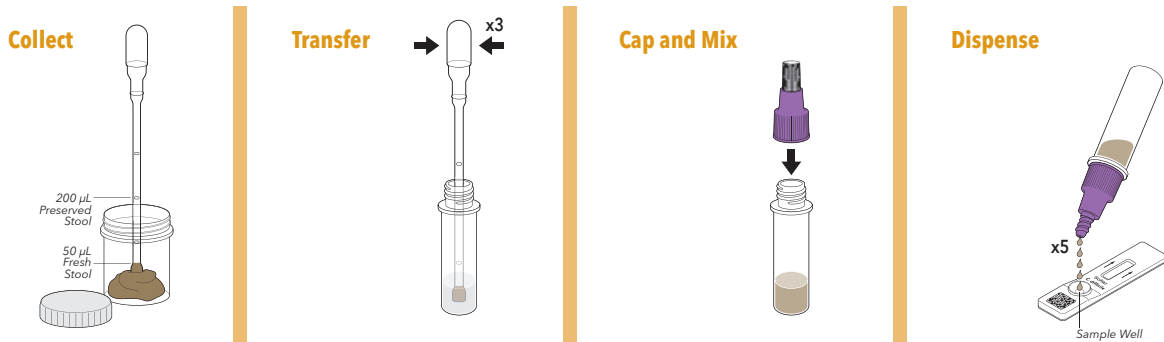


QUIDEL

**Sofia<sup>2</sup>**  
C. difficile FIA

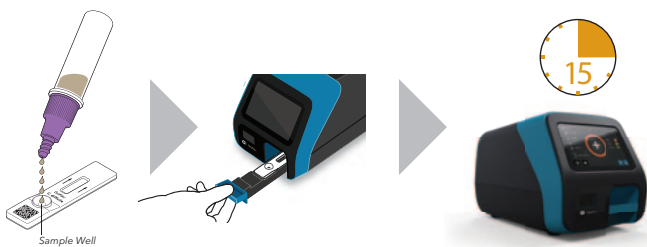
## Sofia 2 C. difficile FIA - Procedure

- Simple procedure designed for everyday users requiring no complex calculations, extractions, or reagent preparations.

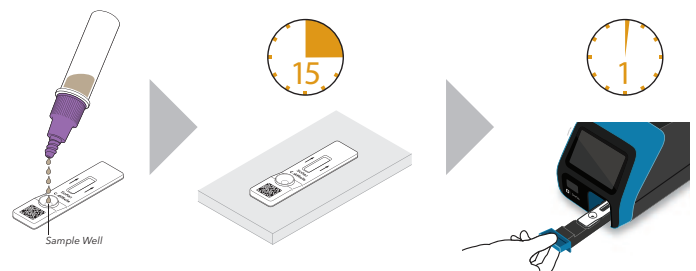


## Sofia 2 Development Modes

### WALK AWAY Mode – Walk away and multitask



### READ NOW Mode – Batch multiple samples per hour



## Sofia 2 C. difficile FIA

- Automatic results reporting with connection to LIS
- A rapid, automated and objective GDH/Toxin test that serves as a complete, standalone assay that complies with 2 step algorithm guidelines
- Simple, hands-off protocol –
  - No mixing reagents,
  - No washing,
  - No manual timing or in-procedure steps
  - No preparation of conjugates, diluents or buffers
  - No “interpretation” of visual results
- 15 minutes procedure that is half the time of the standard combination GDH/Toxin immunoassay
- Room temperature storage of reagents

### Performance of Sofia 2 C. difficile FIA (GDH) versus CCFA Bacterial Culture

	CCFA Bacterial Culture			
	Pos	Neg	Total	
Sofia 2 C diff. FIA Pos	236	92	328	Sensitivity = 86.4% (236/273) (95% CI=81.9% to 90.0%)
Sofia 2 C diff. FIA Neg	37	1215	1252	Specificity = 93.0% (1215/1307) (95% CI=91.4% to 94.2%)
Total	273	1307	1580*	PPV = 72.0% (236/328) (95% CI=66.9% to 76.5%) NPV = 97.0% (1215/1252) (95% CI=96.0% to 97.8%) Prevalence = 17.3% (273/1580)

### Performance of Sofia 2 C. difficile FIA (Toxin A/B) versus Cytotoxic Tissue Culture

	Cytotoxic Tissue Culture			
	Pos	Neg	Total	
Sofia 2 C diff. FIA Pos	90	22	112	Sensitivity = 84.1% (90/107) (95% CI=76.0% to 89.8%)
Sofia 2 C diff. FIA Neg	17	1442	1459	Specificity = 98.5% (1442/1464) (95% CI=97.7% to 99.0%)
Total	107	1464	1571*	PPV = 80.4% (90/112) (95% CI=72.0% to 86.7%) NPV = 98.8% (1442/1459) (95% CI=98.1% to 99.3%) Prevalence = 6.8% (107/1571)

Make the difference!



Sofia<sup>2</sup>  
C. difficile FIA