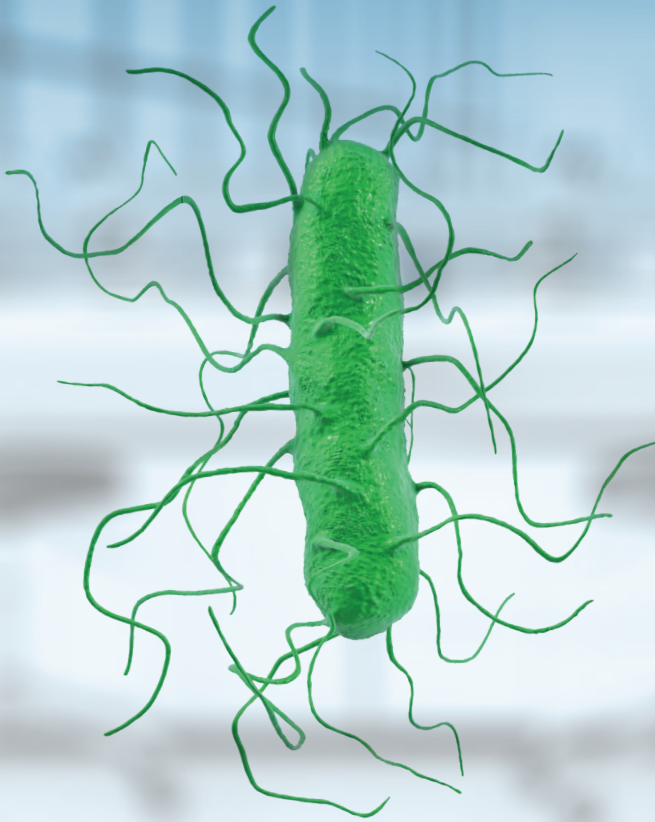




Sofia²
C. difficile FIA

Notoriously difficult

Clostridioides difficile



Miraculously simple

Sofia 2 C. difficile FIA



**Simplify your
C. difficile testing!**

Sofia² C. difficile FIA provides fast, accurate results to help you keep *C. difficile* under control.

Simplified Workflow

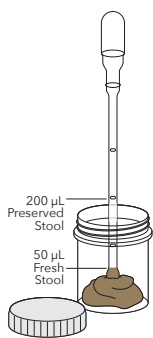
Clostridioides difficile infections (CDI) are associated with a high risk of severe disease and recurrent episodes. This highly contagious pathogen can also cause significant healthcare costs.

Thus, the need for fast and reliable test results.

Many tests for *C. difficile* are complex, material-intensive and associated with in-process waiting times, making them difficult to use at the point of care. The Sofia 2 *C. difficile* FIA helps you overcome these barriers with the following features:

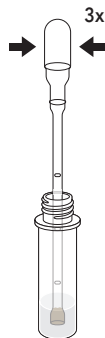
- **GDH & Toxin A/B** results in one step
- **Maximum reduction of manual steps** in sample preparation
- **Largely closed workflow**, reducing risk of contamination when handling potentially infectious stool samples
- **No in-process waiting times** for maximum flexibility
- **Flexible specimen types:** Transport medium or direct/native material
- **Time to results:** ~15 min. for rapid actionable results
- **Objective result interpretation:** Sofia 2 Analyzer uses integrated algorithm for fluorescence signal analysis
- **LIS compatibility** of the Sofia 2 Analyzer

Fast results in just a few easy steps



1. Collect 50 µL (top of flared tip) of Specimen using the Graduated Transfer Pipette provided in the kit.

Note: For specimens in Transport Media (preserved), collect 200 µL (2nd graduation).

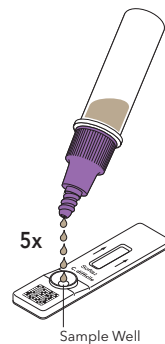


2. Transfer the specimen to the Specimen Tube. Squeeze and release the bulb three times to mix the solution.

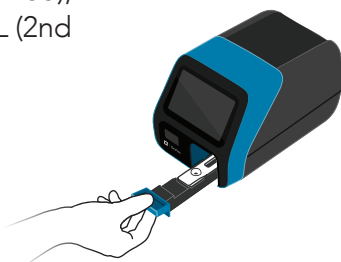
Discard the pipette properly.



3. Screw the purple cap to Specimen Tube and mix well.



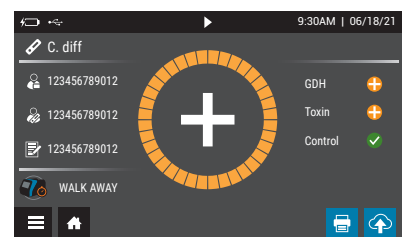
4. Remove the small clear cap, hold the specimen tube vertically and dispense five drops into the Test Cassette sample well.



Insert into the Analyzer



Results in 15 min!



Quidel's optimized workflow provides results in about half the time of comparator assays.

Comparison of competitors to Sofia 2 C. difficile FIA:

Features	Sofia 2 C. difficile FIA	Quik Chek Complete**	Immunocard***		
			GDH	Toxins A&B	GDH + Toxins A&B
Pipetting / mixing steps	2	6 (7)*	6	6	12
Vortexing / mixing steps	1	1	2	2	4
Reagents needed	1	4	3	5	6
Total time to result (min)	15-17	30 (35)*	30	17-20	47-50
Total waiting time (min)	15	25 (30)*	26	15	41
Intra-procedure waiting time (min)	0	15 (20)*	20	10	30
Storage temperature	RT	2°C to 8°C	2°C to 8°C	2°C to 8°C	2°C to 8°C
LIS connectivity	Yes	No	No	No	No
Risk for contamination events (operator, environment, sample)	Low	High	High	High	High
Result interpretation	Objective device algorithm	Visual by operator	Visual by operator	Visual by operator	Visual by operator



*If specimen distribution is not adequate, additional use of diluent solution and 5 min. waiting time needed

**TechLab C. DIFF QUIK CHEK COMPLETE® Package Insert

***Meridian Bioscience Package Inserts for Immunocard® C. difficile GDH as well as for Immunocard® Toxins A&B

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In Line with Current Diagnostic Algorithms

In consensus with the scientific state of the art, the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) recommended and published tiered test algorithms for acute diagnosis in 2016.¹

Fig. 1 Serial Test Algorithm

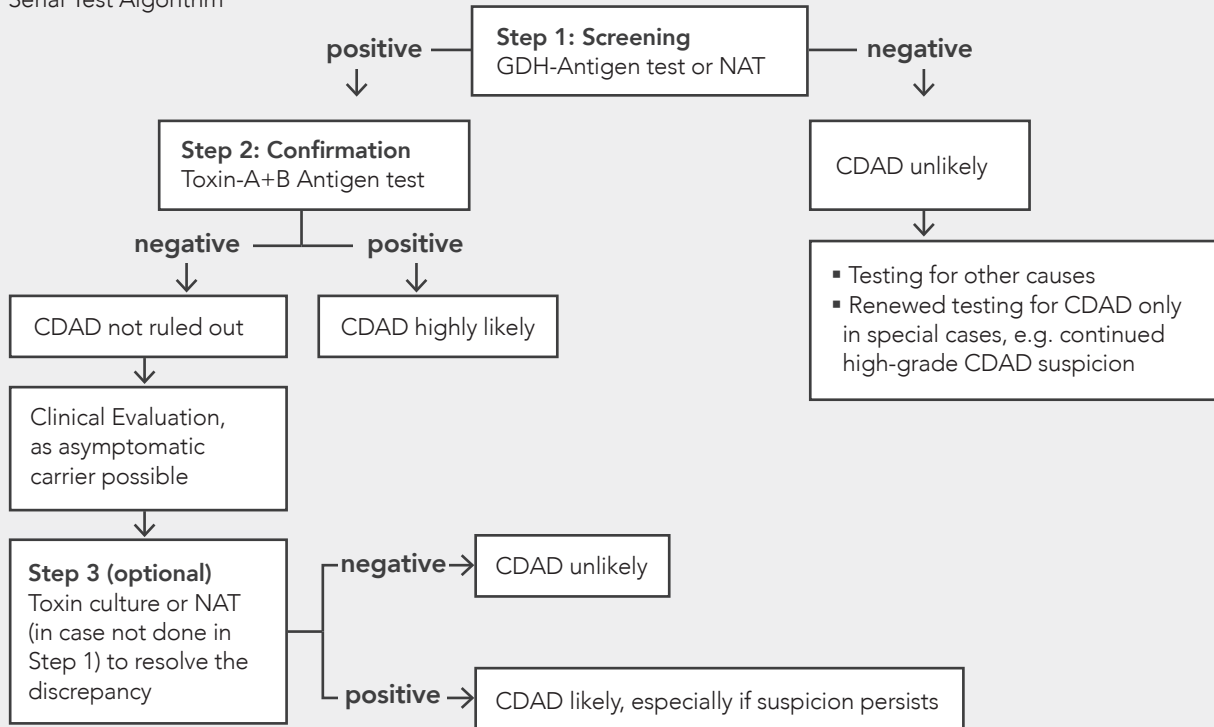
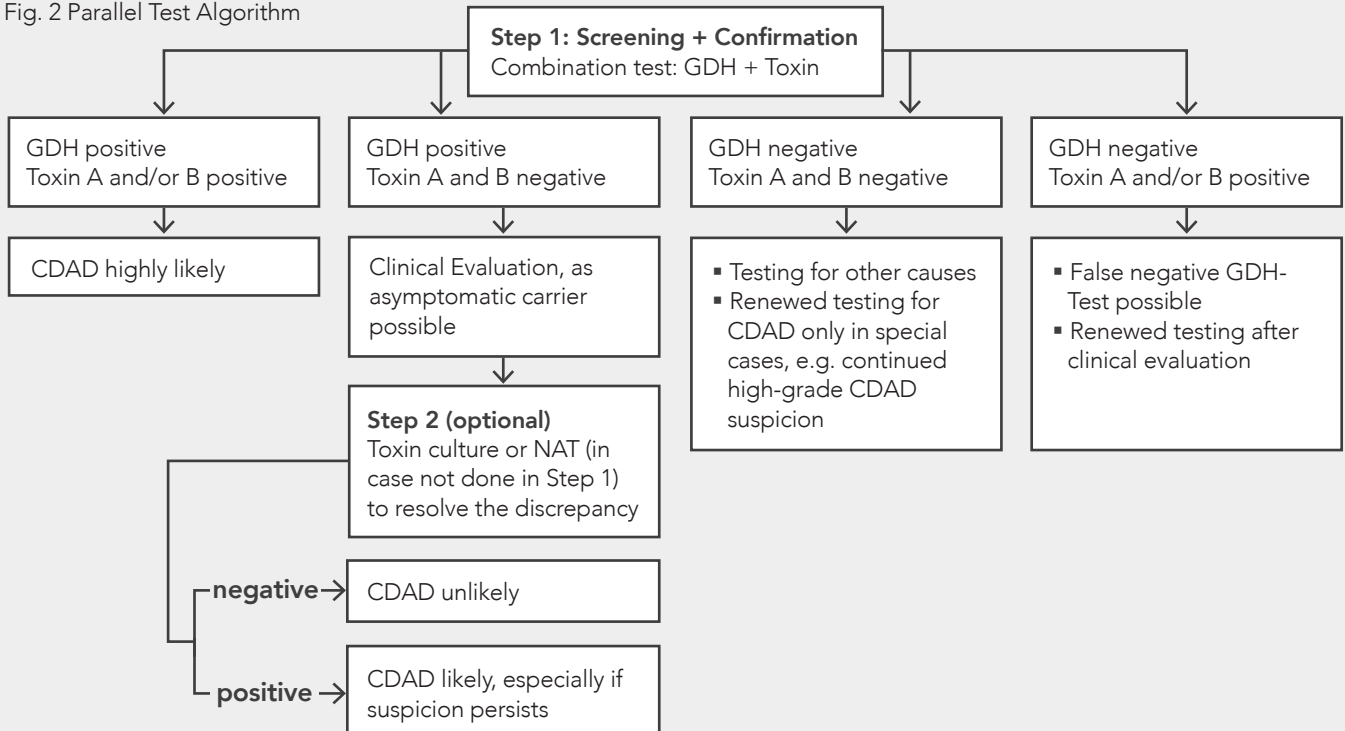


Fig. 2 Parallel Test Algorithm



The recommended test algorithms consist of an initial high-sensitive screening test (molecular or GDH Antigen) followed by a highly specific confirmation test for free toxins (toxin antigen test). Discrepant results can be resolved via a molecular test detecting the toxin genes of *C. difficile*.

GDH and Toxin A/B Results in One Test

Usually, testing is organized as a serial testing algorithm in which positive GDH or PCR results are confirmed by a secondary toxin test (fig. 1) leading to increased time consumption and test frequency.

With Sofia 2 *C. difficile* FIA you can detect GDH and Toxins A/B in one analytical step leading to a reduction of total number of tests and time to results vs. serial testing. This parallel algorithm (fig. 2) is a recommended alternative in the ESCMID guidance.¹

High Performance vs. Culture

The Sofia 2 *C. difficile* FIA provides high sensitivity and specificity for both GDH and Toxin components:²

GDH		Toxin	
Sensitivity	Specificity	Sensitivity	Specificity
86.4%	93%	84.1%	98.5%
236 of 273 correct positive*	1215 of 1307 correct negative*	90 of 107 correct positive**	1442 of 1464 correct negative**
*CCFA Bacterial Culture		**Cytotoxic Tissue Culture	

Study Results

In a recent study³ the sensitivity and specificity of the GDH and toxin components of the Sofia 2 *C. difficile* FIA were compared to another established test (TechLab *C. DIFF QUIK CHEK COMPLETE*) for the simultaneous detection of *C. difficile* GDH and Toxin, determined in a prospective evaluation using anaerobic culture and toxigenic culture as reference. The Sofia 2 *C. difficile* FIA displayed an 8% higher sensitivity of the toxin component in this study.

The authors conclude that Sofia 2 *C. difficile* FIA test provides a rapid turn-around time and a simplified workflow using limited reagents, minimized manual steps and no waiting times during specimen preparation.

In the study, the Sofia 2 *C. difficile* FIA was not inferior to the comparator assay and it can be an alternative method for simultaneous detection of *C. difficile* GDH and toxin in one analytical step. An additional advantage of the Sofia 2 *C. difficile* FIA is the automated and objective test result interpretation performed by the Sofia 2 Analyzer whereas the comparator assay is dependent on a subjective and visual interpretation by the user.

¹ Crobach et al European Society of Clinical Microbiology and Infectious Diseases: update of the diagnostic guidance document for *Clostridium difficile* infection Clin Microbiol Infect. 2016 Aug;22 Suppl 4:S63-81.




² Package Insert Sofia 2 *C. difficile* FIA test for GDH + Toxin

³ Barbut Prospective evaluation of the Sofia *C. difficile* FIA for simultaneous detection of *C. difficile* GDH and Toxin (Poster No. 024 / Session PA02 – 41st RICA Congress, Paris, 13 – 14 December 2021)

Quidel provides the complete solution

Sofia²




-  Excellent performance providing accurate, objective and automated results in only 15 minutes
-  Fast, easy workflow reducing hands-on to 4 easy steps, requiring minimal training
-  Compact footprint: Sofia 2 can be implemented practically anywhere

Sofia² C. difficile FIA



25 Tests per kit: Cat. #20329




-  Besides *C. difficile*, you can run a variety of other tests on Sofia 2, including Legionella and *S. pneumoniae*

Discrepant test results (GDH positive / Toxin negative) can be resolved with our molecular solution:

Quidel's *C. difficile* Assay on our Solana platform

Solana[®]

Molecular testing platform

-  Results in just 25 minutes
-  Batch up to 11 tests per run
-  Gold Standard Sensitivity




Contact Quidel today to see how you can *simplify* your *C. difficile* testing!



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