QUIDEL | Sofia 2

C. difficile FIA

Frequently Asked Questions

What is the CLIA complexity of this test?
This test is a moderately complex test.

Can the Sofia 2 C. difficile FIA be visually interpreted without a Sofia 2 analyzer?
No. The fluorescence-based chemistry is not detectable without a Sofia 2 analyzer. Do not try to interpret the results without proper use of a Sofia 2 analyzer. This is an important feature and ensures objectivity.

How does the test work?
The test employs immunofluorescence for the qualitative detection of *C. difficile* glutamate dehydrogenase (GDH) antigen and Toxins A/B from fecal samples.

Does the test differentiate Toxin A and Toxin B?
The Sofia 2 C. difficile FIA does not differentiate Toxins A and B.

What are Quidel's recommendations for calibration of the Sofia 2 analyzer?
The Sofia 2 Calibration Check Procedure should be performed every 30 days. Refer to the Sofia 2 User Manual for calibration instructions. If the Calibration Check does not perform as expected, contact Quidel Technical Support. The Calibration Check requires an in-date Calibration Cassette.

What are Quidel's recommendations for external quality control for this kit?
External Positive and Negative Controls are supplied in the kit and should be tested using the External Quality Control Test Procedure. Quidel recommends that Positive and Negative Controls be run once for each untrained operator, once for each new kit lot and any additional internal quality control procedures, and in accordance with Local, State, and Federal regulations or accreditation requirements. If the Controls do not perform as expected, repeat the test and/or contact Quidel Technical Support before testing patient specimens.

Are the kit controls infectious? (Can the controls make me sick?)
The kit Positive Control contains non-infectious materials.

How should the kit be stored?
The Sofia 2 C. difficile FIA test kit should be stored at room temperature (15°C to 30°C).

What are the approved sample types?
Unpreserved (neat) fecal samples and fecal samples stored in transport media: Cary Blair and C&S.

How accurate is the Sofia 2 C. difficile FIA?

See table below for clinical performance:*

Performance of Sofia 2 C. difficile FIA (GDH) versus CCFA Bacterial Culture		Performance of Sofia 2 C. difficile FIA (Toxin A/B) versus Cytotoxic Tissue Culture	
Sensitivity	86.4% (236/273) (95% CI=81.9% to 90.0%)	Sensitivity	84.1% (90/107) (95% CI=76.0% to 89.8%)
Specificity	93.0% (1215/1307) (95% CI=91.4% to 94.2%)	Specificity	98.5% (1442/1464) (95% CI=97.7% to 99.0%)
PPV	72.0% (236/328) (95% CI=66.9% to 76.5%)	PPV	80.4% (90/112) (95% CI=72.0% to 86.7%)
NPV	97.0% (1215/1252) (95% CI=96.0% to 97.8%)	NPV	98.8% (1442/1459) (95% CI=98.1% to 99.3%)
Prevalence	17.3% (273/1580)	Prevalence	6.8% (107/1571)

*Refer to the Package Insert for additional performance claims.

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