Campylobacter

Frequently Asked Questions

What is the CMS suggested CPT code and National Limit amount for the for the Sofia 2 Campylobacter FIA?
The suggested CPT code is 87449.* For the current Medicare National Limit amount** click here.

What sample types are approved for use with the Sofia 2 Campylobacter FIA kit?
This test can be performed with stool samples that are fresh, frozen, or stored in Cary Blair or C&S transport media.

What is the sensitivity level of the test?
Sofia 2 Campylobacter demonstrated 100% sensitivity when tested on 811 prospective specimens as well as 100% sensitivity when tested on 70 frozen specimens in the clinical trial.

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

Can the Sofia 2 Campylobacter FIA be run in both WALK AWAY and READ NOW modes?
Yes, Sofia 2 Campylobacter can be run with both test modes. WALK AWAY mode lets the Test Cassette incubate inside Sofia 2 and reports a result automatically after 15 minutes. READ NOW mode lets you incubate multiple Test Cassettes on the bench top and quickly analyze them one by one in Sofia 2. Results must not be interpreted past 30 minutes after inoculation. READ NOW mode allows for batch testing in labs with higher volumes.

What is the shelf life from date of manufacture of the Sofia 2 Campylobacter FIA kit?
How should the kits be stored?
The Sofia 2 Campylobacter FIA kit has a shelf life of 24 months from date of manufacture and should be stored at room temperature (15°C to 30°C, 59°F to 86°F).

What are Quidel's recommendations for external quality control and calibration testing for this kit?
The 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.

External Positive and Negative External Controls are supplied in the kit and should be tested using the procedure described in the package insert. Quidel recommends that Positive and Negative Controls be run:

- Once for each untrained operator.
- Once for each new shipment of kits – provided that each different lot received in the shipment is tested.
- As deemed additionally necessary by your 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 or contact Quidel Technical Support before testing patient specimens.

*__*Under federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service.*__ Policies regarding coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels prior to submitting claims.

**For state by state fee schedule go to www.cms.gov

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