



Legionella FIA

Frequently Asked Questions

What serogroup does the Sofia Legionella FIA detect?

The Sofia Legionella FIA employs immunofluorescence for the qualitative detection of *Legionella pneumophila* serogroup 1.

Can the Sofia Legionella FIA be used for environmental specimen detection?

No, this test is intended for use with human urine specimens.

What is the kit shelf life and storage?

The shelf life is 24 months from the date of manufacturer. The kit should be stored at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight.

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 User Manual for calibration instructions. If the Calibration Check does not perform as expected, contact Quidel Technical Support.

External Positive and Negative Controls are supplied in the kit and should be tested using 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 – and 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.

Are there any age limitations with this kit?

No, there are no age limitations with this test kit.

What volume of patient sample is dispensed by the Fixed Volume Pipettes included in the Sofia Legionella FIA kit?

The Fixed Volume Pipettes dispense 120 µL of urine.

How should the specimens be transported when using the Sofia Legionella FIA kit?

Urine specimens should be collected in standard sterile containers. Boric acid may be used as a preservative. Samples can also be stored at room temperature and tested within 24 hours of collection. Alternatively, specimens may be stored at 2°C to 8°C and tested anytime up to 14 days. Storage at –20°C for up to 20 days is acceptable.

When should the Test Cassette be scanned in the Sofia?

When using the WALK AWAY mode, place the Test Cassette into Sofia immediately after adding the sample to the Sample Well.

When using READ NOW mode, after adding the sample to the Sample Well, allow the test to develop on the bench top for 10 full minutes before placing it into Sofia. Results will remain stable for an additional 10 minutes after the recommended development time of 10 minutes.

Can Legionella be contracted from contact with the included controls?

No. The Positive Control consists of non-infectious Legionella antigen, and the Negative Control consists of heat-inactivated, non-infectious Streptococcus C antigen.

Can the Sofia Legionella FIA Test Cassettes be visually interpreted without Sofia?

No, the fluorescence-based chemistry is not detectable without Sofia. Do not try to interpret the results without proper use of Sofia. This is an important feature and ensures objectivity.

Refer to the Package Insert on our website at quidel.com for additional performance claims.

FQ2024400EN00 (12/15)