

## S. pneumoniae FIA

### Frequently Asked Questions

#### **What sample types may be used for the Sofia S. pneumoniae FIA?**

The Sofia S. pneumoniae FIA employs immunofluorescence for qualitative detection of *Streptococcus pneumoniae* antigen in urine specimens of patients with pneumonia and in cerebral spinal fluid (CSF) specimens of patients with meningitis.

#### **What is the shelf life and how should the kit be stored?**

The kit shelf life is 18 months from the date of manufacturer. Store the kit 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. For information on how to obtain additional external controls, contact Quidel Technical Support or your local Quidel distributor. 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 are the storage requirements for collection and storage of the urine and CSF samples?**

Urine specimens should be collected in standard specimen containers. Boric acid may be used as a preservative. If specimens cannot be tested soon after collection, they may be stored at room temperature (15°C to 30°C) and tested within 24 hours of collection. Alternatively, specimens may be refrigerated at 2°C to 8°C or frozen at –20°C and tested anytime up to 15 days. Make sure to fully thaw frozen samples before testing.

CSF specimens should be collected in standard specimen containers. If specimens cannot be tested soon after collection, they may be stored at room temperature (15°C to 30°C) and tested within 24 hours of collection. Alternatively, specimens may be refrigerated at 2°C to 8°C or frozen at –20°C and tested anytime up to 7 days. Make sure to fully thaw frozen samples before testing.

#### **What volume of patient sample is dispensed by the droppers included in the Sofia S. pneumoniae FIA kit?**

The fixed volume droppers dispense 120 µL of urine.

**Can *S. pneumoniae* be contracted from contact with the included controls?**

No, the Positive Control consists of non-infectious *Streptococcus pneumoniae* antigen, and the Negative Control consists of Streptococcus C antigen.

**Can the Sofia *S. pneumoniae* FIA Test Cassettes be 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 that ensures objectivity.

The performance of any rapid Sofia test is dependent on sample collection and handling and the adherence to the Package Insert.

Refer to the Package Insert on our website at [quidel.com](http://quidel.com) for additional performance claims.

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