



# Sofia®

## Strep A+ FIA

### Frequently Asked Questions

**What is the recommended CPT code and National Limit amount for this test?**

Please refer to the Quidel CodeMap® page for the most current information at: <https://codemap.com/quidel>.

**What is the CLIA complexity of the test?**

This test is CLIA waived.

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

The kit shelf life is 24 months from date of manufacture. Store the kit at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

**How often should calibration be performed?**

The Calibration Check Procedure should be performed every 30 days.

**What are Quidel's recommendations for running external controls?**

Quidel recommends the Positive and Negative External Controls be run once for each untrained operator, once for each new shipment of kits – provided that each different lot received in shipment is tested – and as deemed additionally necessary by your internal control procedures, and in accordance with Local, State and Federal regulations or accreditation requirements.

**Is the Positive Control Swab infectious?**

No. The swab has been inoculated with heat-inactivated Group A *Streptococcal* Antigen and is not infectious.

**What swabs can be used with this kit?**

We recommend using the sterile rayon-tipped swabs provided in the kit to collect throat specimens. The performance claims described in the Package Insert were obtained with these swabs. Do not use calcium alginate, cotton-tipped or wooden shaft swabs.

**How long after collection can swab specimens be stored before testing?**

It is recommended that swab specimens be processed as soon as possible after collection. Swabs can be held in any clean, dry, plastic tube or sleeve up to 24 hours at room temperature (15°C to 30°C), or refrigerated (2°C to 8°C) up to 48 hours.

**How should a sample be added to the Test Cassette?**

Using the clear 120 µL Pipette supplied with the kit, add the sample to the Test Cassette in a drop-wise manner. Do not touch the Pipette to the Test Cassette during delivery of the sample.

**Can I use transport media?**

Yes, BD BBL CultureSwab with Liquid Stuart Media (#220099, single swab, or #220109, dual swab) may be used to store samples for 48 hours at ambient temperature or 2°C to 8°C. Swabs can also be transported via any clean, dry plastic tube as described previously.

**How accurate is the Sofia Strep A+ FIA?**

The performance of the Sofia Strep A+ FIA was compared to standard bacterial culture and identification in a multi-center clinical field study. Sensitivity of the test compared with culture is 93.7%. Specificity of the test is 94.4%.

**Can the Sofia Strep A+ FIA 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.

**How long after antibiotic treatment will the patient show positive?**

This test detects the presence of the antigen. Depending on the individual, and their compliance with antibiotic therapy, the antigen may remain present for 2-3 weeks after initiation of treatment, even though the patient's signs and symptoms of pharyngitis are gone.<sup>1</sup>

**Can the Sofia Strep A+ be used in both Read Now and Walk-Away modes?**

Yes, starting with lot# 703115, this test can now be utilized in both the Read Now and Walk Away modes on Sofia. It is important to note which mode the Sofia is set in prior to testing to ensure the Test Cassettes are incubated for the proper amount of time.

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

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<sup>1</sup>Gerber, Michael A., MD, and Randolph, Martin F., MD. Streptococcal Antigen in the Pharynx After Initiation of Antibiotic Therapy, The Pediatric Infectious Disease Journal, May 1987, Vol. 6, No. 5, p. 489-490.