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**PRINCIPLE**

The Sofia Strep A+ FIA detects Group A Streptococcal antigens from throat swabs from patients with signs and symptoms of pharyngitis, such as sore throat. The Sofia Strep A+ FIA employs immunofluorescence technology that is used with the Sofia analyzer (Sofia) to detect Group A Streptococcal antigen.

The Sofia Strep A+ FIA involves the extraction of the antigenic components of the Group A Streptococcus (GAS) bacteria. The patient’s swab sample is placed in the Reagent Tube containing the Reagent Solution, during which time the bacterial antigens are extracted, making them more accessible to the specific antibodies. An aliquot of the extracted sample is dispensed into the Cassette sample well. From the sample well, the sample migrates through a test strip containing various unique chemical environments. If Group A Streptococcal antigens are present, they will be bound by antibodies coupled to fluorescent microparticles that migrate through the test strip. The fluorescent microparticles containing bound antigen will be captured by antibodies at a defined location on the test strip where they are detected by Sofia. If antigens are not present, the fluorescent microparticles will not be trapped by the capture antibodies nor detected by Sofia.

Sofia scans, measures, and interprets the immunofluorescent signal using method-specific algorithms. Sofia will display the test results (Positive, Negative, or Invalid) on the screen.

**CLINICAL SIGNIFICANCE**

Group A Streptococcus is one of the most common causes of acute upper respiratory tract infection. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and serious complications such as rheumatic fever and glomerulonephritis.1, 2

**REAGENTS AND MATERIALS SUPPLIED:**

25-Test Kit:

. Individually Packaged Test Cassettes (25): Polyclonal rabbit anti-Group A Streptococcus antibodies

. Reagent Tubes (25)

. Reagent Solution Bottles (25): 4M Sodium Nitrite and 0.4N Hydrochloric Acid inside glass ampoule

. Sterile Rayon Throat Swabs (25)

. Fixed Volume Pipettes, 120 µL (25)

. Positive Control Swab (1): Swab is coated with heat-inactivated, non-infectious Group A Streptococcus

. Negative Control Swab (1): Swab is coated with heat-inactivated, non-infectious Group C Streptococcus

. Package Insert (1)

. Quick Reference Instructions (1)

. QC Card (located on kit box)

. Printer Paper (1)

MATERIALS NOT SUPPLIED IN KIT

. Sofia

. Calibration Cassette (supplied with the Sofia Installation Pack)

. Timer or Watch

. Puritan specimen swabs

WARNINGS AND PRECAUTIONS

. For in vitro diagnostic use.

. Do not use the kit contents beyond the expiration date printed on the outside of the box.

. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.

. Use of Nitrile or Latex (or equivalent) gloves is recommended when handling patient samples.

. Dispose of containers and used contents in biohazardous trash.

. Do not reuse any used Cassettes, Reagent Tubes, Fixed Volume Pipettes, solutions, or Control Swabs.

. The Calibration Cassette must be kept in the provided storage pouch between uses.

. To obtain accurate results, the Package Insert instructions must be followed.

. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.

. Sample collection and handling procedures require specific training and guidance.

. Do not use calcium alginate, cotton-tipped or wooden shaft swabs.

. The user should never open the foil pouch of the Test Cassette exposing it to the ambient environment

until the Cassette is ready for immediate use.

. Discard and do not use any damaged Cassette or material.

. The Reagent Solution contains an acidic solution. If the solution contacts the skin or eye, flush with copious amounts of water.

. For more information, consult the Safety Data Sheet available on quidel.com.

. The Reagent Solution Bottle contains glass; break cautiously, and only squeeze once to break the ampoule.

. If the Reagent Solution Bottle is missing the glass ampoule, if the solution is green prior to the breaking of the ampoule, or if the solution does not turn green after breaking the glass and shaking, discard and use another Reagent Solution Bottle.

. Do not pour samples from the Reagent Tube into the Test Cassette sample well. Use the provided 120 µL Fixed Volume Pipette when adding the sample to the Test Cassette.

. The Sofia Strep A+ FIA will automatically be forced into the WALK AWAY Mode when inserted into Sofia.

DO NOT allow the Test Cassette to develop on the bench or counter top prior to placing the Cassette into Sofia.

. Do not write on the barcode of the Cassette. This is used by Sofia to identify the type of test being run and the Cassette’s expiration date.

. Do not attempt to scan a Cassette more than one time. The barcode on the Cassette contains a unique

identifier that will prevent Sofia from performing a second read on a previously scanned Cassette. An error message will be displayed if a Cassette is scanned more than once on the same Sofia.

. As the detection reagent is a fluorescent compound, no visible results will form on the test strip. Sofia

must be used for result interpretation.

**KIT STORAGE AND STABILITY**

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.

**QUALITY CONTROL**

There are three types of Quality Control for Sofia and Strep A+ FIA: Sofia Calibration Check Procedure, built-in procedural control features, and External Controls.

*Sofia Calibration Check Procedure*

The Calibration Check Procedure should be performed every 30 days. Sofia is set to remind the user to complete the Calibration Check Procedure. The Calibration Check is a required function that checks Sofia optics and calculation systems using a specific Calibration Cassette. This Calibration Cassette is shipped with the Sofia Installation Pack. Important: Ensure that the Calibration Cassette is stored in the provided storage pouch between uses to protect it from exposure to light.

1. To check the calibration of Sofia, select “Calibration” from the Main Menu.

2. Following the prompts, insert the Calibration Cassette into Sofia and close the drawer. Sofia performs the Calibration Check automatically with no user input required.

3. Sofia indicates when the Calibration Check is completed. Select OK to return to the Main Menu.

NOTE: If the calibration cannot be completed successfully, notify the Urgent Care office staff or contact Quidel Technical Support for assistance from 7:00 a.m. to 5:00 p.m. Pacific Time at 800.874.1517

**Built-in Procedural Control**

The Sofia Strep A+ test strip contains a built-in procedural control feature. Each time a test is run, Sofia scans this part of the test strip, and the result is displayed on the Sofia screen as “valid” or “invalid.” This documentation is also automatically logged into Sofia with each test result. The printed test results will be saved on the Sofia kit log sheet.

A valid result obtained with this procedural control demonstrates that the test flowed correctly and the

functional integrity of the Cassette was maintained. The procedural control is interpreted by Sofia simultaneously with the end of the assay. If the test does not flow correctly, Sofia will indicate that the result is invalid. Should this occur, review the procedure and repeat the test with a new test Cassette.

**External Quality Control**

External Controls may also be used to demonstrate that the reagents and assay procedure perform properly. These controls will be run every time a new box of kits is opened.

To test External Controls

1. User must first select Run QC on the Main Menu of Sofia.
2. When prompted, scan the QC Card (located on the kit box). This card provides information specific to the kit lot, including lot number and expiration date.
3. External Positive and Negative Control Swabs are supplied in the kit and should be tested using the Test Procedure. **The Positive Control test must be run prior to the Negative Control test.**
4. When the QC run is complete, each result will be displayed as “Passed” or “Failed” for the Positive Control and the Negative Control.

Do not perform patient tests or report patient test results if either of the QC test results fail. Repeat the test before testing patient samples. If both the Positive and Negative Controls fail, repeat testing with new Positive and Negative Controls a second time. If only a single Control fails, the user has the option of repeating both the Positive and Negative Controls OR to repeat only the Control that failed. The user may select “Skip” on the Sofia display in order to skip the Control test that previously passed. The QC Results will show a skipped Control test as “unknown.”

**SAMPLE COLLECTION**

Use the rayon-tipped Swabs provided in the kit to collect throat samples. Collect throat samples by standard clinical methods. Depress the tongue with a tongue blade or spoon. Rub the Swab on the tonsils and back of the throat.

**SPECIMEN TRANSPORT AND STORAGE**

It is recommended that Swab samples 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 (23°C) or refrigerated (2°C to 8°C) up to 48 hours. Collect two throat swab specimens – one swab for testing with Sofia Strep A+ FIA and the second swab for culture if test results are negative

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**TEST PROCEDURE**

*Important:*

All clinical samples and test materials must be at room temperature before beginning the test.

Do not use the Reagent Solution if it is green prior to breaking the glass ampoule or if it does not turn green after breaking the glass ampoule.

Do not allow the Cassette to develop on the bench or counter top prior to placing the Cassette into Sofia. Note: *The Sofia Strep A+ FIA will automatically be run in the WALK AWAY Mode in Sofia once a prepared Test Cassette is insert*e*d.*

Expiration date: Check expiration on outer box before using. *Do not use any Test Cassette past the expiration date on the label.*

1. Squeeze ONCE to break the glass ampoule inside the Reagent Solution Bottle prior to running the assay.

2. Vigorously shake the Reagent Solution Bottle 5 times to mix the solutions. Solution should turn green after the ampoule is broken.

3. To add the Reagent:

a) Flick or shake the Reagent Solution Bottle so that all fluid is in the bottom.

b) Twist off the tab.

c) Slowly dispense the Reagent Solution into the Reagent Tube up to the Fill Line.

4. Add the patient Swab sample to the Reagent Tube. Vigorously mix the solutions by plunging the Swab 5 times in an up and down motion in the Tube. *NOTE: Best results are obtained when the sample is vigorously extracted in the solution.*

5. Leave the Swab in the Reagent Tube for 1 minute.

6. Vigorously mix the solution again by plunging the Swab 5 times in an up and down motion in the tube.

7. Express as much liquid as possible from the Swab by squeezing the sides of the Tube as the Swab is withdrawn in a complete twisting motion. Discard the Swab in biohazard waste.

8. Fill the provided clear 120 μL Fixed Volume Pipette with the sample:

a) FIRMLY squeeze the top bulb and place the Pipette tip into the sample.

b) With the Pipette tip still in the sample, slowly release pressure on the top bulb to fill the Pipette.

9. Empty the contents of the Pipette into the Sample Well by firmly squeezing the top bulb. Extra liquid left over in the overflow bulb should be left behind.

*NOTE: The Fixed Volume Pipette is designed to collect and dispense the correct*

*Set Up Sofia*

10. Select “Run Test” from the main menu on Sofia.

11. Put the User ID using the barcode scanner or manually enter the data using the key pad.

12. Input Patient ID or Order # using the barcode scanner or manually enter the data using the key pad.

13. Press Start Test and the Sofia drawer will automatically open.

*Insert the Cassette into Sofia*

14. Carefully lift the test Cassette and insert the Cassette into Sofia. Gently close the drawer.

15. Sofia will start automatically and display the progress. The test results will be displayed on the screen in approximately 5 minutes.

**INTERPRETATION OF RESULTS**

When the test is complete, the results will be displayed on the Sofia screen. The results will be automatically printed on the integrated printer. Test Lines, which are fluorescent, cannot be seen with the naked eye. The Sofia screen will display results for the procedural control as being “valid” or “invalid,” and will provide a positive or negative result for the detection of Strep A. If the procedural control is “invalid,” retest the patient’s sample with a new Cassette.

Positive: Negative:

 

Invalid Results:



LIMITATIONS

. The contents of this kit are to be used for the qualitative detection of Group A Streptococcal antigens from throat swab samples.

. The test detects both viable and nonviable Group A Streptococcus bacteria and may yield a positive result in the absence of living organisms.

. Respiratory infections, including pharyngitis, can be caused by Streptococcus from serogroups other than Group A, as well as other pathogens.

. The Sofia Strep A+ FIA will not differentiate asymptomatic carriers of Group A Streptococcus from those exhibiting Streptococcal infection.7

. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected, transported, or stored improperly.

. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test

result.

. Patients with symptoms and an antigen negative test should have a follow-up culture.1

. Test results must be evaluated in conjunction with other clinical data available to the physician.

. Negative test results do not rule out possible other infections.

. Positive test results do not rule out co-infections with other pathogens.

. Corynebacterium pseudodiphtheriticum, Enterococcus faecalis, Staphylococcus aureus, Streptococcus

mutans, Streptococcus parasanginis, Streptococcus Groups C, D and F, Adenovirus Types 1 and 3, Epstein Barr Virus, and Mumps (Enders) may interfere with this assay.

. Blood, mucin, and Nacho Flavor Doritos may interfere with the assay.

**EXPECTED VALUES**

Group A Streptococcus bacteria are responsible for about 19% of all upper respiratory tract infections.8

Infection is most prevalent in winter and early spring, with most cases arising in patients living in highly

populated areas.

Normal Range: Negative

Reference Range: Negative or Positive

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