SCOPE: This policy applies to UPMC Pinnacle Hanover.

KEY WORDS: Strep Screen, SS, Strep Antigen

PURPOSE: 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] Conventional procedures for identification of Group A Streptococcus from throat swabs involve the culture, isolation, and subsequent identification of viable pathogen at 24 to 48 hours or longer for results.[3,]

The Sofia Strep A+ FIA employs immunofluorescence technology that is used with the Sofia Analyzer to detect Group A Streptococcal antigen.

POLICY: The Sofia Strep A+ FIA employs immunofluorescence technology to detect Group A Streptococcal antigens from throat swabs of symptomatic patients. All negative test results should be confirmed by bacterial culture because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment. The test is intended for professional and laboratory use as an aid in the diagnosis of Group A Streptococcal infection

REAGENTS:
(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.)

25-Test Kit:

- Individually Packaged Cassettes (25): Polyclonal rabbit anti-Group A Streptococcus antibodies
- Reagent Tubes (25)
- Reagent Solution Bottles (25): 4M Sodium Nitrite and 0.2M Acetic Acid inside glass ampoule
- Fixed Volume Pipettes (25)
- Sterile Rayon Throat Swabs (25)
- Package Insert (1)
- Quick Reference Instructions (1)
- QC Card (located on kit box)
- Printer Paper (1)

MATERIALS NOT SUPPLIED IN KIT

- Timer or watch
- Calibration Cassette (supplied with the Sofia Analyzer Installation Pack)

SPECIMEN: Throat swabs. Collect throat specimens by standard clinical methods. Depress the tongue with a tongue blade or spoon. Rub the swab on the tonsils and back of the throat. 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 (15-30°C), or refrigerated (2-8°C) up to 48 hours. The following transport media and storage conditions have been tested and are also acceptable (Table 1):

Table 1
Recommended Transport Media

Transport Media	Recommended Storage Condition	
	2-8°C	Ambient Temperature
BD BBL CultureSwab with Liquid Stuarts Media (#220109)*	48 hours	24 hours
Remel BactiSwab with Liquid Amies Media (#R723095)*	48 hours	24 hours

*These transport media systems preserve the sample on the swab tip via contact with a media-moistened sponge.

If screen is negative; use second swab for culture or, if single swab , lightly streak the swab on a 5% sheep blood agar plate before using the swab in the Sofia Strep A FIA. Do not perform the Strep A+ FIA before streaking the swab, as the Reagent Solution will destroy the bacteria on the swab, thereby rendering the organism incapable of successful culturing.

Verify that the Sofia is set to desired Analyzer Mode. (Walk-away). All clinical samples and test materials should be at room temperature before beginning test.
Squeeze ONCE to break glass ampule inside the Reagent Solution Bottle prior to running the assay. (Do not use the Reagent Solution if it is green prior to breaking glass ampule or if it does not turn green after breaking the glass    ampule.)

QUALITY CONTROL: There are three types of Quality Control for the Sofia Analyzer and Strep A FIA: Sofia Analyzer Calibration Check Procedure (See separate Calibration Procedure), built-in procedural control features, and External Controls.

- 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

External Quality Control

External Controls may also be used to demonstrate that the reagents and assay procedure perform properly.

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. Per CAP, we will test external QC swabs every 30 days.

The user must first select Run QC on the Main Menu of the Sofia Analyzer and then, 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.

The Analyzer will prompt the user to select Walk AwayMode (as this test may only be run in walk-away mode) and then to run the External Control swabs.

External Positive and Negative Control swabs are supplied in the kit and should be tested using the Test Procedure provided in this Package Insert or in the Quick Reference Instructions. **Run the Positive swab first, followed by the negative swab on the same instrument.** Additional External Control swabs may be obtained separately by contacting Quidel's Customer Support Services at (800) 874-1517 (in U.S.) or (858) 552-1100 (outside U.S.).

When the QC test is complete, each result will be displayed as "Passed" or "Failed" for the Positive Control and the Negative Control.

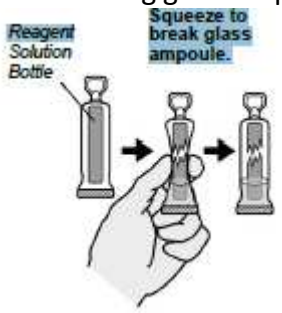
Do not perform patient tests or report patient test results if the QC test does not produce the expected results. Repeat the test or contact Quidel Technical Support before testing patient specimens, if a "Failed" result is obtained with the External Controls.

Built-in Procedural Controls:

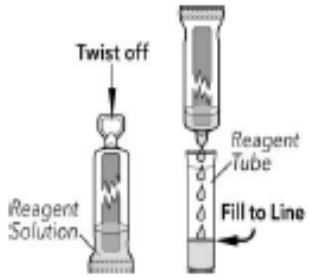
The Sofia Strep A+ FIA contains two built-in procedural control features. The manufacturer's recommendation for daily control is to document these built-in procedural controls for the first sample tested each day.

A control of the extraction procedure is provided by a color change from clear to green as the Reagent Solution is mixed. The color change is an indication of Reagent Solution integrity and is also an indication that the extraction procedure was performed correctly.
Each time a test is run in Sofia, procedural controls in the Test Cassette are interpreted by Sofia, and the result is displayed on the Sofia screen. This information is automatically logged in Sofia with each test result.
A valid result obtained with the procedural controls demonstrates that the extracted sample flowed correctly and the functional integrity of the Cassette was maintained. **This procedural control is interpreted by Sofia after the Cassette has developed for 5 minutes. If the sample has not flowed correctly, Sofia will indicate that the result is invalid.** Should this occur, review the procedure and repeat the test with a new patient sample and a new Test Cassette.

PROCEDURE:

Verify that the Sofia is set to desired Analyzer Mode. (Walk-away). All clinical samples and test materials should be at room temperature before beginning test.
Squeeze ONCE to break glass ampule inside the Reagent Solution Bottle prior to running the assay. (Do not use the Reagent Solution if it is green prior to breaking glass ampule or  if it does not turn green after breaking the glass ampule.)
3.Vigorously shake the Reagent Solution bottle five (5) times to mix the solutions. Solution should turn green after the ampoule is broken. 

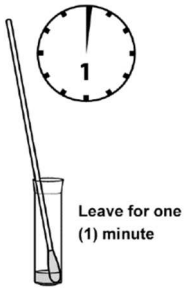
Add Reagent:
a) Flick or shake the Reagent Solution Bottle so that all fluid is in the bottom.
b) Twist off the tab.
c) Slowly dispense the Reagent Solution into the Reagent Tube **up to the Fill Line.**



Immediately add the patient swab sample to the Reagent Tube. Vigorously mix the solutions by plunging the swab **five (5) times** in an up and down motion in the tube.

NOTE: Best results are obtained when the specimen is vigorously extracted in the solution.

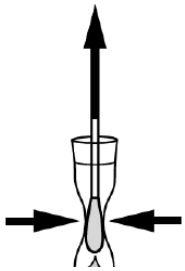
Leave the swab in the Reagent Tube **for one (1) minu**



Vigorously mix the solution again by plunging the swab **five (5) times** in an up and down motion in the tube.

Express as much liquid as possible from the swab by **squeezing th sides of the tube as the swab is withdrawn**.

Discard the swab in accordance with your biohazard waste disposa protocol.

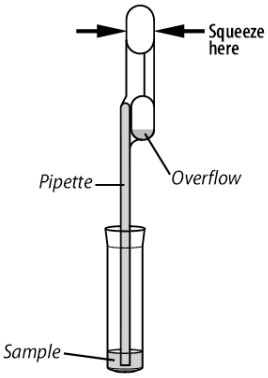


Fill the provided **clear 120µL** fixed volume pipette with the sa

To fill the fixed volume pipette with the sample:

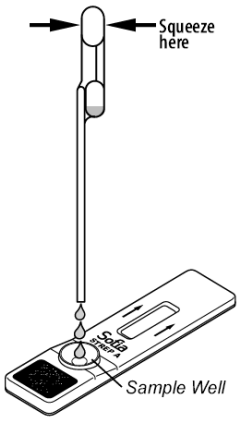
a) FIRMLY squeeze the top bulb and place the Pipette ti the sample.

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



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

NOTE: The fixed volume pipette is designed to collect and dis the correct amount of patient sample. Discard the pipette in biohazard waste.

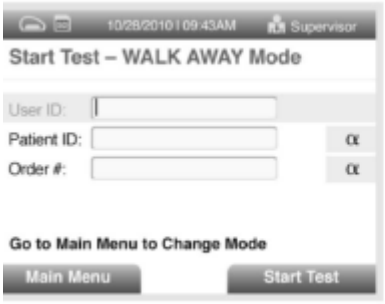


Refer to Sofia User Manual for Operating instructions.I

Select “Run Test” from the Main Menu on Sofia.

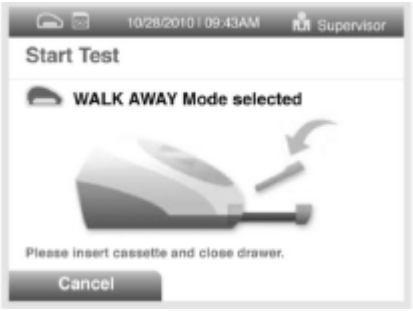
Input the User ID using the barcode scanner or manually enter on key pad.

NOTE: If you mistakenly scan the wrong barcode, use the Arros Buttons on Sofia to re-highlight the field and simply rescan using the correct barcode. This will overwrite the previous one with the correct barcode.

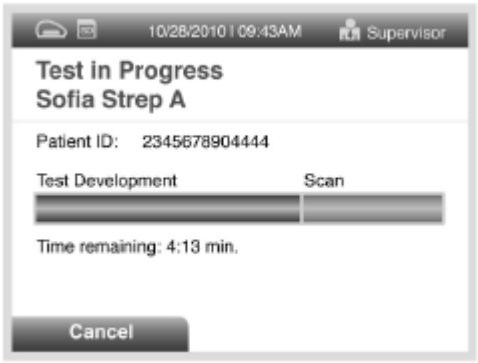


Input Patient Barcode number from the label using the barcode scanner or manually enter using the key pad.

Press Start Test and the Sofia drawer will automatically open. Regardless of the current selected mode, the Sofia Strep A+ FIA will **automatically** be forced into the Walk Away Mode once the Test Cassette is inseted and the drawer closed.



Insert the prepared test cassette into the drawer and gently close the drawer. Sofia will start automatically in WALK AWAY Mode and display the progress as shown in example below. The test results will be displayed on the screen in approximately 5 minutes. See "Interpretation of Results" section.



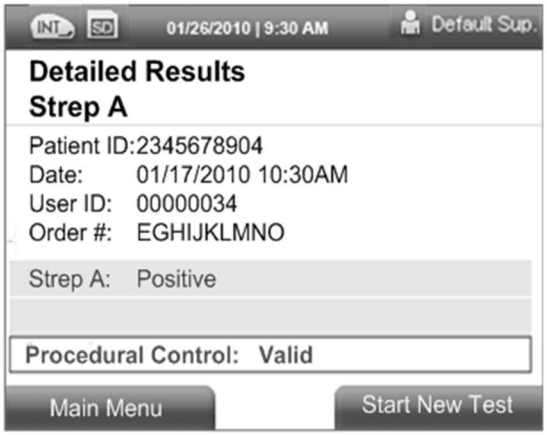
Tips for Batch Testing:
In order to make batch testing easier, the user can prepare one or more Reagent Solution bottles in advance of testing samples. The user can break the ampoule inside each Reagent Solution bottle, shake to mix the solutions, and then store the capped bottles on the benchtop at room temperature for **up to 12 hours** without loss of activity before using with swab sample(s).

INTERPRETATION/RESULTS:

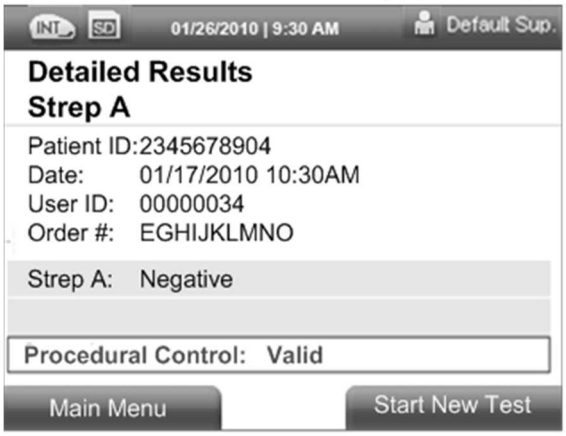
INTERPRETATION OF RESULTS:

(As the detection reagent is a fluorescent compound, no visible results will form on the test strip. The Sofia Analyzer must be used for result interpretation.)

The Sofia Analyzer screen will display results for the procedural control as being "valid or invalid," and will provide a positive or negative result for Strep A. If the procedural control is "invalid," retest with a new patient sample and a new Test Cassette.
For example: This display shows a valid POSITIVE result for Strep A: (A positive result does not rule out co-infection with other pathogens.)



For example: This display shows a valid negative result for Strep A: (A negative result does not rule out other possible infections.)



For example, the results here are invalid and a new test should be performed on a new patient sample and a new Test Cassette.

For example: This result shows an invalid result.

Invalid Result: If the test is invalid, a new test should be performed with a new patient sample and a new Test Cassette.

WARNINGS AND PRECAUTIONS:

- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.[5]
- Use of Nitrile or Latex (or equivalent) gloves is recommended when handling patient samples.
- Dispose of containers and used contents in accordance with Federal, State and Local requirements.
- 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.
- Use the rayon-tipped swabs, provided with this assay, to collect throat samples. The performance claims in the Performance Characteristics section were obtained with the Swabs provided in the kit. 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.

EXPECTED RESULTS: Group A Streptococcus bacteria are responsible for about 19% of all upper respiratory tract

QUALITY ASSURANCE:
Be sure to check collection kits for expiration date. Do not use beyond that date. Patient specimen should have two identifiers---name and date of birth—on every swab submitted for testing.

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