This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete Package Insert. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete Package Insert in accordance with FDA labeling regulation (21 CFR 809.10).

Quidel Corporation provides CLSI procedures for your use. The procedures are required to include the same information as listed in the Package Insert. Any modifications to this document are the sole responsibility of the Laboratory.

Sofia Strep A FIA

For use with the Sofia only

INTENDED USE

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.

SUMMARY AND EXPLANATION

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, 4]

PRINCIPLE OF THE TEST

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 specimen 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 specimen is dispensed into the Cassette sample well. From the sample well, the specimen 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.

Note: Depending upon the user's choice, the Cassette, now containing the specimen, is either placed directly inside Sofia for automatically timed development (WALK AWAY Mode) or placed on the counter or bench top for a manually timed development and then placed into Sofia (READ NOW Mode).

Sofia scans, measures, and interprets the immunofluorescent signal, using on-board method-specific algorithms. Sofia will then report the test results to the user (Positive, Negative, or Invalid) on its display screen, and it can print out the results via an integrated printer or transmit the results via an LIS connection.

REAGENTS AND MATERIALS SUPPLIED

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)
- 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

- Timer or watch for use in READ NOW Mode
- Sofia analyzer
- Calibration Cassette (supplied with Sofia Installation Pack)

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.[5]
- Use of Nitrile or Latex (or equivalent) gloves is recommended when handling patient samples.[5]
- 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 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.
- Testing should be performed in an area with adequate ventilation.
- For more information, consult the Safety Data Sheet available on quidel.com.
- The Reagent Solution Bottle contains glass, break cautiously.
- If the Reagent Solution Bottle is missing the glass ampoule or the solution is green prior to the breaking of the ampoule, discard and use another Reagent Solution Bottle.
- To obtain accurate results, the Package Insert instructions must be followed.
- The Calibration Cassette must be kept in the provided storage pouch between uses.
- Inadequate or inappropriate specimen collection, storage, and transport may yield false test results.
- Specimen collection and handling procedures require specific training and guidance.
- If transport media will be used, use only the Transport Media and configuration recommended in this Package Insert.
- Use Rayon-tipped swabs to collect throat specimens. The performance claims in the Performance Characteristics section were obtained with the swabs provided in the kit. Use of the provided swabs is recommended. Do not use calcium alginate, cotton-tipped or wooden shaft swabs.
- Do not write on the barcode of the Cassette. This is used by Sofia to identify the type of test being run and to identify the individual Cassette so as to prevent a second read of the Cassette by the same Sofia.

- Once a Cassette has been successfully scanned by Sofia, do not attempt to scan the Cassette again in the same Sofia. The barcode on the Cassette contains a unique identifier that will prevent Sofia from performing a second read on a previously scanned Cassette.
- 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

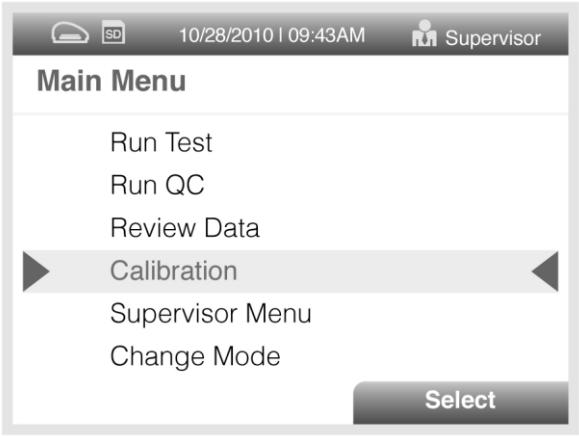
NOTE: This is a "Calibration Check" procedure.

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. Refer to the Sofia User Manual for details regarding the Calibration Check Procedure.

Important: Ensure that the Calibration Cassette is stored in the provided storage pouch between uses to protect it from exposure to light.

1. To perform the calibration check of Sofia, select "Calibration" from the Main Menu.



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

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

NOTE: If the Calibration Check does not pass, notify the on-site Supervisor or contact Quidel Technical Support for assistance from 7:00 a.m. to 5:00 p.m. Pacific Time at 800.874.1517 (in the U.S.); 858.552.1100 (outside the U.S.); Fax: 858.455.4960; custserv@quidel.com (Customer Service); technicalsupport@quidel.com (Technical Support) or contact your local distributor.

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, a procedural control is 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 control demonstrates that the extracted specimen 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 specimen 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.

For example: This result shows that an invalid result had occurred.

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.

The user must first select Run QC on the Main Menu of Sofia 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.

Sofia will prompt the user to select the desired mode (WALK AWAY or READ NOW) 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. Additional External Control Swabs may be obtained separately by contacting Quidel's Customer Support Services at 800.874.1517 (in the U.S.) or 858.552.1100 (outside the 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.

SPECIMEN COLLECTION AND HANDLING

SPECIMEN COLLECTION

Use the Rayon-tipped Swabs provided in the kit to collect throat specimens. The performance claims listed 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. Collect throat specimens by standard clinical methods. Depress the tongue with a tongue blade or spoon. Rub the Swab on the back of the throat, both of the tonsils, the uvula and the posterior pharynx. Be careful not to touch the tongue, sides or top of the mouth with the Swab. Consult standard reference procedures such as the collection method described by Facklam.[6]

SPECIMEN TRANSPORT AND STORAGE

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. 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°C to 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 a culture is desired, 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. Alternatively, two throat Swab specimens can be obtained; in this case one can be used separately for culture and the other for the Sofia Strep A FIA.

TEST PROCEDURE

Important:

- All specimens must be at room temperature (15°C to 30°C) before beginning the test.
- Gloves should be worn when handling human samples.
- Do not use the Reagent Solution if it is green prior to breaking the ampoule.
- Do not open the foil pouch of the test Cassette until it is ready for immediate use.

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

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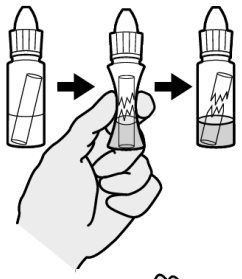
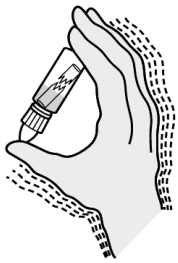
1. Verify that Sofia is set to the desired Mode: **WALK AWAY** or **READ NOW**. See the "Using Sofia" section for more information.

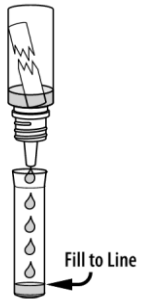


2. Squeeze **ONCE** to break the glass ampoule inside the Reagent Solution Bottle prior to running the assay.

3. Vigorously shake the Bottle 5 times to mix the Solutions. Solution should turn green after the ampoule is broken.

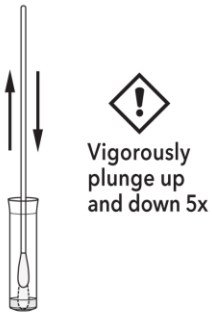


4. Remove the cap. Holding Bottle vertically, fill the Reagent Tube **to the line** (approximately 6 drops).

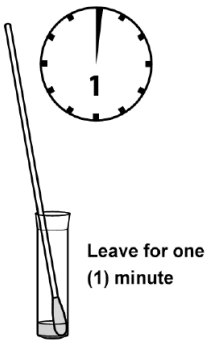


5. Immediately add the patient Swab sample to the Reagent Tube. Vigorously mix the solutions by plunging the Swab **5 times** in an up and down motion in the Tube.

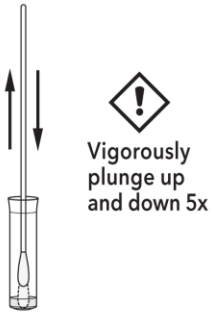
NOTE: Best results are obtained when the specimen is vigorously extracted in the solution.



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

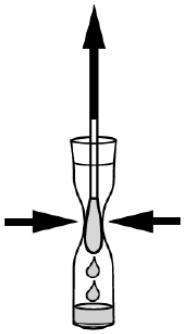


7. **Vigorously** mix the solution again by plunging the Swab **5 times** in an up and down motion in the Tube.

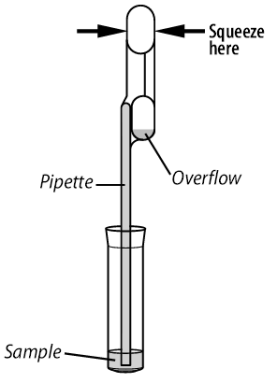


8. Express as much liquid as possible from the Swab by **squeezing the sides of the Tube as the Swab is withdrawn**.

Discard the Swab in accordance with your biohazard waste disposal protocol.



9. Fill the provided **yellow 100 µL** Fixed Volume Pipette with the sample:



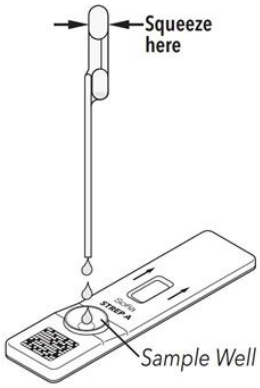
To fill the Fixed Volume Pipette with the sample:

a) FIRMLY squeeze the top bulb.

b) Still squeezing, place the Pipette tip into the sample.

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

10. Firmly squeeze the top bulb to empty the contents of the Fixed Volume Pipette into the Cassette sample well. Extra liquid in the overflow bulb is OK.



NOTE: The Fixed Volume Pipette is designed to collect and dispense the correct amount of patient sample. Discard the Pipette in your biohazard waste.

11. Proceed to the next section, "Using Sofia," to complete the test.

USING SOFIA

WALK AWAY/READ NOW Modes

Refer to the Sofia User Manual for operating instructions.

Sofia may be set to two different modes (WALK AWAY and READ NOW). The procedures for each mode are described below.

WALK AWAY Mode

In WALK AWAY Mode, the user immediately inserts the Cassette into Sofia. The user then returns after 5 minutes to get the test result. In this mode, Sofia will automatically time the test development before scanning and displaying the test result.

READ NOW Mode

Allow the test to develop for the full 5 minutes BEFORE placing it into Sofia.

The user must first place the Cassette onto the counter or bench top for 5 minutes (outside of Sofia) and manually time this development step. Then, the user inserts the Cassette into Sofia. In READ NOW Mode, Sofia will scan and display the test result in less than 1 minute. Note: Results will remain stable for an additional 10 minutes after the recommended development time of 5 minutes.

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

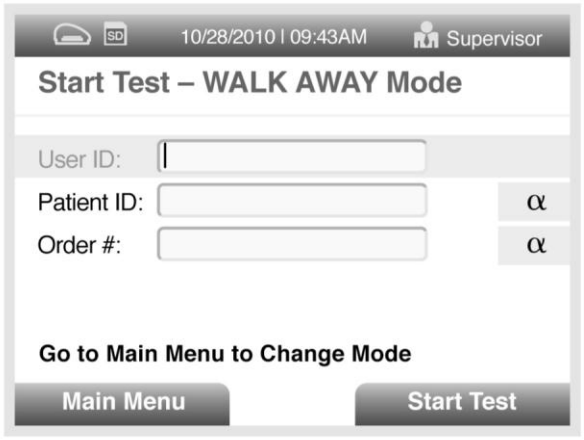
solutions, and then store the capped Bottles on the bench top at room temperature for up to 12 hours without loss of activity before using with Swab sample(s).

Critically important, the user should never open the foil pouch thus exposing the test Cassette to the ambient environment, until it is ready for immediate use.

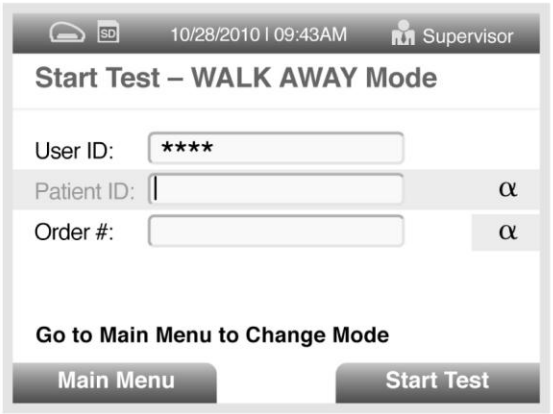
Run Test

1. Input the User ID using the handheld barcode scanner or manually enter the data using the key pad.

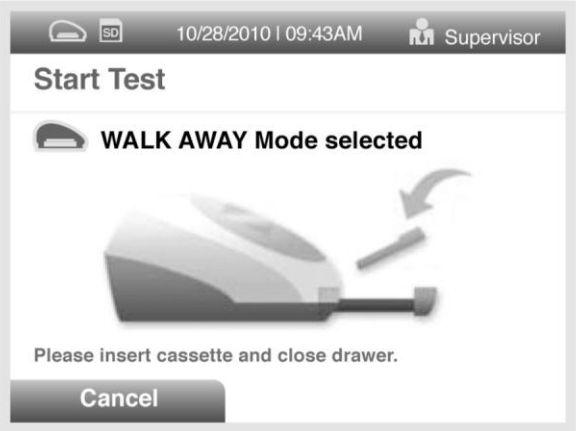
NOTE: *If you mistakenly scan the wrong barcode, use the Arrow Buttons on the Sofia key pad to re-highlight the field. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.*



2. Input Patient ID and/or Order # using the handheld barcode scanner or manually enter the data using the key pad.

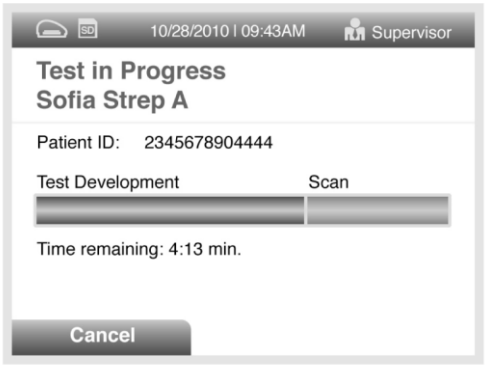


3. Press Start Test and the Sofia drawer will automatically open.



4. Verify that the correct development mode, WALK AWAY or READ NOW, has been selected. Insert the prepared patient test Cassette into the drawer of Sofia and close the drawer.

5. Sofia will start automatically and display the progress as shown in example below. In the WALK AWAY Mode, the test results will be displayed on the screen in approximately 5 minutes. In the READ NOW Mode, the test results will be displayed on the screen in less than 1 minute. See "Interpretation of Results" section.



For example: This display shows that the test in WALK AWAY mode has 4 minutes, 13 seconds remaining. Sofia will read and display the results in about 5 minutes.

INTERPRETATION OF RESULTS

When the test is complete, the results will be displayed on the Sofia screen. The results can be automatically printed on the integrated printer, if this option is selected. Test Lines, which are fluorescent, will never be visible to the naked eye.

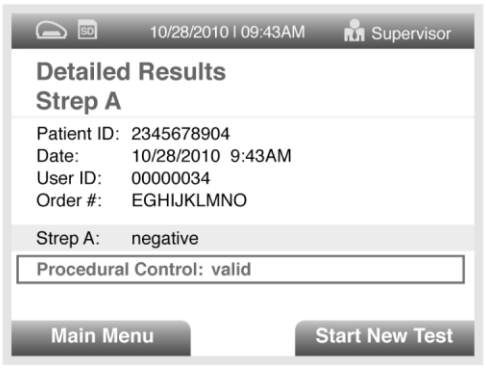
The Sofia screen will display results for the procedural control as being "valid or invalid," and will provide a positive or negative result for Strep A. If the procedural control is "invalid," retest with a new patient sample and a new Test Cassette.

Positive Results:

For example: This display shows a valid positive result for Strep A.

NOTE: A positive result does not rule out co-infections with other pathogens.

Negative Results:



For example: This display shows a valid negative result for Strep A.

NOTE: A negative result does not rule out possible other infections.

Invalid Results:

For example: This result shows that an invalid result was obtained.

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

LIMITATIONS

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

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. Consistent with these figures, in the multi-center clinical study conducted by Quidel during 2011 and 2012, 17.4% (128/736) of the patients presenting with pharyngitis were found to be culture positive for Strep A. Nearly half of these subjects, 46%, were male. The subjects' ages ranged from 3-72 years and 88% (647/736) were children (3-17 years of age).

PERFORMANCE CHARACTERISTICS

Sofia Strep A FIA Performance vs. Cell Culture

The performance of the Sofia Strep A FIA was compared to standard bacterial culture and identification in a multi-center clinical field study. This study was conducted by health care personnel during 2011 and 2012 at eight (8) distinct sites in various geographical regions within the United States and two (2) sites in Australia. In this multi-center, point-of-care (POC) field trial, two (2) throat swabs were collected from 736 patients with symptoms suggestive of bacterial pharyngitis.

One (1) throat swab was transported on cold ice packs to a central Reference Laboratory, streaked on a sheep blood agar plate (SBA) and cultured for up to 48 hours. Immediately after streaking, this same swab was tested in the rapid Sofia Strep A FIA. The performance of the Sofia Strep A FIA was determined by comparison of the rapid test result to the corresponding culture result. The results from these analyses are presented in Tables 2, 3a, and 3b.

Table 2
Sofia Strep A FIA Results: Combined

	Culture		
	Pos	Neg	Total:
Sofia Pos	116	24	140
Sofia Neg	12	584	596
Total:	128	608	736

Sens. = 90.6% (116/128)
(95% CI: 84.3%-94.6%)
Spec. = 96.1% (584/608)
(95% CI: 94.2%-97.3%)
PPV = 82.9% (116/140)
NPV = 98.0% (584/596)
Prev. = 17.4% (128/736)

Table 3a
Sofia Strep A FIA Results: READ NOW Mode

	Culture		
	Pos	Neg	Total:
Sofia Pos	100	23	123
Sofia Neg	12	549	561
Total:	112	572	684

Sens. = 89.3% (100/112)
(95% CI: 82.2%-93.8%)
Spec. = 96.0% (549/572)
(95% CI: 94.0%-97.3%)
PPV = 81.3% (100/123)
NPV = 97.9% (549/561)
Prev. = 16.4% (112/684)

Table 3b
Sofia Strep A FIA Results: WALK AWAY Mode

	Culture		
	Pos	Neg	Total:
Sofia Pos	16	1	17
Sofia Neg	0	35	35
Total:	16	36	52

Sens. = 100% (16/16)
(95% CI: 80.6%-100%)
Spec. = 97.2% (35/36)
(95% CI: 85.8%-99.5%)
PPV = 94.1% (16/17)
NPV = 100% (35/35)
Prev. = 30.8% (16/52)

Reproducibility Studies

The reproducibility of the Sofia Strep A FIA was evaluated at three (3) different laboratories. Two (2) different operators at each site tested a series of coded, contrived samples, prepared in negative clinical matrix, ranging from low negative to moderate positive Group A Streptococcus. The inter-laboratory agreement (Table 4) for negative samples was 96.7%-100% and 96.7%-100% for positive samples. The intra-laboratory agreement (Table 5) for all samples ranged from 97.5%-99.2%.

Table 4
Sofia Strep A FIA Reproducibility Study Inter-laboratory Agreement

Site	Low Negative (no bacteria) (0 cfu/test)	High Negative (C_5) ($1.5x10^3$ cfu/test)	Low Positive (C_{95}) ($3.0x10^3$ cfu/test)	Mod. Positive (C_{3X}) ($2.8x10^4$ cfu/test)
1	30/30	30/30	28/30	30/30
2	30/30	29/30	30/30	30/30
3	30/30	28/30	29/30	30/30
Total	90/90	87/90	87/90	90/90
% Overall Agreement (95% CI)	**100% (90/90) (95.9%-100%)**	**96.7% (87/90) (90.7%-98.9%)**	**96.7% (87/90) (90.7%-98.9%)**	**100% (90/90) (95.9%-100%)**

Table 5
Sofia Strep A FIA Reproducibility Study Intra-laboratory Agreement

Site	Low Negative (no bacteria) (0 cfu/test)	High Negative (C_5) ($1.5x10^3$ cfu/test)	Low Positive (C_{95}) ($3.0x10^3$ cfu/test)	Mod. Positive (C_{3X}) ($2.8x10^4$ cfu/test)	% Overall Agreement (95% CI)
1	30/30	30/30	28/30	30/30	**98.3% (118/120) (94.1%-99.5%)**
2	30/30	29/30	30/30	30/30	**99.2% (119/120) (95.4%-99.9%)**
3	30/30	28/30	29/30	30/30	**97.5% (117/120) (92.9%-99.1%)**

Limit of Detection

The limit of detection (LOD) for the Sofia Strep A FIA was determined using three (3) strains of Group A *Streptococcus pyogenes*. The LOD ranged from $9x10^3$-$2x10^4$ colony forming units (cfu)/test (Table 6).

Table 6
Sofia Strep A FIA Limits of Detection for Three *Streptococcus pyogenes* Strains

Strain	Minimum Detectable Level*
Bruno [CIP 104226]	$1.86x10^4$ cfu/test
CDC-SS-1402	$9.24x10^3$ cfu/test
CDC-SS-1460	$2.34x10^4$ cfu/test

cfu/test = colony forming units/test

*The levels of bacteria were determined by limiting dilution, bacterial culture, and colony counting to give cfu/test.

Analytical Reactivity

Analytical reactivity for the Sofia Strep A FIA was determined using 15 strains of *Streptococcus pyogenes*. Each strain listed below in Table 7 produced positive results in the assay.

Table 7
Analytical Reactivity

***Streptococcus pyogenes* Strain**	**Test Quantity***
*S*train #1 (ATCC 19615)	$6.5x10^4$ cfu/test
*S*train #2 (ATCC 700942)	$7.4x10^4$ cfu/test
*S*train #3 (ATCC 700952)	$8.3x10^4$ cfu/test
*S*train #4 (Field Clinical Isolate)	$3.1x10^4$ cfu/test
*S*train #5 (Field Clinical Isolate)	$7.6x10^4$ cfu/test
*S*train #6 (Field Clinical Isolate)	$7.1x10^5$ cfu/test
*S*train #7 (Field Clinical Isolate)	$6.3x10^4$ cfu/test
*S*train #8 (Field Clinical Isolate)	$6.3x10^4$ cfu/test
*S*train #9 (Field Clinical Isolate)	$5.3x10^4$ cfu/test
*S*train #10 (ATCC 700482)	$6.5x10^4$ cfu/test
*S*train #11 (ATCC BAA 1315)	$7.2x10^4$ cfu/test
*S*train #12 (ATCC 700459)	$5.4x10^4$ cfu/test
*S*train #13 (ATCC 12203)	$6.9x10^4$ cfu/test
*S*train #14 ATCC 700944)	$5.3x10^4$ cfu/test
*S*train #15 (Field Clinical Isolate)	$7.0x10^4$ cfu/test

cfu/test = colony forming units/test

*The levels of bacteria were determined by limiting dilution, bacterial culture, and colony counting to give cfu/test.

Analytical Specificity

Cross Reactivity

The cross reactivity of the Sofia Strep A FIA was evaluated with a total of 61 non-Group A Streptococcus bacterial and fungal microorganisms, and 26 viral isolates. None of the organisms or viruses listed below in Table 8 showed any sign of cross reactivity in the assay. When the same organisms in Table 8 were pre-mixed with Group A Strep and tested in the Sofia Strep A FIA, all results were positive also indicating that the potential cross-reactants did not interfere with the detection of Strep A.

Table 8
Analytical Specificity and Cross Reactivity

Organism/Virus	**Test Quantity***
Arcanobacterium haemolyticum	$3x10^5$ cfu/test
Bacteroides fragilis	$3x10^7$ cfu/test
Bordetella pertussis	$3x10^7$ cfu/test
Candida albicans	$3x10^4$ cfu/test

Organism/Virus	Test Quantity*
Corynebacterium diphtheria	$3x10^5$ cfu/test
Corynebacterium pseudodiphtheriticum	$3x10^6$ cfu/test
Enterococcus faecalis	$3x10^6$ cfu/test
Enterococcus faecium	$3x10^6$ cfu/test
Escherichia coli	$1.5x10^7$ cfu/test
Fusobacterium necrophorum	$3x10^6$ cfu/test
Haemophilus influenzae	$3x10^7$ cfu/test
Haemophilus parahaemolyticus	$3x10^6$ cfu/test
Klebsiella pneumoniae	$3x10^7$ cfu/test
Moraxella catarrhalis	$3x10^6$ cfu/test
Neisseria lactamica	$3x10^6$ cfu/test
Neisseria gonorrhoeae	$3x10^6$ cfu/test
Neisseria meningitidis	$3x10^6$ cfu/test
Neisseria sicca	$3x10^7$ cfu/test
Neisseria subflava	$3x10^7$ cfu/test
Proteus vulgaris	$3x10^7$ cfu/test
Pseudomonas aeruginosa	$3x10^6$ cfu/test
Serratia marcescens	$3x10^7$ cfu/test
Staphylococcus aureus	$3x10^6$ cfu/test
Staphylococcus epidermidis	$3x10^6$ cfu/test
Staphylococcus haemolyticus	$3x10^5$ cfu/test
Staphylococcus intermedius	$3x10^5$ cfu/test
Staphylococcus saprophyticus	$3x10^6$ cfu/test
Streptococcus anginosus	$3x10^6$ cfu/test
Streptococcus gordonii	$3x10^4$ cfu/test
Streptococcus mitis	$3x10^4$ cfu/test
Streptococcus mutans	$3x10^6$ cfu/test
Streptococcus oralis	$3x10^6$ cfu/test
Streptococcus parasanguis	$3x10^6$ cfu/test
Streptococcus pneumoniae	$3x10^6$ cfu/test
Streptococcus salivarius	$3x10^5$ cfu/test
Streptococcus sanguinis	$3x10^6$ cfu/test
Streptococcus sp. Group B strain #1	$3x10^6$ cfu/test
Streptococcus sp. Group B strain #2	$3x10^6$ cfu/test
Streptococcus sp. Group B strain #3	$3x10^6$ cfu/test
Streptococcus sp. Group B strain #4	$3x10^6$ cfu/test
Streptococcus sp. Group B strain #5	$3x10^6$ cfu/test
Streptococcus sp. Group C strain #1	$3x10^6$ cfu/test

Organism/Virus	Test Quantity*
Streptococcus sp. Group C strain #2	$3x10^6$ cfu/test
Streptococcus sp. Group C strain #3	$3x10^6$ cfu/test
Streptococcus sp. Group C strain #4	$3x10^6$ cfu/test
Streptococcus sp. Group C strain #5	$3x10^5$ cfu/test
Streptococcus sp. Group D strain #1	$3x10^6$ cfu/test
Streptococcus sp. Group D strain #2	$3x10^6$ cfu/test
Streptococcus sp. Group D strain #3	$3x10^6$ cfu/test
Streptococcus sp. Group D strain #4	$3x10^6$ cfu/test
Streptococcus sp. Group D strain #5	$3x10^6$ cfu/test
Streptococcus sp. Group F strain #1	$3x10^5$ cfu/test
Streptococcus sp. Group F strain #2	$3x10^6$ cfu/test
Streptococcus sp. Group F strain #3	$3x10^6$ cfu/test
Streptococcus sp. Group F strain #4	$3x10^5$ cfu/test
Streptococcus sp. Group F strain #5	$3x10^5$ cfu/test
Streptococcus sp. Group G strain #1	$3x10^7$ cfu/test
Streptococcus sp. Group G strain #2	$3x10^6$ cfu/test
Streptococcus sp. Group G strain #3	$3x10^6$ cfu/test
Streptococcus sp. Group G strain #4	$3x10^6$ cfu/test
Yersinia enterocolitica	$3x10^6$ cfu/test
Adenovirus Type 1	$3x10^{11}$ $TCID_{50}$/test
Adenovirus Type 3	$3x10^5$ $TCID_{50}$/test
Adenovirus Type 4	$1.5x10^2$ $TCID_{50}$/test
Adenovirus Type 5	$3x10^5$ $TCID_{50}$/test
Adenovirus Type 11	$3x10^4$ $TCID_{50}$/test
Coronavirus 229E	$3x10^4$ $TCID_{50}$/test
Coronavirus OC43	$3x10^4$ $TCID_{50}$/test
Coxsackievirus B5 (Faulkner)	$3x10^6$ $TCID_{50}$/test
Cytomegalovirus	$3x10^3$ $TCID_{50}$/test
Echovirus Type 3	$1.5x10^4$ $TCID_{50}$/test
Epstein Barr virus	$3x10^7$ $TCID_{50}$/test
Herpes Simplex virus 1	$3x10^4$ $TCID_{50}$/test
Herpes Simplex virus 2	$3x10^4$ $TCID_{50}$/test
Influenza A H1N1	$3x10^4$ $TCID_{50}$/test
Influenza A H3N2	$3x10^4$ $TCID_{50}$/test
Influenza B Hong Kong	$3x10^4$ $TCID_{50}$/test
Influenza B Panama	$1.5x10^4$ $TCID_{50}$/test
Influenza C Taylor	$1.5x10^4$ $TCID_{50}$/test
Measles (Edmonston)	$3x10^4$ $TCID_{50}$/test

Organism/Virus	Test Quantity*
Mumps (Enders)	$3x10^3$ $TCID_{50}$/test
Parainfluenza virus 1	$3x10^4$ $TCID_{50}$/test
Parainfluenza virus 2	1.2 $TCID_{50}$/test
Parainfluenza virus 3	$3x10^6$ $TCID_{50}$/test
Parainfluenza virus 4A	$3x10^4$ $TCID_{50}$/test
Rhinovirus Type 15	$3x10^4$ $TCID_{50}$/test
Rhinovirus Type 1B	$3x10^3$ $TCID_{50}$/test

cfu/test = colony forming units/test $TCID_{50}$/test = 50% tissue culture infectious dose

*The levels of bacteria were determined by limiting dilution, bacterial culture, and colony counting to give cfu/test. Virus concentrations were determined by standard virology methods, Reed-Muench.

Interfering Substances

Several over-the-counter (OTC) products, whole blood, and blood agar were evaluated and did not interfere with the Sofia Strep A FIA at the levels tested (Table 9).

Table 9
Non-interfering Substances

Substance	Concentration
Crest Pro-Health Night Mint (Cetylpyridnium chloride)	25% v/v
Listerine Antiseptic (Eucalyptol, Menthol, Methyl salicylate, and Thymol)	25% v/v
Listerine Cool Mint (Eucalyptol, Menthol, Methyl salicylate, and Thymol)	25% v/v
Cepacol Dual Relief Spray (Benzocaine and Menthol)	25% v/v
Chloraseptic Max: Sore Throat Relief (Phenol and Glycerin)	25% v/v
Children's Dimetapp DM Cold & Cough Elixir (Brompheniramine maleate, Dextromethorphan HBr, and Phenylephrine HCl)	25% v/v
Children's Wal-Tap Elixir Cold & Allergy (Brompheniramine maleate and Phenylephrine HCl)	25% v/v
Children's Wal-Tap DM Elixir Cold & Cough (Brompheniramine maleate, Dextromethorphan HBr, and Phenylephrine HCl)	25% v/v
Rite Aid Tussin CF (Dextromethorphan HBr, Guaifenesin, and Phenylephrine HCl)	25% v/v
Robitussin Cough & Cold-CF Max (Dextromethorphan HBr, Guaifenesin, and Phenylephrine HCl)	25% v/v
Robitussin Nighttime Cough, Cold, & Flu (Acetaminophen, Diphenhydramine HCl, and Phenylephrine HCl)	25% v/v
Cepacol Sore Throat: Cherry Flavor (Benzocaine and Menthol)	25% w/v
Halls Cherry Mentholyptus (Menthol)	25% w/v
Halls Mentholyptus (Menthol)	25% w/v
Ricola Mountain Herb Throat Drops-Sugar Free (Menthol)	25% w/v
Sucrets Complete-Vapor Cherry (Dyclonine Hydrochloride and Menthol)	25% w/v

Substance	Concentration
Sucrets Complete-Cool Citrus (Dyclonine Hydrochloride and Menthol)	25% w/v
Chlorasceptic Throat Drops-Cherry (Phenol and Glycerin)	25% w/v
BreathSavers 3 Hour Mint-Spearmint (Cetylpyridnium chloride)	25% w/v
Tic Tac Freshmints (Eucalyptol, Menthol, Methylsalicylate, and Thymol)	25% w/v
Whole Blood	5% v/v
Sheep Blood Agar (5% Sheep Blood)	2.16 mg/mL
Horse Blood Agar (5% Horse Blood)	1.67 mg/mL

ASSISTANCE

If you have any questions regarding the use of this product, or if you want to report a test system problem, please call Quidel's Technical Support Number 800.874.1517 (in the U.S.) or 858.552.1100, Monday through Friday, from 7:00 a.m. to 5:00 p.m., Pacific Time. If outside the U.S., contact your local distributor or technicalsupport@quidel.com.

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LOG SHEET

Sofia® Strep A FIA

Record Built-in Procedural Controls on the first patient tested each day.

	Date	Patient ID	Valid Procedural Control	Test Results At 5 minutes	Lot Number and Expiration Date	Technician Initials
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

QC LOG SHEET

Sofia® Strep A FIA

Facility Name: _____

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 you have any questions or concerns, please contact Quidel Technical Support at 800.874.1517 or at technicalsupport@quidel.com.

	Date MM/DD/YY	Kit Lot #	Positive Control passed?	Negative Control passed?	Comments	Technician Initials
1						
2						
3						
4						
5						
6						
7						
8						
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