Simplexa™ Group A Strep Direct

REF MOL2850
Rev. C

A real-time PCR assay intended for the *in vitro* qualitative detection of Group A Strep bacterial DNA.

For *in-vitro* diagnostic use
CLIA – Moderate Complexity
R_x Only

INTENDED USE

The Focus Diagnostics Simplexa™ Group A Strep Direct assay is intended for use on the 3M Integrated Cycler for the in vitro qualitative detection of Group A Streptococcus (GAS) from throat swabs collected from human patients with signs and symptoms of pharyngitis, such as sore throat. This test is intended for use as an aid in the diagnosis of GAS infection. The assay is intended for use in hospital, reference, or state laboratory settings. The device is not intended for point-of-care use.

SUMMARY AND EXPLANATION

Streptococcus pyogenes, also known as Group A *Streptococcus*, is a beta-hemolytic bacterium that belongs to Lancefield serogroup A.[1] Group A *Streptococcus* is the major cause of bacterial acute pharyngitis accounting for 15-30% of the acute pharyngitis cases in children and 5-20% of the cases in adults.[2,3] Acute pharyngitis can also be caused by viruses such as adenovirus, influenza virus, parainfluenza virus, rhinovirus, and respiratory syncytial virus.[4] The symptoms of bacterial and viral acute pharyngitis overlap broadly and can often be very difficult to differentiate. Identification of Group A Streptococcus infection allows the disease to be treated effectively with antibiotics. If left undiagnosed and untreated, Group A Streptococcus can cause a number of severe complications including acute rheumatic fever, scarlet fever, glomerulonephritis, and streptococcus toxic shock syndrome.[5,6,7]

The gold standard for the diagnosis of streptococcal pharyngitis is throat swab culture, which has a sensitivity of 90–95%.[8] However, the assay requires 1-2 days to obtain a conclusive result. Rapid antigen detection tests (RADT) that target the presence of Group A Streptococcal carbohydrate on the cell surface can provide test results from a throat swab in 10-20 minutes. However RADT immunoassays produced within the last 10 years have been well characterized as having good specificity (95.0-98.7%) with lower sensitivity (90.6-97.6%) in comparison to culture, therefore the requirement for throat swab culture confirmation of negative results has been variable depending on performance. Real-time PCR assays have been applied successfully for detecting Group A Streptococcus from throat swabs.[9,10] Some of these assays provide a sensitivity and specificity level comparable to that of culture, but they require the end user to perform a DNA extraction step. The Simplexa™ Group A Strep Direct assay is designed to significantly shorten turnaround time for Group A Streptococcus detection. The Simplexa™ Group A Strep Direct is a real-time PCR assay that amplifies the universal Group A Streptococcus pyrogenic exotoxin B DNA directly from a throat swab without the traditional DNA extraction procedure. The Simplexa™ Group A Strep Direct assay is easy to perform and the assay can be completed in about one hour.

Simplexa™ Group A Strep Direct allows for the accurate detection of Group A Streptococcus without the need for culture confirmation.

PRINCIPLES OF THE PROCEDURE

The Simplexa™ Group A Strep Direct assay system is a real-time PCR system that enables the direct amplification and qualitative detection of Group A Strep bacterial DNA from throat swabs that have not undergone a nucleic acid extraction. The system consists of the Simplexa™ Group A Strep Direct assay, the 3M Integrated Cycler (with Integrated Cycler Studio Software), the Direct Amplification Disc (DAD) and associated accessories.

In the Simplexa™ Group A Strep Direct assay, bi-functional fluorescent probe-primers are used together with corresponding reverse primers to amplify Group A Strep bacterial DNA and the Internal Control (DNA IC). The assay targets a conserved region of Group A Strep (pyrogenic exotoxin B gene) to identify this bacteria in the specimen. The DNA IC is used to detect PCR failure and/or inhibition.

MATERIALS PROVIDED

The Focus Diagnostics Simplexa™ Group A Strep Direct assay contains sufficient reagents for 24 reactions. Upon receipt, store at -10 to -30 ºC (do not use a frost-free freezer). Each vial contains sufficient material for one use. Use within 30 minutes of thawing from the freezer.

Kit Description

Component Name	REF	EC SYMBOL ON LABEL		Abbreviated Name	Cap Color	Number of Vials	Reactions per Vial/Kit	Volume per Vial
Simplexa™ Group A Strep Direct Reaction Mix	**MOL2851**	**REAG**	**A**	**RM**	Brown	24	1/24	50 µL

Component Description

<table>
<tr><th>Kit Component</th><th>Contents</th></tr>
<tr><td>Simplexa™ Group A Strep Direct Reaction Mix (RM)</td><td>
DNA polymerase, buffer and dNTPs, internal control DNA Template, Dye-labeled fluorescent primers specific for detection of Group A Strep and for the Internal Control
<table>
<tr><th>Target</th><th>Probe Fluorophore (Dye)</th><th>Excitation</th><th>Emission</th><th>Targeted Gene</th></tr>
<tr><td>Group A Strep</td><td>FAM</td><td>495</td><td>520</td><td>Pyrogenic Exotoxin B</td></tr>
<tr><td>Internal Control DNA (IC)</td><td>Q670</td><td>644</td><td>670</td><td>N/A</td></tr>
</table>
</td></tr>
<tr><td>Simplexa™ Group A Strep Direct Barcode Card</td><td>Assay specific parameters and lot information.</td></tr>
</table>

MATERIALS SUPPLIED SEPARATELY

1. Direct Amplification Disc Kit (REF MOL1455)
    a) Direct Amplification Discs for use on the Integrated Cycler

MATERIALS REQUIRED BUT NOT SUPPLIED

1. 3M Integrated Cycler with Integrated Cycler Studio Software version 6.0 or higher.
2. Simplexa™ Group A Strep Positive Control Pack (REF MOL2860).
3. 50 µL fixed volume pipette (VWR Signature™ Fixed Volume Ergonomic High-Performance Pipettor Model VWR FE50 or equivalent).
4. Sterile, nuclease-free disposable pipette tips with filters (Extra Long tips ≥ 91 mm are recommended for pipetting directly from primary collection tubes.
5. Freezer (manual defrost) at -10 to -30 °C (for kit component and specimen frozen storage).
6. Refrigerator at 2 to 8 °C (for specimens).
7. Disposable, powder-free gloves.

RECOMMENDED MATERIALS

1. Liquid Amies medium Buffer to be used as a No Template Control (NTC).
2. Replacement Foil Wedges (REF MOL1550).

REAGENT HANDLING AND STORAGE

1. Store reagents at -10 to -30 °C (do not use a frost-free freezer).
2. Allow reagents to thaw at room temperature (approximate range 18 to 25 °C) before use.
3. Do not use kits or reagents beyond their expiration dates.
4. After removing Reaction Mix from freezer storage, initiate the test within 30 minutes.
5. Do not vortex the Reaction Mix.
6. Do not refreeze the Reaction Mix.

WARNINGS AND PRECAUTIONS

1. Wear personal protective equipment, such as (but not limited to) gloves and lab coats when handling kit reagents. Wash hands thoroughly when finished performing the test.
2. Do not smoke, drink, eat, handle contact lenses or apply make-up in areas where kit reagents and/or human specimens are being used.

3. Dispose of unused kit reagents and human specimens according to local, state and federal regulations.
4. Contamination of patient specimens or Reaction Mix can produce erroneous results. Use aseptic techniques.
5. Only use the protocol described in this insert. Deviations from the protocol or the use of times or temperatures other than those specified may give erroneous results.
6. Assay setup should be performed at room temperature (approximate range 18 to 25 °C).
7. Use calibrated fixed volume pipettes or equivalent to transfer sample and Reaction Mix.
8. Avoid touching the underside of the foil that will be in contact with the wells and disc surface.
9. To prevent potentially erroneous results, make sure that the sample and reagent are added to the appropriate input wells.
10. Finish loading and applying adhesive foil cover to one wedge before opening the foil of adjacent wedge.
11. Initiate the run within 30 minutes of removing the Reaction Mix vial from the freezer.
12. Do not attempt to reuse a wedge that has been used in previous runs or remove adhesive foil cover from a wedge that has been used.
13. Discs may be reused until all 8 wedges have been used. Dispose of used discs without detaching foil cover. Dispose of used discs without detaching foil cover in biohazardous waste container.
14. Reaction Mix contains > 1% glycerol, which may cause irritation upon inhalation or skin contact. Upon inhalation or skin contact, first aid measures should be taken.
15. If kit packaging or contents appear to be broken or damaged do not use and contact Focus Diagnostics. Contact information is on the last page of this document.
16. The spectral matrix must be installed in each 3M Integrated Cycler and should not be changed unless an updated QR code for the instrument is provided by Focus Diagnostics. The spectral matrix is unique to each 3M Integrated Cycler. The spectral matrix was provided with the 3M integrated cycler instrument on the cover of the 3M Integrated Cycler Hardware Manual. If the matrix label will not scan or cannot be found contact Focus Diagnostics. The contact information is on the last page of this document.
17. Changing or not installing the spectral matrix can result in false results.

INSTRUCTIONS FOR USE

A. SPECIMEN COLLECTION

Acceptable specimen types are throat swabs in Amies media: Copan Catalog numbers 480C and 481C or equivalent. Use the swab provided with the transport media. Do not use calcium alginate swabs, as they may contain substances that inhibit PCR testing. Throat swabs should be used within 72 hours post collection.

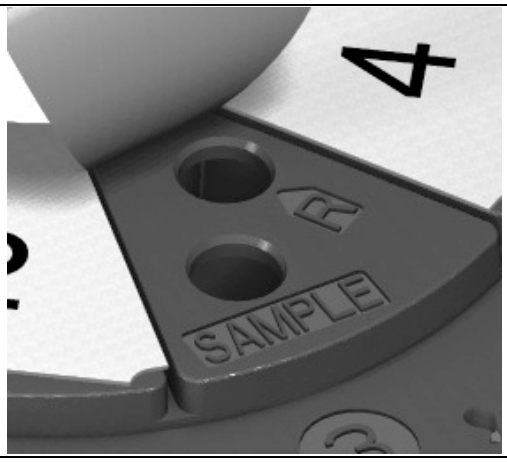
B. REAL-TIME PCR INSTRUMENT SETUP

1. Refer to the Integrated Cycler Operator Manual for details on how to configure the Integrated Cycler Studio Software to add an assay definition, setup and analyze runs on the 3M Integrated Cycler.

C. DIRECT AMPLIFICATION DISC LOADING AND REAL-TIME PCR AMPLIFICATION

NOTE: No sample extraction is needed prior to PCR amplification step.

1. Select samples that need to be tested.
2. Thaw Reaction Mix vials at room temperature (approximate range 18 to 25 °C). Use one Reaction Mix vial per sample to be tested.
3. Scan the barcode on the Simplexa™ Group A Strep Direct Reaction Mix vial or on the barcode card**.**
4. Scan the disc barcode on the DAD.
5. Scan or type in each sample identifier.
6. For one wedge at a time, peel the adhesive foil back to expose the Sample (SAMPLE) and Reaction (R) wells without completely removing the adhesive foil cover (Figure 1 & 2). Avoid touching the underside of the foil that will be in contact with the wells and disc surface.
7. Ensure that the Reaction Mix is completely thawed. Briefly spin down the tubes as needed. (Do not vortex the Reaction Mix).
8. Use the fixed volume pipette to transfer 50 µL of the Reaction Mix into the reaction (R) well.
9. Use the fixed volume pipette to transfer 50 µL of the sample or control; pipette sample or control into Sample well (SAMPLE).
10. Cover the wedge sealing the wells with the peeled adhesive foil, pressing down firmly near the edge of the disc. If the original foil is torn it should be replaced with an extra Replacement Foil Wedge.
11. Carefully remove the tab portion of the foil cover at the perforation.
12. Repeat steps 6 to 11 for the next sample(s).
13. Load the sealed DAD into the 3M Integrated Cycler and start the run.

Figure 1 - Disc with pre-use foil lifted from Sample and Reaction Wells for wedge #3	Figure 2 –Sample [Sample] and Reaction [R] Wells
	

NOTES *(for informational purposes - no user action/interpretation required)*:

1. Focus Diagnostics kits may contain version numbers for Assay Definitions. If the version number exists, it will be appended to the Assay Definition i.e. 'Sample IVD Assay.2'. When multiple versions exist, the software automatically uses the assay definition associated with the scanned lot number.

QUALITY CONTROL

Simplexa™ Group A Strep Positive Control Pack (MOL2860) may be used as an external control for QC testing, training or proficiency testing. Each laboratory should establish its own Quality Control ranges and frequency of QC testing based on applicable local laws, regulations and standard good laboratory practice. Refer to the Simplexa™ Group A Strep Positive Control Pack Package Insert (PI.MOL2860) for instructions on running the Positive Control.

Expected Control Results

Control Type	Group A *Streptococcus*	Internal Control (DNA IC)
Simplexa™ Group A Strep Direct Positive Control[1]	Detected[1]	Not applicable[2]
No Template Control (NTC)	Not Detected	Valid

[1] Typical Ct values for the Positive Control range between 25 to ≤45.
[2] Detection of the Simplexa™ DNA Internal Control (DNA IC) is not required for a valid result.

RESULTS

Upon completion of the run, the software automatically interprets and displays results.

1. For each accession ID (Sample ID) entered, software displays a result ("Detected", "Not Detected" or "Invalid") for Group A Strep.
   a. **"Detected"** result indicates the presence of Group A Strep DNA in the patient sample.
   b. **"Not Detected"** result indicates the absence of Group A Strep DNA in the patient sample.
   c. **"Invalid"** result indicates inability to conclusively determine presence or absence of Group A Strep DNA in the patient sample. This result may be due to 1) Internal Control (IC) failure, or 2) failure to detect sufficient specimen volume. The sample needs to be retested. See "Invalid Results" section below.
   d. **"EC500"** result indicates a data quality error for the bacterial analyte. The software was unable to determine a valid amplification for the analyte.
   e. **"EC505"** result indicates a data quality error for the bacterial analyte. The software was unable to determine a valid amplification for the analyte. Contact Technical Assistance at Focus Diagnostics which can be found on the last page of this document.
2. Print the report as needed.
   a. Export the results as needed.

INVALID RESULTS

In case of an "Invalid" result or an error code, retest the sample with a new reaction-mix vial from the same kit or a new kit. If the problem is unresolved, contact Technical Assistance at Focus Diagnostics. Contact information can be found on the last page of this document.

LIMITATIONS

1. For *in vitro* diagnostic use. In the United States, this product is intended for use in healthcare facilities with a minimum CLIA certification of moderate complexity.
2. All results from this and other tests must be considered in conjunction with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
3. Additional follow-up testing using the culture method is required if the result is negative and clinical symptoms persist, or in the event of an acute rheumatic fever (ARF) outbreak.
4. The prevalence of bacterial infections may affect the test's predictive value.
5. As with other tests, negative results do not rule out Group A Strep infection.
6. False-negative results may occur if the bacteria have genomic mutations, insertions, deletions, or rearrangements or if performed very early in the course of illness.
7. False-negative results may occur if inadequate numbers of bacteria are present in the specimen due to improper collection, transport or handling. False-negative results may also occur if the bacteria are present at a level that is below the analytical sensitivity of the assay.
8. As with other tests, false-positive results may occur. Repeat testing or testing with a different device may be indicated in some settings.
9. This test cannot rule out infections caused by other viral or bacterial pathogens.
10. Information on the kit barcode can only be transferred into the Integrated Cycler Studio through a bar-code scanner. If the scanner is not working, or if you are unable to transfer the information for any reason, contact Focus Diagnostics at the contact numbers in the back page of this document.
11. The performance of this test has not been established for use in donor screening tests.

PERFORMANCE CHARACTERISTICS

CLINICAL PROSPECTIVE STUDY

One thousand three hundred and ninety seven (1397) samples that were prospectively collected from four (4) geographically diverse sites between May 6, 2014 and October 28, 2014 from patients with signs and symptoms of Group A Strep infections of the pharynx. One thousand three hundred and fifty two (1352) samples were evaluable on Simplexa™ Group A Strep Direct and the comparator culture method. Samples were tested on Simplexa™ Group A Strep Direct at the collection sites and comparator culture method was performed at one (1) central laboratory. The invalid rate of the clinical prospective study using Simplexa™ Group A Strep Direct was 0.57% (eight out of one thousand three hundred and ninety six 8/1396 samples). Discrepant analysis was performed using a validated bidirectional sequencing assay.

Clinical Prospective Study: (Overall)			
Simplexa™ Group A Strep Direct Result	**Culture Method**		
	Detected	**Not Detected**	**Total**
Detected	152	57[a]	209
Not Detected	4[b]	1139	1143
Total	156	1196	1352
%Sensitivity	97.4%(152/156) 95% CI: 93.6% to 99.0%	%Specificity	95.2%(1139/1196) 95% CI: 93.9% to 96.3%
% Positive Predictive Value (PPV)	72.7%(152/209) 95% CI: 66.3% to 78.3%	%Negative Predictive Value (NPV)	99.7%(1139/1143) 95% CI: 99.1% to 99.9%

[a]46/57 discrepant samples were Group A Strep Positive, 9/57 were "Group A Strep Negative and 2/57 were Indeterminate when tested using a validated bidirectional sequencing assay.
[b]2/ 4 discrepant samples were Group A Strep Positive and 2/4 were Group A Strep Negative when tested using a validated bidirectional sequencing assay.

REPRODUCIBILITY

Three (3) investigative sites assessed the device's inter-site, inter-day and inter/intra-assay reproducibility. Each of the laboratories tested a panel of six (6) members that included contrived samples at low positive, (approximately 1 X LoD) and moderately positive sample (approximately 3 X LoD) for M1 and M3 serotypes of Group A *Streptococcus*, a positive and negative control were also included in the panel. The assays were performed in triplicate (3) on five (5) different days. Each site had two (2) operators who each assayed the sample panel once (1) per day, for a total of two (2) sets of data per day. Combined results for all sites are presented in the tables below.

Sample Panel Member	**Testing Site 1**			**Testing Site 2**			**Testing Site 3**			**Overall**	
	% Agreement with Expected Results	**Avg. Ct**	**% CV**	**% Agreement with Expected Results**	**Avg. Ct**	**% CV**	**% Agreement with Expected Results**	**Avg. Ct**	**% CV**	**Total %**	**95% CI**
Negative	100.0% (30/30)	NA	NA	96.7% (29/30)	41.9	NA	100.0% (30/30)	NA	NA	98.9% (89/90)	94.0 to 99.8%
Positive Control (PC)	100.0% (30/30)	29.5	1.4	100.0% (30/30)	29.5	3	100.0% (30/30)	30	1.2	100.0% (90/90)	95.9 to 100.0%
Group A Strep M1 Serotype Low Positive	100.0% (30/30)	38.6	4.4	83.3% (25/30)	39.4	5.6	96.7% (29/30)	38	3.5	93.3% (84/90)	86.2 to 96.9%

Sample Panel Member	Testing Site 1			Testing Site 2			Testing Site 3			Overall	
	% Agreement with Expected Results	Avg. Ct	% CV	% Agreement with Expected Results	Avg. Ct	% CV	% Agreement with Expected Results	Avg. Ct	% CV	Total %	95% CI
Group A Strep M1 Serotype Moderate Positive	100.0% (30/30)	35.9	2.6	93.3% (28/30)	36.3	4.8	100.0% (30/30)	36	1.8	97.8% (88/90)	92.3 to 99.4%
Group A Strep M3 Serotype Low Positive	96.7% (29/30)	38.5	2.9	90.0% (27/30)	39.2	4.8	96.7% (29/30)	39	4.5	94.4% (85/90)	87.6 to 97.6%
Group A Strep M3 Serotype Moderate Positive	100.0% (30/30)	36.3	2.6	90.0% (27/30)	36.7	3.2	100.0% (30/30)	37	2.7	96.7% (87/90)	90.7 to 98.9%
All	99.4% (179/180)			92.2% (166/180)			98.9% (178/180)			96.9% (523/540)	95.0 to 98.0%

ANALYTICAL SENSITIVITY/LIMIT OF DETECTION

The Limit of Detection (LoD) was determined for the Simplexa™ Group A Strep Direct by performing a dilution series. The LoD samples used for the study were contrived using two (2) serotypes of Group A *Streptococcus*; M1 and M3 that were verified (re-grown and re-titered) bacterial stock. For each serotype, eight (8) different concentrations were spiked in simulated matrix from the verified bacterial stock material and confirmed using thirty two (32) replicates. The Limit of Detection (LoD) was determined to be the following;

Simplexa™ Group A Strep Direct – Limit of Detection	
Group A Strep Serotype	**Concentration (cfu/mL)**
M1	682
M3	2350

ANALYTICAL REACTIVITY / CROSS REACTIVITY

Analytical Reactivity

Analytical Reactivity was assessed for the ability of Simplexa™ Group A Strep Direct to detect sixty (60) Group A Streptococcus strains not present in the LoD study. Analytical Reactivity was observed in testing of twenty one (21) strains. All were detected as positive for Group A Strep at or below 5000 cfu/mL. Analytical Reactivity was tested using in silico NCBI BLAST sequence analysis methods for thirty nine (39) GAS strains distinct from the wet tested strains.

Streptococcus pyogenes Serotype	Concentration (cfu/mL	Simplexa™ Group A Strep Direct Qualitative Result % Detection
M2	1.50×10^3	100% (3/3)
M4	1.50×10^3	100% (3/3)
M5	1.50×10^3	100% (3/3)
M6	1.50×10^3	100% (3/3)

Streptococcus pyogenes Serotype	Concentration (cfu/mL	Simplexa™ Group A Strep Direct Qualitative Result % Detection
M9	3.00×10^3	100% (3/3)
M12	1.50×10^3	100% (3/3)
M13	1.50×10^3	100% (3/3)
M14	1.50×10^3	100% (3/3)
M18	5.00×10^3	100% (3/3)
M22	1.50×10^3	100% (3/3)
M27	3.00×10^3	100% (3/3)
M28	1.50×10^3	100% (3/3)
M29	1.50×10^3	100% (3/3)
M49	1.50×10^3	100% (3/3)
M73	3.00×10^3	100% (3/3)
M75	3.00×10^3	100% (3/3)
M77	3.00×10^3	100% (3/3)
M78	1.50×10^3	100% (3/3)
M82	1.50×10^3	100% (3/3)
M87	1.50×10^3	100% (3/3)
M89	3.00×10^3	100% (3/3)

Cross Reactivity (Analytical Specificity)

Analytical reactivity was evaluated for the Simplexa™ Group A Strep Direct by testing the ability to exclusively identify Group A *Streptococcus* with no cross reactivity to organisms that are closely related, or cause similar clinical symptoms, or present as normal flora in the pharynx. Negative specimens were spiked with potentially cross-reactive organisms at known concentrations. Spiked specimens were examined for reactivity with the Group A Strep Direct. Sixty-four (64) organisms were tested. *Bacteroides ovalis* and *Tremella fuciformis* were not available for testing therefore data from In-Silico NCBI BLAST sequence analysis was performed. No cross reactivity was found.

Cross Reactant	Tested Concentration	Simplexa™ Group A Strep Direct Qualitative Results: % Detection (# Detected/#Tested)
Baseline1	Not Applicable	0.0% (0/5)
Baseline2	Not Applicable	0.0% (0/5)
Adenovirus 1	1.00×10^5 $TCID_{50}$/mL	0.0% (0/3)
Adenovirus 7A	1.00×10^5 $TCID_{50}$/mL	0.0% (0/3)
Arcanobacterium haemolyticum	1.00×10^6 $TCID_{50}$/mL	0.0% (0/3)
Bacillus cereus	1.00×10^6 cfu/mL	0.0% (0/3)
Bacteroides ovatus	1.00×10^6 cfu/mL	0.0% (0/3)
Bordetella pertussis	1.00×10^6 cfu/mL	0.0% (0/3)
Burkholderia cepacia	1.00×10^6 cfu/mL	0.0% (0/3)
Campylobacter rectus	1.00×10^6 cfu/mL	0.0% (0/3)
Candida albicans	1.00×10^6 cfu/mL	0.0% (0/3)
Chlamydia pneumoniae	1.00×10^6 cfu/mL	0.0% (0/3)

Cross Reactant	Tested Concentration	Simplexa™ Group A Strep Direct Qualitative Results: % Detection (# Detected/#Tested)
Coronavirus 229E	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Corynebacterium diphtheriae	1.00 X 10^6 $TCID_{50}$/mL	0.0% (0/3)
Cytomegalovirus (CMV)	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Enterococcus faecalis vanB	1.00 X 10^6 cfu/mL	0.0% (0/3)
Enterovirus 71	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Epstein-Barr virus (B95-8)	1.00 X 10^5 copies/mL	0.0% (0/3)
Escherichia coli	1.00 X 10^6 cfu/mL	0.0% (0/3)
Fusobacterium necrophorum	1.00 X 10^6 cfu/mL	0.0% (0/3)
Haemophilus influenzae	1.00 X 10^6 cfu/mL	0.0% (0/3)
HSV-1 McIntyre	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
HSV-2 G	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Influenza A/Hong Kong/8/68 H3N2	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Influenza B/Panama/45/90	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Klebsiella pneumoniae	1.00 X 10^6 cfu/mL	0.0% (0/3)
Lactobacillus acidophilus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Legionella pneumophila	1.00 X 10^6 cfu/mL	0.0% (0/3)
Metapneumovirus-9	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Moraxella catarrhalis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Mycoplasma pneumoniae	1.00 X 10^6 CCU/ml	0.0% (0/3)
Neisseria gonorrhoeae	1.00 X 10^6 cfu/mL	0.0% (0/3)
Neisseria meningitidis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Parainfluenza 1	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Parainfluenza 2	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Parainfluenza 3	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Peptostreptococcus micros	1.00 X 10^6 cfu/mL	0.0% (0/6)
Pseudomonas aeruginosa	1.00 X 10^6 cfu/mL	0.0% (0/3)
Rhinovirus 1A	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
RSV-B 9320	1.00 X 10^5 $TCID_{50}$/mL	0.0% (0/3)
Staphylococcus aureus (MRSA), ATCC 43300	1.00 X 10^6 cfu/mL	0.0% (0/3)
Staphylococcus epidermidis (MRSE), ATCC 29887	1.00 X 10^6 cfu/mL	0.0% (0/3)
Stenotrophomonas maltophilia	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus agalactiae	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus anginosus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus canis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus constellatus subsp. constellatus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus cristatus	1.00 X 10^6 cfu/mL	0.0% (0/3)

Cross Reactant	Tested Concentration	Simplexa™ Group A Strep Direct Qualitative Results: % Detection (# Detected/#Tested)
Streptococcus dysgalactiae	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus equi subsp. zooepidemicus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus equinus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus gallolyticus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus gordonii	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus intermedius	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus mitis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus mutans	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus oralis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus parasanguinis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus pneumoniae	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus salivarius	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus sanguinis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus sobrinus	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus uberis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Streptococcus vestibularis	1.00 X 10^6 cfu/mL	0.0% (0/3)
Treponema denticola	1.00 X 10^6 spirochetes/mL	0.0% (0/3)
Veillonella parvula	1.00 X 10^6 cfu/mL	0.0% (0/3)

INTERFERENCE

The performance of Simplexa™ Group A Strep Direct was evaluated with potentially interfering substances that may be present in pharynx. The potentially interfering substances were evaluated in a contrived sample that contained Group A *Streptococcus* at low positive concentrations (approximately 1 X LoD) and moderate positive concentrations (approximately 3 X LoD) of Group A *Streptococcus* serotypes M1 and M3. There was no evidence of interference caused by the substances at the concentrations tested.

Potential Interferent	Active Ingredient	Interferent Concentration	GAS Bacterial Serotype	Simplexa™ Group A Strep Direct Qualitative Result (# Detected/# Tested)
Baseline	Not Applicable	Not Applicable	M1	100.0%(5/5)
Baseline	Not Applicable	Not Applicable	M3	100.0%(5/5)
Afrin nasal Spray	Oxymetazoline Hydrochloride	15% v/v	M1	100.0%(3/3)
Afrin nasal Spray	Oxymetazoline Hydrochloride	15% v/v	M3	100.0%(3/3)
Antibiotic	Amoxicillin	0.5 mg/mL	M1	100.0%(3/3)
Antibiotic	Amoxicillin	0.5 mg/mL	M3	100.0%(3/3)
Antibiotic	Cephalexin	0.04 mg/mL	M1	100.0%(3/3)
Antibiotic	Cephalexin	0.04 mg/mL	M3	100.0%(3/3)
Antibiotic	Clindamycin	0.06 mg/mL	M1	100.0%(5/5)
Antibiotic	Clindamycin	0.06 mg/mL	M3	100.0%(3/3)
Antibiotic	Erythromycin	1 mg/mL	M1	100.0%(3/3)
Antibiotic	Erythromycin	1 mg/mL	M3	100.0%(3/3)

Potential Interferent	Active Ingredient	Interferent Concentration	GAS Bacterial Serotype	Simplexa™ Group A Strep Direct Qualitative Result (# Detected/# Tested)
Antibiotic	Penicillin	1200 U/mL	M1	100.0%(3/3)
Antibiotic	Penicillin	1200 U/mL	M3	100.0%(3/3)
Aspirin	Aspirin	0.62 mg/mL	M1	100.0%(3/3)
Aspirin	Aspirin	0.62 mg/mL	M3	100.0%(3/3)
Benadryl	Diphenhydramine HCl	10 µL/swab	M1	100.0%(3/3)
Benadryl	Diphenhydramine HCl	10 µL/swab	M3	100.0%(3/3)
Blood	Blood	10% v/v	M1	100.0%(3/3)
Blood	Blood	10% v/v	M3	100.0%(3/3)
Chloraseptic Sore Throat Spray	Phenol	10% v/v	M1	100.0%(3/3)
Chloraseptic Sore Throat Spray	Phenol	10% v/v	M3	100.0%(3/3)
Contac Cold + Flu tablet	Acetaminophen Chlorpheniramine Maleate Phenylephrine HCl	16.2 mg/mL 0.06 mg/mL 0.16 mg/mL	M1	100.0%(3/3)
Contac Cold + Flu tablet	Acetaminophen Chlorpheniramine Maleate Phenylephrine HCl	16.2 mg/mL 0.06 mg/mL 0.16 mg/mL	M3	100.0%(3/3)
Corticosterone	Corticosterone	4 mg/swab	M1	100.0%(3/3)
Corticosterone	Corticosterone	4 mg/swab	M3	100.0%(3/3)
Crest Complete Toothpaste	Sodium Fluoride	0.1 mg/mL	M1	100.0%(3/3)
Crest Complete Toothpaste	Sodium Fluoride	0.1 mg/mL	M3	100.0%(3/3)
Finafta Oral Anesthetic / Analgesics	Ethyl Alcohol Salicylic Acid Benzocaine	1/10X dilution	M1	100.0%(3/3)
Finafta Oral Anesthetic / Analgesics	Ethyl Alcohol Salicylic Acid Benzocaine	1/10X dilution	M3	100.0%(3/3)
Listerine	Eucalyptol Menthol Methyl Salicylate Thymol	10 µL/swab	M1	100.0%(3/3)
Listerine	Eucalyptol Menthol Methyl Salicylate Thymol	10 µL/swab	M3	100.0%(3/3)
Mucin	Purified Mucin Protein	60 µg/mL	M1	100.0%(3/3)
Mucin	Purified Mucin Protein	60 µg/mL	M3	100.0%(3/3)
Neo-Synephrine	Phenylephrine HCl	15% v/v	M1	100.0%(3/3)
Neo-Synephrine	Phenylephrine HCl	15% v/v	M3	100.0%(3/3)
Nyquil	Dextromethorphan Hydrobromide Doxylamine Succinate	1/200 X dilution	M1	100.0%(3/3)

Potential Interferent	Active Ingredient	Interferent Concentration	GAS Bacterial Serotype	Simplexa™ Group A Strep Direct Qualitative Result (# Detected/# Tested)
Nyquil	Dextromethorphan Hydrobromide Doxylamine Succinate	1/200 X dilution	M3	100.0%(3/3)
Pain Medication	NSAID	0.1 mg/mL	M1	100.0%(3/3)
Pain Medication	NSAID	0.1 mg/mL	M3	100.0%(3/3)
Pain Medication	Tylenol	1 mg/mL	M1	100.0%(3/3)
Pain Medication	Tylenol	1 mg/mL	M3	100.0%(3/3)
Robitussin Cough / Chest Congestion Cough Syrup	Dextromethorphan HBr Guaifenesin	2.0 mg/mL	M1	100.0%(3/3)
Robitussin Cough / Chest Congestion Cough Syrup	Dextromethorphan HBr Guaifenesin	2.0 mg/mL	M3	100.0%(3/3)
Saline Nasal Spray	Sodium Chloride with Preservatives	15% v/v	M1	100.0%(3/3)
Saline Nasal Spray	Sodium Chloride with Preservatives	15% v/v	M3	100.0%(3/3)
Saliva	Water, Electrolytes, Mucus, Etc.	50 µL/swab	M1	100.0%(3/3)
Saliva	Water, Electrolytes, Mucus, Etc.	50 µL/swab	M3	100.0%(3/3)
Scope	Glycerin Sodium Saccharin Sodium Benzoate Cetylpyridinum Chloride Benzoic Acid Blue 1 Yellow 5	10 µL/swab	M1	100.0%(3/3)
Scope	Glycerin Sodium Saccharin Sodium Benzoate Cetylpyridinum Chloride Benzoic Acid Blue 1 Yellow 5	10 µL/swab	M3	100.0%(3/3)
Sore Throat Lozenge	Menthol	1.7 mg/mL	M1	100.0%(3/3)
Sore Throat Lozenge	Menthol	1.7 mg/mL	M3	100.0%(3/3)
Sore Throat Lozenge	Pectin	0.34 mg/mL	M1	100.0%(3/3)
Sore Throat Lozenge	Pectin	0.34 mg/mL	M3	100.0%(3/3)
Sore Throat Lozenge	Zinc Gluconate Glycine	0.1 mg/mL	M1	100.0%(3/3)
Sore Throat Lozenge	Zinc Gluconate Glycine	0.1 mg/mL	M3	100.0%(3/3)
Thymol	Thymol	400 mg/swab	M1	100.0%(3/3)
Thymol	Thymol	400 mg/swab	M3	100.0%(3/3)
Zicam Oral Mist	Zincum Aceticum Zincum Gluonicum	0.625% v/v	M1	100.0%(3/3)

Potential Interferent	Active Ingredient	Interferent Concentration	GAS Bacterial Serotype	Simplexa™ Group A Strep Direct Qualitative Result (# Detected/# Tested)
Zicam Oral Mist	Zincum Aceticum Zincum Gluonicum	0.625% v/v	M3	100.0%(3/3)

INHIBITION BY OTHER MICROORGANISMS

The Simplexa™ Group A Strep Direct was evaluated by testing the ability to identify Group A Strep Direct when potentially inhibitory organisms are present. The panel of sixty four (64) potentially inhibitory organisms was individually spiked into a pool with a low concentration (approximately 1 X LoD) and moderate concentration (approximately 3 X LoD) of Group A *Streptococcus* M1 or M3 serotypes. If signal was not detected for Group A Strep in any of the three (3) replicates, an additional five (5) replicates were tested for confirmation. *Bacteroides ovalis* and *Tremella fuciformis* were not available for testing therefore data from In-Silico NCBI BLAST sequence analysis was performed. No inhibitory effects were confirmed for the Simplexa™ Group A Strep Direct at the concentrations tested.

Organism	Tested Concentration	GAS Serotype: M1	GAS Serotype: M3
		Simplexa™ Group A Strep Direct Qualitative Results: %Detection (# Detected/#Tested)	Simplexa™ Group A Strep Direct Qualitative Results: %Detection (# Detected/#Tested)
Baseline	Not Applicable	100.0%(11/11)	100.0%(10/10)
Adenovirus 1	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Adenovirus 7A	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Arcanobacterium haemolyticum	1.00 X 10^6 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Bacillus cereus	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Bacteroides ovatus	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Bordetella pertussis	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Burkholderia cepacia	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Campylobacter rectus	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Candida albicans	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Chlamydia pneumoniae	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Coronavirus 229E	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Corynebacterium diphtheriae	1.00 X 10^6 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Cytomegalovirus (CMV)	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Enterococcus faecalis vanB	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Enterovirus 71	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Epstein-Barr virus (B95-8)	1.00 X 10^5 copies/mL	100.0%(3/3)	100.0%(3/3)
Escherichia coli	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Fusobacterium necrophorum	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Haemophilus influenzae	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
HSV-1 McIntyre	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
HSV-2 G	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Influenza A/Hong Kong/8/68 H3N2	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Influenza	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)

Organism	Tested Concentration	GAS Serotype: M1	GAS Serotype: M3
		Simplexa™ Group A Strep Direct Qualitative Results: %Detection (# Detected/#Tested)	Simplexa™ Group A Strep Direct Qualitative Results: %Detection (# Detected/#Tested)
B/Panama/45/90			
Klebsiella pneumoniae	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Lactobacillus acidophilus	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Legionella pneumophila	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Metapneumovirus-9	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Moraxella catarrhalis	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Mycoplasma pneumoniae	1.00 X 10^6 CCU/ml	100.0%(3/3)	100.0%(3/3)
Neisseria gonorrhoeae	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Neisseria meningitidis	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Parainfluenza 1	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Parainfluenza 2	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Parainfluenza 3	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Peptostreptococcus micros[***]	1.00 X 10^6 cfu/mL	100.0%(6/6)	100.0%(6/6)
Pseudomonas aeruginosa	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Rhinovirus 1A	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
RSV-B 9320	1.00 X 10^5 $TCID_{50}$/mL	100.0%(3/3)	100.0%(3/3)
Staphylococcus aureus (MRSA), ATCC 43300	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Staphylococcus epidermidis (MRSE), ATCC 29887	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Stenotrophomonas maltophilia	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus agalactiae	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
*Streptococcus anginosus**	1.00 X 10^6 cfu/mL	100.0%(5/5)	100.0%(3/3)
Streptococcus canis	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus constellatus subsp. constellatus	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus cristatus	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus dysgalactiae	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus equi subsp. zooepidemicus	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus equinus	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus gallolyticus	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus gordonii	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus intermedius	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus mitis	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus mutans	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus oralis	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)

Organism	Tested Concentration	GAS Serotype: M1	GAS Serotype: M3
		Simplexa™ Group A Strep Direct Qualitative Results: %Detection (# Detected/#Tested)	Simplexa™ Group A Strep Direct Qualitative Results: %Detection (# Detected/#Tested)
Streptococcus parasanguinis	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus pneumoniae	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus salivarius	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
*Streptococcus sanguinis***	1.00 X 10^6 cfu/mL	100.0%(5/5)	100.0%(3/3)
Streptococcus sobrinus	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus uberis	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Streptococcus vestibularis	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
Treponema denticola	1.00 X 10^6 spirochetes/mL	100.0%(3/3)	100.0%(3/3)
Veillonella parvula	1.00 X 10^6 cfu/mL	100.0%(3/3)	100.0%(3/3)
*1/3 initial replicate had low volume (not fluid check error) so three more replicates were tested. Therefore total of 5 replicates evaluated.			
**1/3 initial replicate was “invalid” due to “IC Failure” so three more replicates were tested. Therefore total of 5 replicates evaluated.			
***Sample tested twice due to different name listed into protocol for the same organisms. Therefore total of 6 replicates evaluated.			

CARRY-OVER CONTAMINATION

The amplification carry-over for the Simplexa™ assays including the Simplexa™ Group A Strep Direct assay was assessed from Simplexa™ Flu A/B & RSV Direct REF MOL2650 (K120413) assay and can be found on the FDA website. The study can be applied to the Simplexa™ Group A Strep Direct assay as the study is not analyte specific. In the Simplexa™ Flu A/B & RSV Direct REF MOL2650 (K120413), the amplification carry-over study searched for the presence of contamination in negative samples. The study was designed by alternately placing high positive and negative samples on each disc. No evidence of carry-over contamination was seen.

EXPECTED VALUES

The prevalence of Group A *Streptococcus* is affected by patient population and epidemiology. In the Simplexa™ Group A Strep Direct prospective study, two hundred and nine (209) of the one thousand three hundred and fifty two (1352) samples or 15.4% of the samples tested were positive from four (4) geographically diverse sites between May 6, 2014 and October 28, 2014.

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