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Owner	Rhonda Troglia: Lead-Med Lab Scientist (MLS)
Section Name	Laboratory
Applicability	Ascension Via Christi Hospital Pittsburg, Inc.

Cobas Liat Strep A

CLIA Complexity: WAIVED

For use with throat swab specimens.

NOTE: For the remainder of this Package Insert, the cobas® Liat® Analyzer may be referred to as the Analyzer and the cobas® Liat® System may be referred to as the System.

1. Intended Use

The cobas® Strep A nucleic acid test for use on the cobas® Liat® System (cobas® Strep A) is a qualitative in vitro diagnostic test for the detection of Streptococcus pyogenes (Group A β-hemolytic Streptococcus, Strep A) in throat swab specimens from patients with signs and symptoms of pharyngitis.

The cobas® Strep A assay utilizes nucleic acid purification and polymerase chain reaction (PCR) technology to detect Streptococcus pyogenes by targeting a segment of the Streptococcus pyogenes genome.

2. Summary and Explanation

Strep A causes a wide range of human infections, including pharyngitis, sinusitis, lymphadenitis, pyoderma, endocarditis, meningitis, septicemia, tonsillitis, impetigo, and upper respiratory tract infections. Accurate diagnosis of the pathogen is necessary to properly treat the disease using appropriate antibiotic therapy. If left untreated, Strep A infections can lead to serious, sometimes life-threatening conditions, such as rheumatic fever, scarlet fever, peritonsillar abscess, glomerulonephritis, necrotizing fasciitis, and streptococcal toxic shock syndrome.

Conventional methods for detection of Strep A involve 24-48 hour culture of throat swab specimens

followed by identification using physiological, biochemical, or immunological traits. Faster results can be obtained using rapid antigen detection tests (RADT), but these tests generally have lower sensitivity. Reported sensitivities for RADTs vary widely and a review of nearly 100 studies reported an average sensitivity of 86% and specificity of 95%.1 The cobas® Strep A assay is a rapid and easy to use molecular test that provides improved sensitivity over RADT, eliminating the need for confirmatory culture testing in adults and children.

3. Principle of the Procedure

The cobas® Strep A assay is an automated in vitro diagnostic test for the qualitative detection of Strep A DNA in throat swab specimens. The sample-to-result time is ~15 minutes.

The assay is performed on the cobas® Liat® System. The System automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in biological samples using real-time PCR. The assay targets a well-conserved region of the Strep A genome. An Internal Process Control (IPC) is also included. The IPC is present to control for adequate processing of the target bacteria through all steps of the assay process and to monitor the presence of inhibitors in the sample preparation and PCR.

The cobas® Liat® Analyzer consists of an instrument with integrated software for running tests and analyzing the results. The System consists of the Analyzer and a single-use disposable cobas® Strep A Tube that contains the nucleic acid purification and PCR reagents, and hosts the sample preparation and PCR processes. Other than adding the sample to the cobas® Strep A Tube, no reagent preparation or additional steps are required. Because each cobas® Strep A Tube is self-contained, the risk of cross-contamination between samples is reduced.

4. Reagents and Instruments

Materials Provided

The cobas® Strep A assay Pack (Cat # 07341911190) contains sufficient reagents to process 20 specimens or quality control samples. The pack contains 20 sets of a cobas® Strep A assay tube and a transfer pipette. A Package Insert Barcode Card (Cat # 07997060001) with a lot-specific barcode is also included.

Equipment

cobas® Liat® Analyzer, Cat # 07341920190

Materials Available but Not Provided

- Liquid Amies Swab Collection Kits, each kit containing:
    - Liquid Amies Medium, 1 mL
    - Collection Swab

Acceptable collection kits include Copan ESwab™ Collection Kit, Becton Dickinson Liquid Amies Elution Swab (ESwab) Collection and Transport System (BD Cat # 220245, Copan Cat # 480C), or equivalent.

- cobas® Strep A Quality Control Kit, Cat # 07402678190, containing:
    - cobas® Strep A Positive Control (Positive Control), Cat # 07758502001
    - cobas® Strep A Dilution Amies (Dilution Amies), Cat # 07763808001
    - Transfer Pipette
    - Control Kit Barcode Card, Cat # 07945272001
        - Negative Control Barcode Label, Cat # 07945264001
        - Positive Control Barcode Label, Cat # 07945256001

5. Storage and Handling

• Store the cobas® Strep A Tube at 2 – 8ºC.
• Do not use kits or reagents beyond their expiration dates.
• Do not open individual tube packaging until you are ready to perform testing.

6. Warnings and Precautions

• Treat all biological specimens, including used cobas® Strep A tubes and pipettes, as if capable of transmitting infectious agents. Because it is often impossible to know which specimens might be infectious, all biological specimens should be treated with universal precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention and the Clinical and Laboratory Standards Institute.
• Follow your institution's safety procedures for working with chemicals and handling biological samples.
• Do not use a damaged cobas® Strep A tube. Do not use a cobas® Strep A Tube that has been dropped after removal from its foil pouch.
• Do not open individual tube packaging until you are ready to perform testing.
• Each single-use cobas® Strep A tube is used to process one test. Do not reuse a spent cobas® Strep A tube. If a cobas® Strep A tube is not housed in a sleeve, or if the Tube sample compartment already contains a liquid, this Tube has been spent; do NOT use such Tubes.
• Do not puncture the cobas® Strep A tube or the seal at the bottom of the sample compartment. If either is damaged while adding the sample, discard both the cobas® Strep A tube and the transfer pipette and repeat the test with a new transfer pipette and cobas® Strep A tube.
• Do not open the cap of the cobas® Strep A tube during or after the run on the Analyzer.
• Dispose of a used cobas® Strep A tube, pipette and specimen tubes according to your institution's safety guidelines for hazardous material.
• Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
• Due to the high sensitivity of the assays run on the Analyzer, contamination of the work area with previous positive samples may cause false positive results. Handle samples according to standard laboratory practices. Clean instruments and surrounding surfaces according to instructions provided in the cleaning section of the instrument User Manual using 5-10% bleach solution followed by isopropanol.
• Sample collection should be performed by specifically trained personnel using the recommended swabs. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
• Use only the transfer pipettes contained in the cobas® Strep A assay Kit and cobas® Strep A Quality

Control Kit. Use of alternative transfer pipettes may lead to invalid results.

7. Specimen Collection, Handling, and Storage

A. Throat Swab Collection

Materials: Liquid Amies Collection and Transport System, containing a sterile swab and a tube filled with 1 mL of Amies liquid transport medium. Do NOT use cotton or calcium alginate swabs, or swabs with wood shafts. After sample collection, place the swab into 1 mL of Amies transport medium.

Procedure:

1. Place the patient in a seated position facing the light.
2. Remove the swab from the protective packaging.
3. Instruct patient to open mouth as wide as possible. If needed, use tongue depressor to press the tongue downward to the floor of the mouth so that the throat can be seen.
4. Rub the swab tip up and down the back of the throat, the tonsils, and against any white patches in the tonsillar area. Remove swab from mouth.

Note: Do NOT touch the tongue, cheeks, teeth, or gums with the swab.

5. Insert the swab into the Amies transport media tube. Swirl the swab against the inside wall of the tube 3 times. Break the swab shaft and leave the swab in the tube. Attach the cap securely.

B. Specimen Handling & Storage

Specimens should be tested immediately after collection. Specimens not tested immediately may be refrigerated (2-8°C, preferred) or stored at room temperature (20-25°C) for up to 48 hours.

Specimens should be transported at 2-8°C. Ensure that all applicable regulations for the transport of biological agents are met.

8. Assay Procedure

Note:

• Consult the System User Manual on the detailed operations of the cobas® Liat® System.

• To avoid error and sample cross contamination, change gloves between samples and work on one sample at a time. DO NOT add multiple samples into multiple cobas® Strep A tubes at the same time.

A. Add cobas® Strep A Tube Lot

Before using a new lot of cobas® Strep A tubes, the Add Lot procedure must be performed on the Analyzer to validate the cobas® Strep A tube lot at your site. The procedure comprises running a negative and a positive control sample.

The Analyzer will prompt you to add the lot if you try to run an assay from a new un-validated lot. You can also compare the lot number on the cobas® Strep A tube against the list of validated tube lots in step 1 below to check if the lot was previously added.

Helpful Hint: 4 barcodes are needed for this procedure. Make sure to scan the right barcode when prompted by the Analyzer.

• Package Insert Barcode: on the Package Insert Barcode Card contained in this cobas® Strep A assay

Tube Pack. This barcode is lot-specific; match the lot number next to the barcode with the lot number on the cobas® Strep A tubes.
• cobas® Strep A tube barcode: on the cobas® Strep A assay tube sleeve.
• Negative Control Barcode: on the Control Kit Barcode Card contained in the QC Kit. Match the lot number next to the barcode with the lot number on the Dilution Amies tube.
• Positive Control Barcode: on the Control Kit Barcode Card contained in the QC Kit. Match the lot number next to the barcode with the lot number on the Positive Control tube.

Materials:
• From cobas® Strep A assay Tube Pack:

- ? Package Insert Barcode Card
- ? 2 cobas® Strep A tubes

• From the cobas® Strep A Quality Control (QC) Kit:

- ? Negative Control: Negative Control Barcode, (see Control Kit Barcode Card), 1 Dilution Amies tube (used as the negative control sample)
- ? Positive Control: Positive Control Barcode, (see Control Kit Barcode Card), 1 Positive Control tube, 1 Dilution Amies tube (used to mix with the positive control), 1 transfer pipette

Procedure:

1. Prepare and test Negative Control sample

a. Obtain:

- ? Package Insert Barcode on the Package Insert Barcode Card contained in cobas® Strep A assay Tube Pack?
    - Negative Control Barcode on the Control Kit Barcode Card
    - ? 1 Dilution Amies tube (used as the negative control sample)
    - ? 1 cobas® Strep A tube from this lot

b. Select Assay Menu on the main menu of an Analyzer.
c. Select New Lot at the bottom of the list.
d. Select Scan and scan the Package Insert Barcode on the Package Insert Barcode Card from the cobas® Strep A assay Tube Pack.
e. Select Scan and scan the Negative Control Barcode on the Control Kit Barcode Card. The Analyzer will prompt “Add Negative Control & scan Liat® Tube ID.”
f. Take a Dilution Amies tube from the QC Kit; this is used as the negative control sample. Hold the Dilution Amies tube by the tube cap and shake down the liquid in the tube using a quick, sharp, downward wrist motion. Visually check that the Dilution Amies has pooled at the bottom of the tube. If not, repeat the shake down procedure.
g. Using the Dilution Amies as sample, run the assay following the Running cobas® Strep A assay procedure, step B.2.c-i (Add Sample) and B.3 (Insert cobas® Strep A tube).
h. If “Negative Control Result Accepted” is displayed at the end of the run, select OK. If the result is rejected, repeat the negative control run (step A.1). If repeated control runs do not produce the expected

results, contact your Roche Service Representative.
i. Select Back.

2. Prepare Positive Control sample

a. Take the following from the QC kit:.

- 1 transfer pipette
- ? 1 Positive Control tube, containing a pellet of dried chemically-inactivated Strep A at the bottom of the tube
- ? 1 Dilution Amies tube, containing a unit dose of Amies medium to be mixed with the positive control

b. Hold the Dilution Amies tube by the tube cap and shake down the liquid in the tube using a quick, sharp, downward wrist motion. Visually check that the liquid has pooled at the bottom of the tube. If not, repeat the shake down procedure.
c. Using a transfer pipette, transfer the liquid from the Dilution Amies tube into the Positive Control tube:

- Check that the Positive Control pellet is at the bottom of the tube prior to addition of the Dilution Amies. Do not use the Positive Control if a pellet is not visible prior to rehydration.
- Squeeze the bulb of pipette until the bulb is fully flat. While holding the bulb fully flat, insert the pipette tip into the liquid just below the liquid surface in the Dilution Amies tube.
- Slowly release the bulb completely while keeping the pipette tip below the liquid surface. You will see the liquid Amies medium rising into the pipette. After releasing the bulb completely, withdraw the pipette from the Dilution Amies tube. It is normal for a small volume of liquid to remain in the Dilution Amies tube after the pipette bulb is fully released.
- Insert pipette into the Positive Control tube until the pipette tip is at the bottom of the tube.
- Slowly squeeze the bulb to empty the contents of pipette. Do not release the pipette bulb.
- While still squeezing the pipette bulb, withdraw the pipette from the tube. Dispose of the transfer pipette according to your institution’s guidelines for safe disposal of hazardous material. Do not reuse transfer pipettes.
- Cap the Positive Control tube. Hold the Positive Control tube by the cap and shake down the liquid in the tube using a quick, sharp, downward wrist motion.

d. Let the Positive Control tube sit for 5 minutes. During this time, the dried positive control material within the tube will begin to dissolve.
3. Test Positive Control sample
a. Obtain:

- ? Positive Control Barcode on the Control Kit Barcode Card
- ? 1 cobas® Strep A tube from this lot

b. On the Analyzer used for the Negative Control test, select Scan and scan the Positive Control Barcode on the Control Kit Barcode Card. The Analyzer will prompt “Add Positive Control & scan Liat® Tube ID”.
c. After the Positive Control tube from step A.2 has sat for 5 minutes, use the transfer pipette from the cobas® Strep A tube pouch to slowly pipette the sample up and down 10 times to dissolve and mix the

positive control sample.
d. Using the Positive Control as sample, run the assay following the Running cobas® Strep A assay procedure, step B.2.c-i (Add Sample) and B.3 (Insert cobas® Strep A tube).
e. If "Positive Control Result Accepted. Lot … added" is displayed at the end of the run, select OK to return to the assay menu. If the result is rejected, repeat the positive control run (steps A.2 and A.3). If repeated control runs do not produce the expected results, contact your Roche Service Representative.

B. Running cobas® Strep A assay

The recommended environmental operating conditions for the cobas® Strep A assay are 15-32°C, 15-80% relative humidity, and ≤2,000m (6,500 feet) above sea level.

Materials:

cobas® Strep A tube from a lot that has been added to the Analyzer. See section A for Add cobas® Strep A Tube Lot instructions.

Procedure:

1. Scan Barcode

Tear open the foil packaging of the cobas® Strep A tube and remove the tube and the transfer pipette.
a. Select Run Assay on the main menu using the touch screen or function button.
b. Select Scan and scan the cobas® Strep A tube barcode on the tube sleeve by placing the tube on the table and sliding the tube towards the Analyzer until the red scan light is over the entire barcode.
c. Select Scan again and scan the Patient or Sample barcode, or select Enter and type in a Sample or Patient ID. The Analyzer will prompt "Add throat swab sample & re-scan tube ID."

2. Add Sample

Use the transfer pipette to load ~200 µL of sample into the cobas® Strep A tube. You do not need to measure the sample volume; the Analyzer will adjust the sample volume if more sample was loaded, or output an error if not enough sample was loaded.
a. Vigorously shake the throat swab sample tube for 5 seconds to evenly disperse the patient specimen in the liquid medium.
Note: Failure to disperse the patient specimen thoroughly by vigorous shaking could adversely affect test performance and lead to the generation of false negative results.
b. Unscrew the sample tube cap. Lift the cap and any attached swab to allow a pipette to be inserted into the sample tube. Avoid lifting the swab completely out of the sample tube.
c. Obtain the transfer pipette from the cobas® Liat® tube pouch. Firmly squeeze the bulb of the pipette until the bulb is fully flat.
d. While holding the pipette bulb fully flat, insert the pipette tip into the sample just below the liquid surface.
e. Slowly release the bulb while keeping the pipette tip below the liquid surface. This will draw up ~200 µL of sample into the pipette. After releasing the bulb completely, withdraw the pipette from the sample.
f. Unscrew the cap from the cobas® Strep A tube.
g. While watching through the viewing window in the sleeve, carefully insert the pipette into the cobas®

Strep A tube. Place the pipette tip near the bottom of the sample compartment. Do not puncture the tube or the seal at the bottom.
Note: If you do puncture the seal at the bottom of the sample compartment, discard both the cobas® Strep A tube and the transfer pipette according to your institution's guidelines for safe disposal of hazardous material and repeat the test staring at Step 2.b. with a new transfer pipette and cobas® Strep A tube.
h. Slowly squeeze the bulb to empty the contents of the pipette into the cobas® Strep A tube. Do not release the pipette bulb.
i. While still squeezing the pipette bulb, withdraw the pipette from the tube. Screw the cap back on the cobas® Strep A tube. Dispose of the transfer pipette according to your institution's guidelines for safe disposal of hazardous material. Do not reuse transfer pipettes.
Note: Start the cobas® Liat® assay run on the Analyzer as soon as possible, but no later than 4 hours after adding the sample to the cobas® Strep A tube.

3. Insert cobas® Strep A tube

a. Select Scan and re-scan the cobas® Strep A tube barcode. The tube entry door on top of the Analyzer will open automatically.
b. Remove the cobas® Strep A Tube sleeve.
c. Immediately insert the cobas® Strep A tube into the Analyzer until the tube clicks into place. The cobas® Strep A tube only fits in one way. If the tube is not inserted by the time the door closes, re-scan the cobas® Strep A tube barcode (step 3a) and insert the cobas® Strep A tube again. Once the cobas® Strep A tube is properly inserted, the Analyzer will close the door automatically and begin the test.
4. View Result
During the test, the Analyzer displays the running status and estimated time remaining. Once the test is complete, the Analyzer displays the message, "Please remove the tube slowly…" and opens the tube entry door automatically.
a. Lift the cobas® Strep A tube out of the Analyzer.
b. Select Report to see the Result Report.
c. Select Print to print the report (if applicable).
Select Back, and then Main to return to the main menu for the next test.

C. Viewing and Interpreting Results

The Analyzer reports results as Strep A "Detected", "Not Detected", "Indeterminate", or "Assay Invalid".

The manual data interpretation and reviewing PCR curves that you may be familiar with from other systems is no longer required. The Analyzer automatically interprets the results from measured fluorescent signals. Embedded calculation algorithms determine the PCR cycle threshold (Ct) and evaluate the Ct and fluorescence endpoint against the valid range to generate a positive or negative PCR result.

Additionally, pattern recognition algorithms inspect the PCR curves to determine if the curve pattern is within specification or abnormal. If Strep A is detected but its PCR curve is determined to be abnormal, the result is called "Strep A Indeterminate. Repeat Assay."

Like the Strep A target, the IPC target is also evaluated in every assay run. In the case that Strep A target is not detected, the IPC target must be detected for the result to be called “Not Detected”; if the IPC is also not detected or if the IPC PCR curve is abnormal, the result is called “Assay Invalid. Repeat Assay.” In some cases, high concentration of Strep A may inhibit the amplification of IPC; as such, IPC is not taken into consideration when Strep A is detected.

The table below shows the “Report Results” and the corresponding interpretation.

Interpretation of Results:

Interpretation of Results

Report Results	Interpretation
Strep A Not Detected	Negative test for Strep A (no Strep A DNA detected)
Strep A Detected	Positive for Strep A (Strep A DNA present)
Strep A Indeterminate. Repeat Assay.	Presence or absence of Strep A cannot be determined. Repeat assay with same sample or, if possible, new sample.
Assay Invalid. Repeat Assay.	Presence or absence of Strep A cannot be determined. Repeat assay with same sample or, if possible, new sample.
[Error] Assay Aborted	Presence or absence of Strep A cannot be determined. Repeat assay with same sample or, if possible, new sample.

D. Reasons to Repeat the Assay

If the test result is “Indeterminate” or “Invalid”, repeat the assay with the same patient specimen, or if possible, collect a new specimen from the patient and repeat the assay using the new specimen. Specimens that have repeat “Indeterminate” or “Invalid” results should be sent to a laboratory for confirmatory testing by an alternative method.

If an “Error” is reported by the Analyzer and/or the assay is aborted, repeat the test with the same patient specimen, or if possible, collect a new specimen from the patient and repeat the assay using the new specimen. Contact your Roche Service Representative if repeat “Errors” are reported.

E. Quality Control

Internal Process Control (IPC): is a chemically-inactivated bacterium that is included in each cobas® Strep A tube to verify adequate processing of the Strep A. The IPC verifies that sample purification of Strep A has occurred and verifies that the specimen processing is adequate. Additionally, this control detects potential specimen-associated inhibition in the sample preparation or the PCR. The IPC should be positive in a negative sample and can be negative or positive in a Strep A positive sample. The IPC is valid if it meets the acceptance criteria.

External Controls: provide additional quality control to demonstrate positive or negative assay results

using the System and cobas® Strep A tube. External Controls are run during the Add cobas® Strep A tube Lot procedure (section A). Additional External Controls should be tested in accordance with local, state, federal and/or accrediting organization requirements as applicable. If testing either the Positive or Negative Control does not produce the expected results, repeat the affected control run with a fresh External Control. If repeated control runs do not produce the expected results, do not test patient specimens and contact your Roche Service Representative.

Negative Control

Materials:

- ? 1 cobas® Strep A tube
- ? From QC Kit: 1 Dilution Amies tube (used as the negative control sample), and Negative Control Barcode on the Control Kit Barcode Card

Procedure:

The Dilution Amies is used as the sample for the Negative Control run.
1. Take a Dilution Amies tube from the QC Kit.
2. Hold the Dilution Amies tube by the tube cap and shake down the liquid in the tube using a quick, sharp, downward wrist motion (as if shaking down a mercury thermometer). Visually check that the Dilution Amies has pooled at the bottom of the tube. If not, repeat the shake down procedure.
3. Using the Dilution Amies as sample, run the assay following the Running cobas® Strep A tube assay procedure (section B, skip step B.2.a-b). Scan the Negative Control Barcode on the Control Kit Barcode Card as the Sample ID.
4. View the Results Report by touching or clicking Report after the completion of the assay. The Report Result must be “Strep A Not Detected” for the negative control to pass.

Positive Control

Materials:

- ? 1 cobas® Strep A tube
- ? From QC Kit: 1 Positive Control tube, 1 Dilution Amies tube, 1 transfer pipette, and Positive Control Barcode on the Control Kit Barcode Card

Procedure:

The Positive Control is a unit-dose of dried chemically-inactivated Strep A. Follow the directions below to dissolve the positive control in Dilution Amies and run it on the cobas® Strep A assay.
1. Follow step A.2. of the Add cobas® Strep A Tube Lot procedure to prepare the Positive Control sample.
2. After the Positive Control tube from step A.2 has sat for 5 minutes, use a transfer pipette from the cobas® Strep A tube package to slowly pipette the sample up and down 10 times to dissolve and mix the positive control sample.
3. Using the Positive Control as sample, run the assay following the Running cobas® Strep A assay procedure (section B, skip step B.2.a-b). Scan the Positive Control Barcode on the Control Kit Barcode Card as the Sample ID.

4. View the Results Report by touching or clicking Report after the completion of the assay. The Report Result must be “Strep A Detected” for the positive control to pass.

9. Limitations

• The performance of the cobas® Strep A assay was evaluated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the test.

• As with other tests, negative results do not preclude Strep A infection and should not be used as the sole basis for treatment or other patient management decisions. Results from the cobas® Strep A assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician.

• Additional follow-up testing by culture may be required if the cobas® Strep A assay result is negative and clinical symptoms persist, or in the event of an outbreak of acute rheumatic fever (ARF).

• Analyte targets (bacterial nucleic acid) may persist in vivo, independent of pathogen viability. Detection of analyte target does not imply that the corresponding pathogen is infectious, or is the causative agent for clinical symptoms.

• False negative results may occur if a specimen is improperly collected, transported or handled; or if inadequate numbers of organisms are present in the specimen.

• This test has not been evaluated for patients without signs and symptoms of Strep A infection.

• This test is a qualitative test and does not provide the quantitative value of detected organism present.

• Cross-reactivity with organisms other than those tested can lead to erroneous results.

• This test cannot rule out diseases caused by other bacterial or viral pathogens besides Group A Strep.

• Good laboratory practices and changing gloves between handling patient specimens are recommended to avoid contamination of specimens or reagents.

10. Expected Values

Strep A Not Detected: Negative test for strep (No Step A DNA detected) is expected.

See Package Insert for results of manufacturer clinical studies.

11. Performance Characteristics

A. Clinical Performance: See Package Insert

B. Reproducibility: See Package Insert

C. Limit of Detection

The Limit of Detection (LOD) of the cobas® Strep A assay was determined by limiting dilution studies using titered bacteria of 4 Strep A strains. The bacteria were spiked into throat swab sample matrix, and then tested using the cobas® Strep A assay. The LOD was determined as the lowest bacterial concentration that was detected ≥95% of the time (i.e. at least 19 out of 20 replicates tested positive).

The cobas® Strep A assay detected all strains tested, with an LOD in the range of 5 - 20 CFU/mL, or 1 - 4 CFU/test.

D. Analytical Reactivity

A Reactivity Study was performed to evaluate the ability of the cobas® Strep A assay to detect Strep A strains representing temporal and geographical diversity. In addition to those strains tested in LOD study, the cobas® Strep A assay was evaluated for reactivity with 5 Strep A strains at 20 - 80 CFU/mL, or 4 - 16 CFU/test. The bacteria were spiked into throat swab sample matrix, and then tested using the cobas® Strep A assay. The assay detected all strains tested.

E. Cross Reactivity

A Cross-reactivity Study was performed to evaluate the potential of the cobas® Strep A assay to cross-react with other microorganisms that may be present in throat swab samples. The cobas® Strep A assay was evaluated against a panel of 72 microorganisms. Bacteria were tested at ≥106 CFU/mL. Viruses were tested at ≥105 TCID50/mL or the highest available concentration. The cobas® Strep A assay showed no cross reactivity with the tested microorganisms.

See Package Insert for a complete list.

F. Interfering Microorganisms

An Interfering Microorganism Study was performed to evaluate whether other microorganisms that may be present in throat swab samples can interfere with the detection of Strep A by the cobas® Strep A assay. The 72 microorganisms were tested for potential interference on Strep A detection. Bacteria were tested at ≥106 CFU/mL, and viruses were tested at ≥105 TCID50/mL, or the highest available concentration, in the presence of Strep A at 3x LOD concentration in throat swab matrix. Results show that the presence of the tested microorganisms did not interfere with the detection of Strep A.

See Package Insert for a complete list.

G. Interfering Substances

The cobas® Strep A assay was evaluated with 28 substances that may be encountered in throat swab specimens. Medically and/or physiologically relevant concentrations of potential interferents were tested in throat swab matrix in the presence and absence of Strep A at 3x LOD. Results showed that none of the substances tested interfered with the cobas® Strep A assay.

See Package Insert for a complete list.

12. Manufacturer

Technical Support

If you have any questions or problems, please contact your Roche Service representative. Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (phone: 1-800-FDA-1088; fax: 1-800-FDA-0178; http://www.fda.gov/ medwatch).

13. References

1. JF Cohen, et. al. Rapid antigen detection test for group A streptococcus in children with pharyngitis. Cochrane Database Syst Rev. 2016 Jul 4.

Attachments

cobas-Strep-A-Package-Insert.pdf

Approval Signatures

Step Description	Approver	Date
Admin Approval	Tammy Battaglia: Physician	6/5/2023
Admin Approval	Drew Talbott: President	5/16/2023
Department Leadership	Lori Billesbach: Mgr-Lab	5/15/2023
	Rhonda Troglia: Lead-Med Lab Scientist (MLS)	5/15/2023