GeneXpert®
Powered By CEPHEID INNOVATION

Xpert® Xpress Strep A

REF **XPRSTREPA-10**

REF **XPRSTREPA-120**

Instructions for Use
CLIA Complexity: Moderate
IVD

Cepheid®

In Vitro Diagnostic Medical Device

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See Section 26, Revision History for a description of changes.

Xpert® Xpress Strep A

For *In Vitro* Diagnostic Use

℞only

1 Proprietary Name

Xpert® Xpress Strep A

2 Common or Usual Name

Xpert Xpress Strep A

3 Intended Use

The Xpert Xpress Strep A test, performed on the GeneXpert® Instrument Systems, is a rapid, 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 Xpert Xpress Strep A test can be used as an aid in the diagnosis of Group A Streptococcal pharyngitis. The test is not intended to monitor treatment for Group A *Streptococcus* infections.

The Xpert Xpress Strep A test utilizes an automated real-time polymerase chain reaction (PCR) to detect *Streptococcus pyogenes* DNA.

4 Summary and Explanation

Group A streptococci are gram-positive, beta-hemolytic bacterial pathogens that commonly cause infections in the throat (pharyngitis or "strep throat") or on skin (cellulitis and impetigo), and can cause a wide range of other infections (e.g., sepsis, pneumonia, and meningitis). Pharyngitis may also be caused by other bacteria including *Neisseria gonorrhoeae* and *Corynebacterium diphtheriae*, for which specific culture methods are required. If left untreated, mild infections can lead to more serious infections. The most severe but least common forms of invasive Group A streptococcal disease are necrotizing fasciitis and streptococcal toxic shock syndrome (STSS). Approximately 9,000 to 11,500 cases of invasive Group A streptococcal (GAS) disease occur annually in the United States, resulting in 1,000 to 1,800 deaths, although several million cases of strep throat and impetigo occur each year.[1] Treating an infected person with an appropriate antibiotic generally prevents the spread of the infection and reduces the risk of post-infectious complications, such as rheumatic fever and acute glomerular nephritis.[2]

The Xpert Xpress Strep A test is a rapid PCR test for the qualitative detection of Group A streptococci from throat swab specimens without the need for culture confirmation of negative Xpert Xpress Strep A results. For negative samples, the time to result is 24 minutes. For positive samples, the time to result can be as early as 18 minutes.

5 Principle of the Procedure

The test is performed on the Cepheid GeneXpert Instrument Systems. With this platform, the operator can run the test by performing three simple steps: 1) transfer liquid sample to the cartridge with a transfer pipette, 2) run the test on the GeneXpert instrument, and 3) read the results. The GeneXpert automates and integrates sample preparation, nucleic acid extraction, amplification, and detection of the target sequences in clinical specimens by using real-time PCR. The system consists of a GeneXpert instrument, computer, and disposable fluidic cartridges that are designed to complete sample

preparation and real-time PCR. The system requires the use of single-use disposable GeneXpert cartridges that hold the PCR reagents and host the PCR processes. Because the cartridges are self-contained, the risk of cross-contamination between samples is minimized.

The Xpert Xpress Strep A test includes reagents for the detection of Group A streptococcal bacterial DNA from throat swab specimens obtained from patients with signs and symptoms of pharyngitis. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge. The SPC is present to control for an adequate amplification process and to monitor for the presence of inhibitors in the PCR reaction. The PCC verifies reagent rehydration, PCR tube filling, and all reaction components, including probes and dyes, are present and functional in the cartridge.

An Early Assay Termination function provides positive results if the signal from the target DNA reaches a predetermined threshold before the full 43 PCR cycles have been completed. When the Strep A target level is high enough to generate very early Cts (≤ 30 Cts), the SPC amplification curve will be not seen and its results will not be reported as the SPC Ct may not reach the expected cycle threshold in high Strep A titer specimens.

6 Reagents and Instruments

6.1 Materials Provided

The Xpert Xpress Strep A kit (XPRSTREPA-10) contains sufficient reagents to process 10 specimens or quality control samples and the Xpert Xpress Strep A kit (XPRSTREPA-120) contains sufficient reagents to process 120 specimens or quality control samples.

Each kit contains the following:

Xpert Xpress Strep A Cartridges with Integrated Reaction Tubes	**10 per kit**	**120 per kit**
Bead 1, Bead 2, Bead 3 (freeze-dried)	1 of each per cartridge	1 of each per cartridge
Lysis Reagent (Guanidinium Thiocyanate)	1.5 mL per cartridge	1.5 mL per cartridge
Sodium Hydroxide	1.5 mL per cartridge	1.5 mL per cartridge
Elution Reagent	2.0 mL per cartridge	2.0 mL per cartridge
Disposable Transfer Pipettes	**12 per kit**	**144 per kit**
Instructions for Use (Package Insert) (For use with the GeneXpert Xpress System only)	**1 per kit**	**1 per kit**
Quick Reference Instructions (For use with the GeneXpert Xpress System only)	**2 per kit**	**2 per kit**
CD • Assay Definition File (ADF) • Instructions to import ADF into GeneXpert software • Instructions for Use (Package Insert) CLIA Complexity: Moderate (For use with the GeneXpert Dx and Infinity Systems only)	**1 per kit**	**1 per kit**

Note Safety Data Sheets (SDS) are available at www.cepheid.com or www.cepheidinternational.com under the **SUPPORT** tab.

Note The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and post-mortem testing. During processing, there was no mixing of the material with other animal materials.

7 Storage and Handling

- Store the Xpert Xpress Strep A cartridges at 2–28 °C until the expiration date provided on the label.
- Do not open the cartridge lid until you are ready to perform testing.
- Do not use cartridges that have passed the expiration date.
- Do not use a cartridge that is wet or has leaked.

8 Materials Required but Not Provided

- Copan Liquid Amies Elution Swab (ESwab™) Collection and Transport System. Any of the following ESwab collection kits may be used:
  - Copan 480C with 50 kits per shelf pack, white capture cap collection kit
  - Copan 480CE with 50 kits per shelf pack, pink capture cap collection kit
  - Copan catalog number 480CFA with 50 kits per shelf pack; purple non-capture cap collection kit
- GeneXpert Dx Instrument or GeneXpert Infinity Systems (catalog number varies by configuration): GeneXpert instrument, computer, barcode scanner, Operator Manual.
  - For GeneXpert Dx System: GeneXpert Dx software version 4.7b or higher
  - For GeneXpert Infinity-80 and Infinity-48s systems: Xpertise software version 6.4b or higher
- Printer: If a printer is required, contact Cepheid Customer Support to arrange for the purchase of a recommended printer.

9 Materials Available but Not Provided

- NATtrol™ Strep A negative control, ZeptoMetrix Corporation catalog number NATSDG-6MC (inactivated *Streptococcus dysgalactiae* cells)
- NATtrol Strep A positive control, ZeptoMetrix Corporation catalog number NATSPY-6MC (inactivated *Streptococcus pyogenes* cells)

10 Warnings and Precautions

10.1 General

- For *in vitro* diagnostic use.
- For prescription use only.
- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. All biological specimens should be handled using standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention[3] and the Clinical and Laboratory Standards Institute.[4]
- Follow safety procedures set by your institution for working with chemicals and handling biological samples.
- Performance characteristics of this test have been established with the specimen type listed in Section 3, Intended Use only. The performance of this test with other specimen types or samples has not been evaluated.
- Reliable results are dependent on adequate specimen collection, transport, storage and processing. Incorrect test results may occur from improper specimen collection, handling or storage, technical error, sample mix-up or because the number of organisms in the specimen is below the limit of detection of the test. Careful compliance with the IFU instructions and the *GeneXpert System Operator Manual* are necessary to avoid erroneous results.
- Performing the Xpert Xpress Strep A test outside the recommended storage temperature ranges and time may produce erroneous or invalid results.

10.2 Specimen

- For collection and transport of throat swab specimens, use the ESwab collection kit.
- Throat swab specimens must be collected and tested before the printed expiration date on the ESwab collection kit label.

- Maintain proper storage conditions during specimen transport to ensure the integrity of the specimen (see Section 12, Specimen Collection, Transport, and Storage). Specimen stability under shipping conditions other than those recommended has not been evaluated.
- Do not freeze ESwab specimens.
- Proper sample collection, storage, and transport are essential for correct results.

10.3 Test/Reagent

- Do not open the Xpert Xpress Strep A cartridge lid except when adding specimen.
- Do not use a cartridge that has been dropped after removing it from the packaging.
- Do not shake the cartridge. Shaking or dropping the cartridge after opening the cartridge lid may yield invalid results.
- Do not place the sample ID label on the cartridge lid or on the barcode label of the cartridge.
- Do not use a cartridge with a damaged barcode label.
- Do not use a cartridge that has a damaged reaction tube.
- It is recommended that the Xpert Xpress Strep A cartridges be at room temperature (20 – 30°C) when used for testing.
- Each single-use Xpert Xpress Strep A cartridge is used to process one test. Do not reuse processed cartridges.
- Each single-use disposable pipette is used to transfer one specimen. Do not reuse disposable pipettes.
- Do not use a cartridge if it appears wet or if the lid seal appears to have been broken.
- Wear clean lab coats and gloves. Change gloves between the handling of each specimen.
- In the event of contamination of the work area or equipment with samples or controls, thoroughly clean the contaminated area with a 1:10 dilution of household chlorine bleach and then repeat the cleaning of the work area with 70% denatured ethanol. Wipe work surfaces and allow to dry completely before proceeding.
- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific disposal. If country or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

11 Chemical Hazards[5,6]

Sodium Hydroxide

- Signal Word: WARNING 

Lysis Reagent

- Contains Guanidinium Thiocyanate
- Signal Word: WARNING 
- **UN GHS Hazard Statements:**
  - Harmful if swallowed.
  - Causes skin irritation.
  - Causes serious eye irritation.
- **UN GHS Precautionary Statements:**
- **Prevention**
  - Wash thoroughly after handling.
  - Wear protective gloves/protective clothing/eye protection/face protection.
- **Response**
  - IF ON SKIN: Wash with plenty of soap and water.
  - Specific treatment, see supplemental first aid information.
  - Take off contaminated clothing and wash before reuse.

- If skin irritation occurs: Get medical advice/attention.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- If eye irritation persists: Get medical advice/attention.

12 Specimen Collection, Transport, and Storage

Proper specimen collection, storage and transport are critical to ensure the integrity of the specimen and performance of the test. Inadequate specimen collection, improper specimen handling and/or transport may yield incorrect results. Follow your institution's guidelines for collecting swab specimens using a recommended collection and transport device (see Section 8, Materials Required but Not Provided) and/or follow the instructions below.

12.1 Swab Collection Procedure

1. Use the ESwab Collection and Transport System. Remove the swab from the wrapper.
2. Swab the posterior pharynx, tonsils, and other inflamed areas. Avoid touching the tongue, cheeks, and teeth with the swab when collecting specimens.
3. Uncap the ESwab transport tube.
4. Place the specimen containing swab into the ESwab transport tube and break the swab at the indicated score line.
5. Cap the ESwab transport tube.

Note Do not place multiple swabs in the same ESwab transport tube.

Note To reduce the potential for false negative results, do not collect throat swab specimens immediately after patients have used antiseptic mouthwash.

12.2 Specimen Transport and Storage

Specimen stability under shipping and storage conditions other than those listed in Table 1 have not been evaluated with the Xpert Xpress Strep A test.

Table 1. Specimen Transport and Storage Conditions

Specimen Collection Device	Specimen Transport and Storage Temperature (°C)	Specimen Storage Time
ESwab (Copan 480C or Copan 480CE or Copan 480CFA)	15-30 °C	Up to 48 hours
	2-8 °C	Up to 6 days

13 Procedure

Important **Start the test within 30 minutes of adding the sample to the cartridge.**

13.1 Preparing the Cartridge

To add the specimen to the GeneXpert cartridge:

1. Obtain the following items: Xpert Xpress Strep A cartridge, 300 µL transfer pipette (provided), and an appropriately collected and labeled test sample.
2. Inspect the test cartridge for damage. If damaged, do not use it.
3. Mix the patient specimen by vigorously shaking the specimen transport tube for 5 seconds.
4. Open the cartridge by lifting the cartridge lid.

5. Unscrew the specimen transport tube cap (do not remove the cap). Remove the transfer pipette from the wrapper by opening the end next to the bulb. Follow the steps below in Option 1 or Option 2 according to the transfer pipette type included in the kit.

Note Do not place unwrapped pipette on the workbench.

Pipette Option 1:

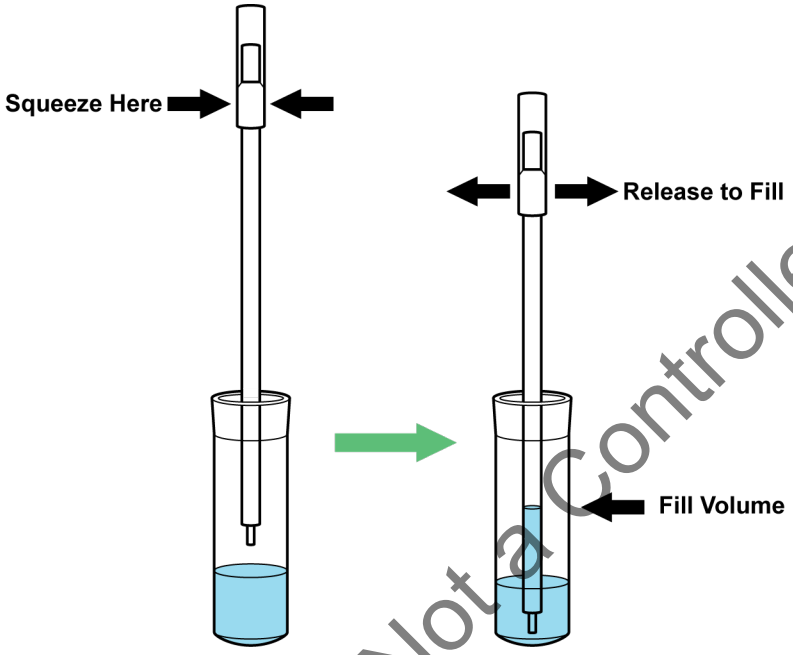

Figure 1. Transfer Pipette

1. Open the cap on the specimen transport tube. Squeeze the bulb of the transfer pipette **completely** and place the pipette tip in the ESwab transport medium tube containing the patient specimen (see Figure 1).

Note If using Copan collection kit 480C or 480CE, lift the cap with the attached swab from the transport tube (do not remove the swab completely from the transport tube).

2. Release the bulb of the pipette to fill the pipette with the patient specimen. Check that the pipette does not contain bubbles.
3. To transfer the patient specimen to the cartridge, squeeze the bulb of the transfer pipette completely again to empty the contents of the pipette into the large opening (Sample Chamber) in the cartridge shown in Figure 2.

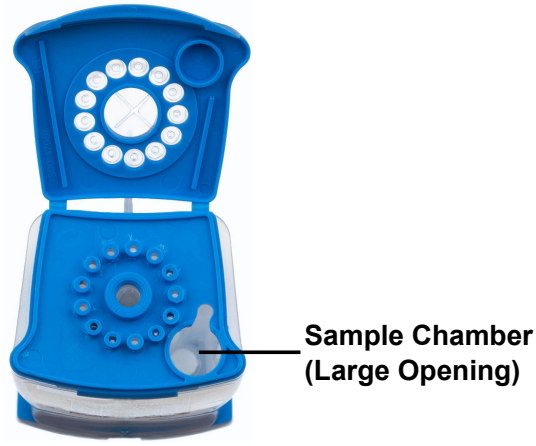

Figure 2. Cartridge (Top View)

Note Take care to dispense the **entire** volume of liquid into the sample chamber. False negative or **INVALID** results may occur if insufficient sample is added to the cartridge.

4. Close the cartridge lid.
5. Dispose of the used pipette in an appropriate waste container.

Pipette Option 2:

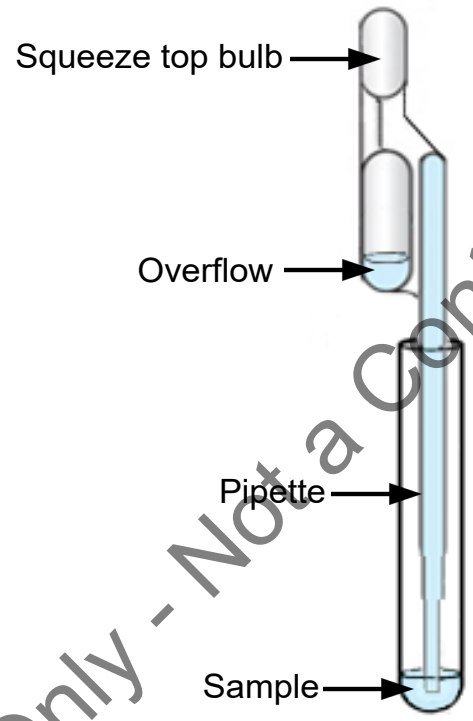

Figure 3. Transfer Pipette

1. Open the cap on the specimen transport tube. Squeeze the top bulb of the transfer pipette **completely** and place the pipette tip in the ESwab transport medium tube containing the patient specimen (see Figure 3).

Note If using Copan collection kit 480C or 480CE, lift the cap with the attached swab from the transport tube (do not remove the swab completely from the transport tube).

2. Release the bulb of the pipette to fill the pipette with the patient specimen. Check that the pipette does not contain bubbles.
3. To transfer the patient specimen to the cartridge, squeeze the top bulb of the transfer pipette completely again to empty the contents of the pipette into the large opening (Sample Chamber) in the cartridge shown in Figure 4. It is okay to have excess specimen left in the overflow reservoir of the pipette (Figure 3).

Figure 4. Cartridge (Top View)

Note Take care to dispense the **entire** volume of liquid into the sample chamber. False negative or **INVALID** results may occur if insufficient sample is added to the cartridge.

4. Close the cartridge lid.
5. Dispose of the used pipette in an appropriate waste container.

13.2 External Controls

External controls described in Section 9 are available but not provided and may be used in accordance with local, state, and federal accrediting organizations, as applicable.

To run a control using the Xpert Xpress Strep A test, perform the following steps:

1. Shake NATtrol sample vigorously for 5 seconds.
2. Open the cartridge lid. Using a clean 300 µL transfer pipette, transfer 300 µL (one draw) of the NATtrol sample to the sample chamber with large opening in the cartridge (Figure 2). Refer to the instructions for the pipette included in the kit.
3. Close cartridge lid.

13.3 Starting the Test

Important **Before you start the test, make sure that the system is running GeneXpert Dx software version 4.7b or higher or Infinity Xpertise software 6.4b or higher and that the Xpert Xpress Strep A Assay Definition File (ADF) is imported into the software. This section lists the default steps to operate the GeneXpert Dx System and GeneXpert Infinity System. For detailed instructions, see the *GeneXpert Dx System Operator Manual* or the *GeneXpert Infinity System Operator Manual*, depending on the model that is being used.**

Note The steps you follow may be different if the system administrator has changed the default workflow of the system.

1. Turn on the GeneXpert Instrument System:
   - GeneXpert Dx:

     If using the GeneXpert Dx instrument, first turn on the instrument and then turn on the computer. Log into the Windows operating system. The GeneXpert software may launch automatically or may require double-clicking the GeneXpert Dx software shortcut icon on the Windows® desktop.

     or
   - GeneXpert Infinity System:

     If using the GeneXpert Infinity instrument, power up the instrument by turning the power switch clockwise to the ON position. Wait 2 minutes for the system to boot. Log into the Windows operating system. On the Windows desktop, double-click the Xpertise Software shortcut icon to launch the software.
2. Log on to the System software. The login screen appears. Type your user name and password.
3. In the GeneXpert System window, click **Create Test** (GeneXpert Dx) or **Orders** followed by **Order Test** (Infinity).

4. Scan or type in the Patient ID (optional). If typing the Patient ID, make sure the Patient ID is typed correctly. The Patient ID is shown on the left side of the View Results window and is associated with the test result.
5. Scan or type in the Sample ID. If typing the Sample ID, make sure the Sample ID is typed correctly. The Sample ID is shown on the left side of the View Results window and is associated with the test result.
6. Scan the barcode on the Xpert Xpress Strep A cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Reagent Lot ID, Cartridge SN, Expiration Date, and Selected Assay.

Note If the barcode on the Xpert Xpress Strep A cartridge does not scan, then repeat the test with a new cartridge.

7. Click **Start Test** (GeneXpert Dx) or **Submit** (Infinity) if Auto-Submit is not enabled. In the dialog box that appears, type your password, if required.

   For the GeneXpert Dx Instrument:

   a. Locate the module with the blinking green light, open the instrument module door and load the cartridge.
   b. Close the door. The test starts and the green light stops blinking. When the test is finished, the light turns off and the door will unlock. Remove the cartridge.
   c. Dispose of used cartridges in the appropriate sample waste containers according to your institution's standard practices.

   or

   For the GeneXpert Infinity System:

   a. After clicking **Submit**, you will be asked to place the cartridge on the conveyor belt. After placing the cartridge, click OK to continue. The cartridge will be automatically loaded, the test will run and the used cartridge will be placed onto the waste shelf for disposal.
   b. When all samples are loaded, click on the **End Order Test** icon.

Note Do not turn off or unplug the instruments while a test is in progress. Turning off or unplugging the GeneXpert instrument or computer will stop the test.

Note Time to result is 24 minutes. A strongly positive sample will have a time to result as early as 18 minutes.

13.4 Data Management and Archiving Tasks

For instructions on performing Database Management or archiving tasks, see the appropriate GeneXpert Instrument Systems operator manual, depending on the instrument model that is being used.

14 Viewing and Printing Results

For detailed instructions on how to view and print the results, see the appropriate GeneXpert Instrument Systems operator manual.

15 Quality Control

Each cartridge includes a Sample Processing Control (SPC) and Probe Check Control (PCC).

- **Sample Processing Control (SPC):** Ensures the sample was processed correctly. The SPC verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR test, ensures the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the assigned acceptance criteria.
- **Probe Check Control (PCC):** Before the start of the PCR reaction, the GeneXpert Instrument measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. The PCC passes if it meets the assigned acceptance criteria.
- **External Controls:** External controls may be used in accordance with local, state, federal accrediting organizations, as applicable.

16 Interpretation of Results

The results are interpreted automatically by the GeneXpert Instrument Systems and are shown in the View Results window. The possible results and interpretations are shown in Table 2.

Table 2. Xpert Xpress Strep A Results and Interpretations

Result	Interpretation
Strep A NOT DETECTED See Figure 5	Strep A target DNA is not detected. ● SPC: PASS; SPC has a Ct within the valid range and endpoint above the threshold setting. ● PCC: PASS; all probe check results pass.
Strep A DETECTED See Figure 6 and Figure 7	Strep A target DNA is detected. ● Strep A: Ct is within the valid range. ● SPC: NA (not applicable); SPC signal is not part of the result interpretation algorithm if Strep A is detected since SPC signal may be suppressed due to competition with Strep A. ● PCC: PASS; all probe check results pass.
INVALID See Figure 8.	Presence or absence of the target DNA cannot be determined. ● Strep A: INVALID ● SPC: does not meet acceptance criteria. ● PCC: PASS; all probe check results pass. Repeat test according to the instructions in Section 17.2, Retest Procedure below.
ERROR See Figure 9.	Presence or absence of Strep target DNA cannot be determined. ● Strep A: NO RESULT ● SPC: NO RESULT ● PCC: FAIL*; all or one of the probe check results fail. *If the probe check passed or shows NA, the error is caused by the maximum pressure limit exceeding the acceptable range or by a system component failure. Repeat test according to the instructions in Section 17.2, Retest Procedure below.
NO RESULT See Figure 10.	Presence or absence of Strep A target DNA cannot be determined. A NO RESULT indicates that insufficient data were collected. For example, cartridge integrity test failed, the operator stopped a test that was in progress or a power failure occurred. ● Strep A: NO RESULT ● SPC: NO RESULT ● PCC: NA (not applicable)* * If the probe check shows NA, the error caused by the maximum pressure limit exceeding the acceptable range terminates the run prior to probe check. Repeat test according to the instructions in Section 17.2, Retest Procedure below.

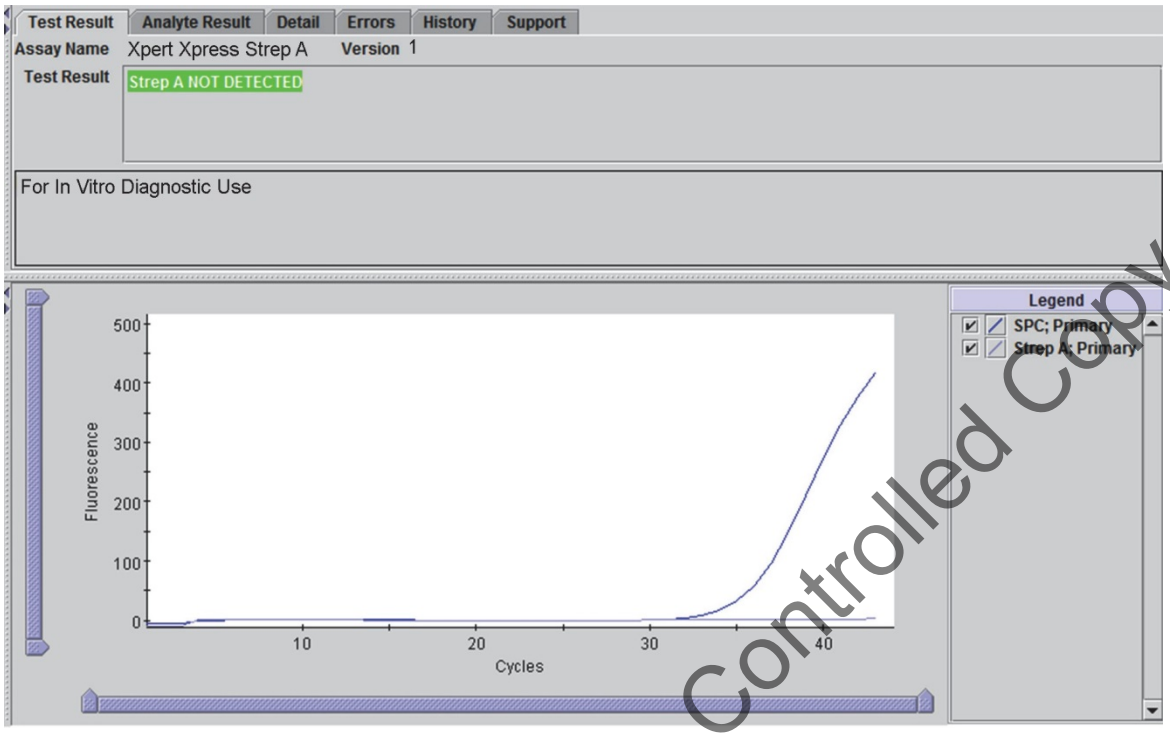

Figure 5. Example of Strep A Negative Strep A NOT DETECTED Test Result

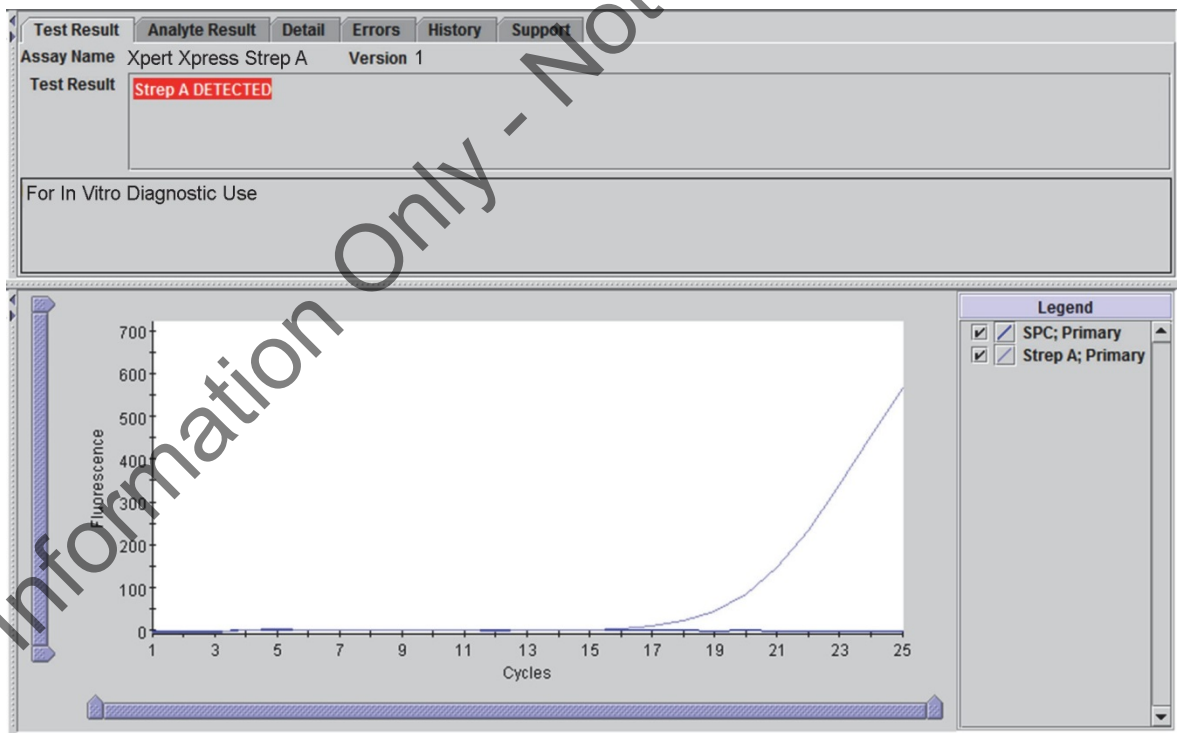

Figure 6. Example of Strep A Positive Strep A DETECTED Test Result (Early Assay Termination)

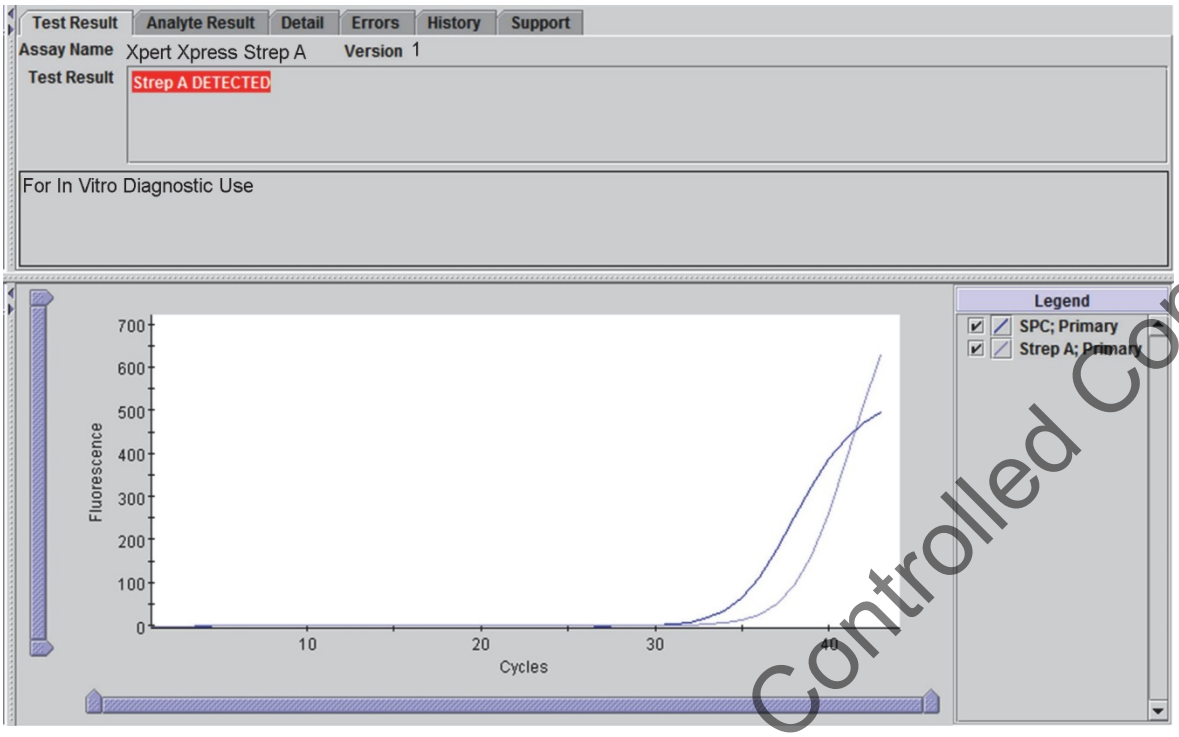

Figure 7. Example of Strep A Positive Strep A DETECTED Test Result

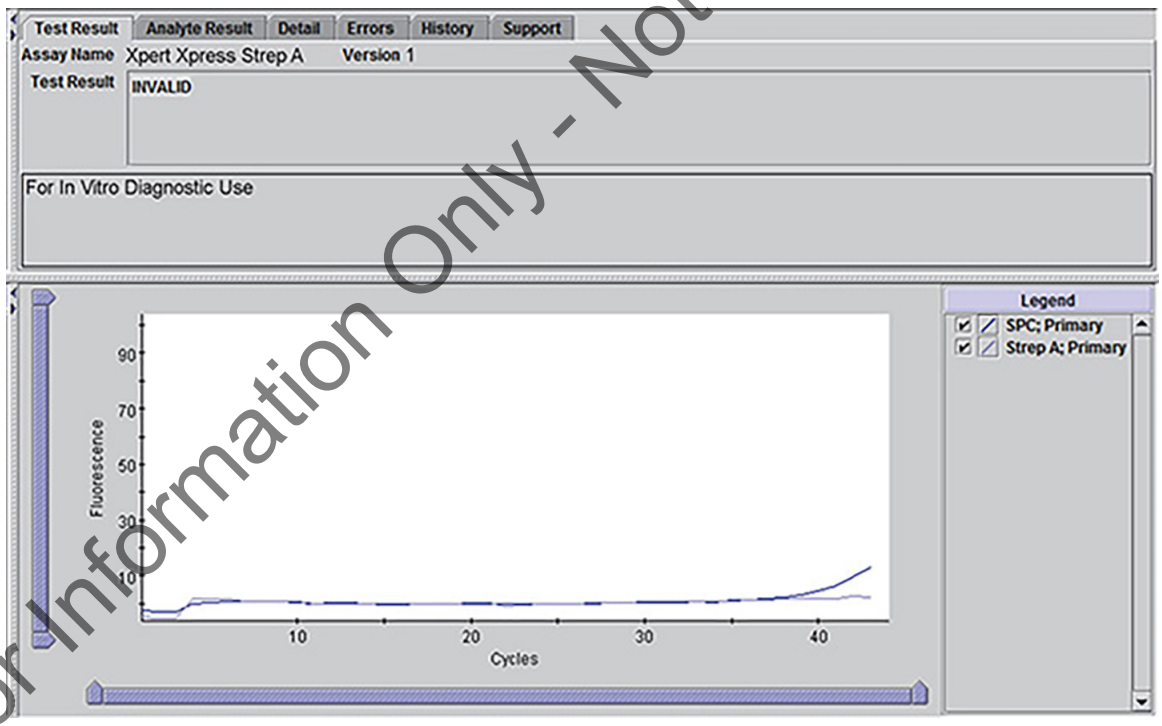

Figure 8. Example of INVALID Test Result

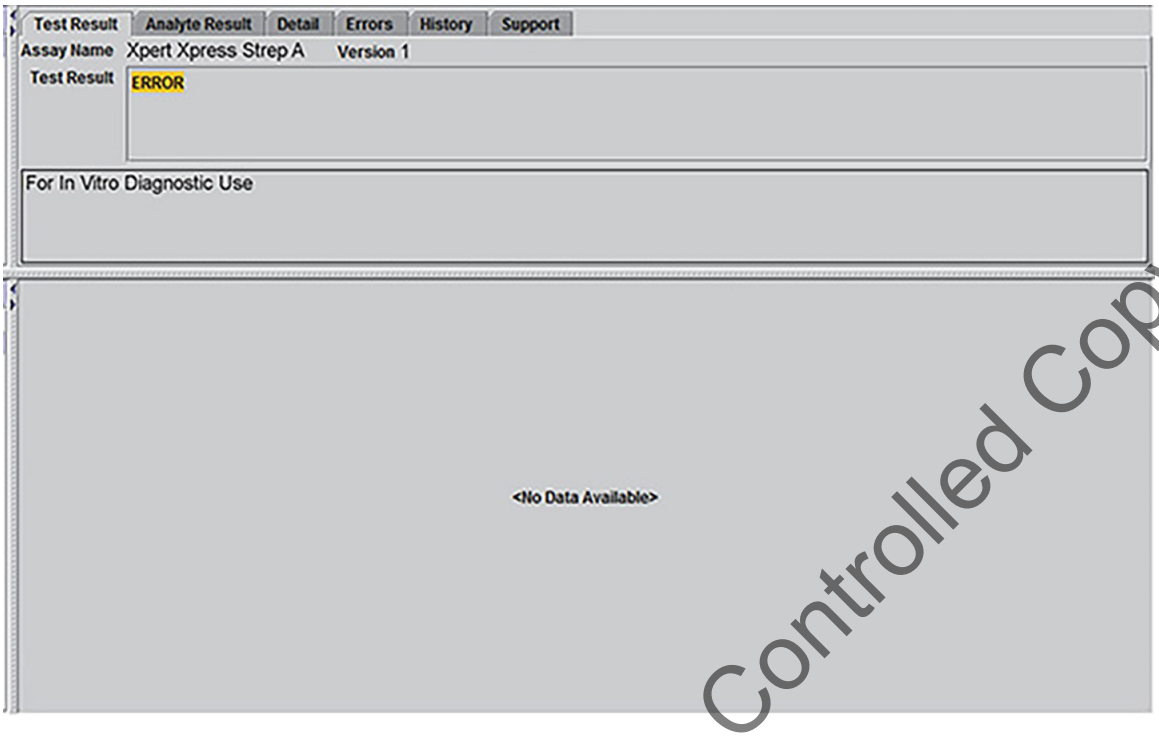

Figure 9. Example of ERROR Test Result

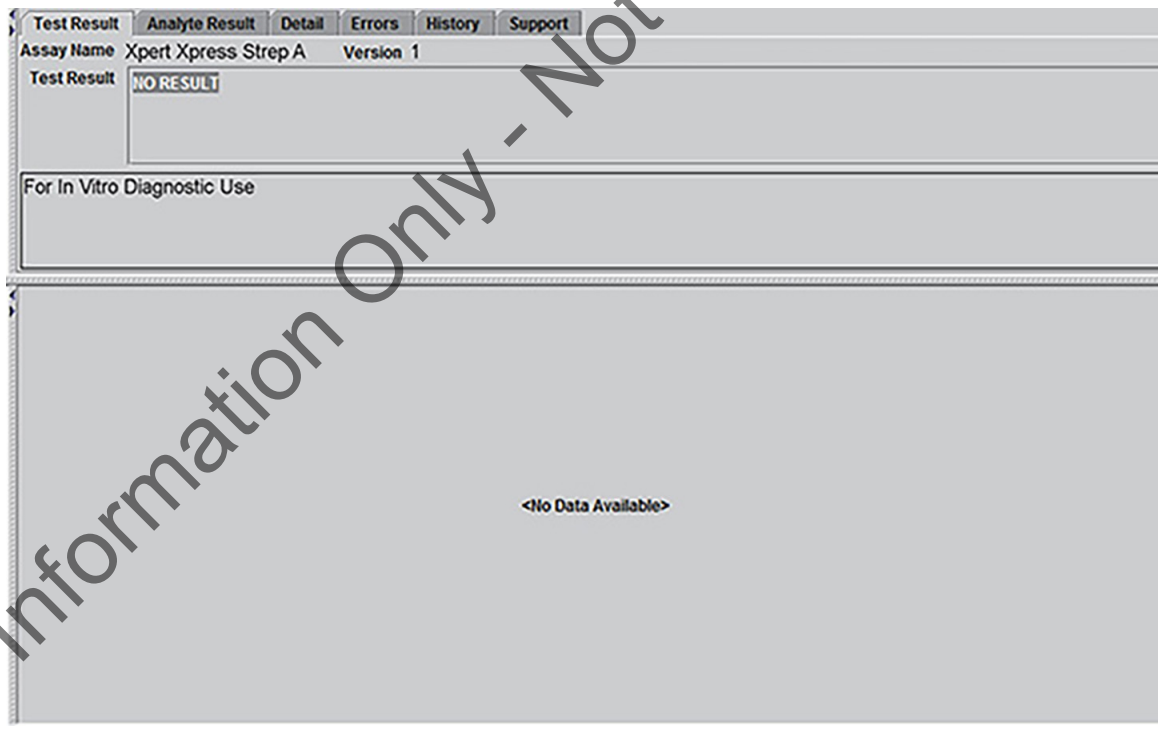

Figure 10. Example of NO RESULT Test Result

17 Retests

17.1 Reasons to Repeat the Test

If any of the test results mentioned below occur, repeat the test once according to the instructions in Section 17.2, Retest Procedure.

- An **INVALID** result indicates that the control SPC failed. The sample was not properly processed, PCR is inhibited, or the sample was not properly collected.
- An **ERROR** result could be due to, but not limited to, Probe Check Control failure, system component failure, or the maximum pressure limits were exceeded.
- A **NO RESULT** indicates that insufficient data were collected. For example, cartridge failed integrity test, the operator stopped a test that was in progress, or a power failure occurred.
- If an External Control fails to perform as expected, repeat external control test and/or contact Cepheid for assistance.

17.2 Retest Procedure

To retest an **INVALID**, **NO RESULT**, or **ERROR** result (indeterminate result), use a new cartridge.

Use the leftover sample from the original ESwab transport medium tube.

1. Mix the leftover patient specimen by vigorously shaking the specimen transport tube for 5 seconds.
2. Open the cartridge by lifting the cartridge lid.
3. Unscrew the specimen transport tube cap (do not remove the cap). Remove the transfer pipette from the wrapper by opening the end next to the bulb.
4. Lift the cap with the attached swab from the transport tube (do not remove the swab completely from the transport tube). Squeeze the bulb of the transfer pipette completely and place the pipette tip in the ESwab transport medium tube containing the patient specimen (Figure 1).
5. Release the bulb of the pipette to fill the pipette with the patient specimen.
6. To transfer the patient specimen to the cartridge, squeeze the bulb of the transfer pipette completely again to empty the contents of the pipette into the large opening (Sample Chamber) shown in Figure 2.
7. Close the cartridge lid.
8. Dispose of the used pipette in an appropriate waste container.

18 Limitations

- Additional follow-up testing by culture is required if the Xpert Xpress Strep A test result is negative and clinical symptoms persist, or there is an outbreak of acute rheumatic fever (ARF).
- The performance of the Xpert Xpress Strep A test was evaluated using the procedures provided in this IFU only. Modifications to these procedures may alter the performance of the test.
- Careful compliance with the instructions in this IFU and in the Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System IFU is necessary to avoid erroneous results.
- The Xpert Xpress Strep A test has been validated only with Copan Liquid Amies Elution Swab (ESwab) Collection Kit (Copan 480C or Copan 480CE or Copan 480CFA).
- Because the detection of *Streptococcus pyogenes* is dependent on the organism's DNA present in the sample, reliable results are dependent on proper sample collection, handling, and storage.
- The Xpert Xpress Strep A test provides qualitative results and does not provide the quantitative value of the organism detected in the specimen.
- Mutations or nucleotide polymorphisms in primer or probe binding regions may affect detection of new or unknown *Streptococcus pyogenes* strains resulting in a false negative result.
- A negative test result does not exclude the possibility of infection because the test result may be affected by improper specimen collection, technical error, sample mix-up, or because the number of organisms in the sample is below the limit of detection of the test.
- As with many diagnostic tests, negative results from the Xpert Xpress Strep A test do not preclude a Strep A infection and should not be used as the sole basis for treatment or other patient management decisions. The Xpert Xpress Strep A test does not differentiate asymptomatic carriers of Group A streptococci from those exhibiting streptococcal infection.

The results from the Xpert Xpress Strep A test should be interpreted in conjunction with other laboratory and clinical data available to the clinician.

- This test has not been evaluated for patients without signs and symptoms of pharyngitis.
- This test cannot rule out pharyngitis caused by other bacterial or viral pathogens besides Group A streptococci.
- Cross-reactivity with organisms other than those listed in the Exclusivity Table, Table 11 may lead to erroneous results.
- The analyte target (bacterial nucleic acid) may persist in vivo, independent of pathogen viability. Detection of the analyte target does not imply that the corresponding pathogen is infectious, or is the causative agent of the clinical symptoms.

19 Expected Values

In multi-center clinical studies for the Xpert Xpress Strep A, 577 throat swab specimens were analyzed. Of the 577 specimens, 326 (56.5%) were collected from female subjects and 251 (43.5%) from male subjects. The distribution by age range, along with the number and percentage of cases positive for Strep A, as determined by the Xpert Xpress Strep A, are shown in Table 3.

Table 3. Number and Percent of Specimen by Age Range

Age Range	N	% of Total	Number of Positives	Positivity
0-1 year	3	0.5%	0	0%
2-5 years	76	13.2%	28	36.8%
6-12 years	189	32.8%	80	42.3%
13-21 years	129	22.4%	25	19.4%
22-65 years	170	29.5%	30	17.6%
>65 years	10	1.7%	1	10.0%
Total	577	100%	164	28.4%

20 Performance Characteristics

20.1 Clinical Performance

Clinical specimens were collected from two multi-center investigational studies using throat ESwab specimens (flocked swab in Liquid Amies medium) from patients presenting with signs and symptoms of pharyngitis. One study enrolled consented subjects from whom a second prospective throat swab specimen was collected following the collection of a standard of care (SOC) throat swab. Another study tested specimens from subjects for which leftover excess standard of care (SOC) throat swab specimens were available. Across the two studies, the Xpert Xpress Strep A test was evaluated by 9 clinical sites from geographically diverse regions within the United States between December 2016 and March 2017.

Eight hundred and forty-four (844) specimens were initially enrolled in the two studies. Of these, 261 were excluded from the analysis of performance due to failure to comply with the inclusion criteria (19), reference culture procedural error (184), delay in reference culture inoculation (31), delay in shipment (26) or labeling error (1).

Among the 583 specimens included in the analysis of performance, 96.9 (565/583) were successful on the initial test and upon retest 99.0% (577/583) gave valid results.

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the Xpert Xpress Strep A were established relative to culture and latex agglutination for Strep A typing. The overall performance of the Xpert Xpress Strep test from both studies combined is presented in Table 4. Results of the first study (second swab specimens) and the second study (SOC throat swab, i.e., first swab) are presented separately in Table 5. Discordant results between Xpert Xpress Strep A and culture were investigated using an alternative PCR/bidirectional sequencing test, the results of which are footnoted in Table 4 and Table 5.

Table 4. Overall Performance of the Xpert Xpress Strep A vs. Reference Method (First and Second Swab Data Combined)

Reference Method				
Xpert Xpress Strep A	Strep A	Positive	Negative	Total
	Positive	138	26[a]	164
	Negative	0	413	413
	Total	138	439	577[b]
Sensitivity		100% (95% CI: 97.3-100)		
Specificity		94.1% (95% CI: 91.5-95.9)		
PPV		84.1% (95% CI: 77.8-88.9)		
NPV		100% (95% CI: 99.1-100)		

[a] Results from alternative PCR with bidirectional sequencing: 21 of 26 were Strep A Positive; 4 of 26 were Strep A Negative; 1 of 26 samples was not tested.
[b] On initial testing, 18/583 specimens (3.1%) produced indeterminate results; 16/18 were retested, of which 12 produced valid results that were included in the analysis of performance for a final indeterminate rate of 6/583 (0.9%).

Table 5. Performance of the Xpert Xpress Strep A vs. Reference Method (Data for First and Second Swab)

	First Swab[a]		Second Swab[b]	
	N	**% (95% CI)**	**N**	**% (95% CI)**
Sensitivity	65/65	100% (94.4-100)	73/73	100% (95.0-100)
Specificity	244/253[c]	96.4% (93.4-98.1)	169/186[d]	90.9% (85.9-94.2)
NPV	244/244	100% (98.5-100)	169/169	100% (97.8-100)
PPV	65/74	87.8% (78.5-93.5)	73/90	81.1% (71.8-87.9)

[a] On initial testing, 9/321 specimens (2.8%) produced indeterminate results; 7/9 were retested, of which 6 produced valid results that were included in the analysis of performance for a final indeterminate rate of 3/321 (0.9%).
[b] On initial testing, 9/262 specimens (3.4%) produced indeterminate results; all 9 were retested, of which 6 produced valid results that were included in the analysis of performance for a final indeterminate rate of 3/262 (1.1%).
[c] Results from alternative PCR with bidirectional sequencing: 7 of 9 were Strep A Positive; 1 of 9 was Strep A Negative; 1 of 9 samples was not tested.
[d] Results from alternative PCR with bidirectional sequencing: 14 of 17 were Strep A Positive; 3 of 17 were Strep A Negative.

20.2 Reproducibility

A three member reproducibility panel with varying concentrations of *Streptococcus pyogenes* was tested 4 times per day on six different days by two different operators at three sites (3 specimens x 4 times/day x 6 days x 2 operators x 3 sites). Three lots of Xpert Xpress Strep A cartridges were used, with each representing two days of testing. The samples were prepared in simulated throat swab matrix at the different concentration levels and are presented in Table 6. When the study was initially performed, there was an unexpectedly high rate of indeterminate results (47/432 = 10.8%), although no false positive or false negative results were observed. Upon retest of the indeterminate samples, the indeterminate rate was reduced to 2.8% (12/432). Despite the high indeterminate rate, the analytical performance of the test was acceptable in the initial reproducibility study; the percent concordance met the acceptance criteria for the negative, Strep A low positive, and Strep A moderate positive samples at 100% (144/144), 100% (138/138), and 100% (138/138), respectively. Following an investigation, the study was repeated with fresh panels and different lots of reagents. Results of the repeat reproducibility study are summarized in Table 7 by study site/operator.

Table 6. Reproducibility Panel

Strain	Panel Member
Not applicable	Negative
ATCC BAA-946 (*Streptococcus pyogenes*)	Low Positive (~1X LoD)
ATCC BAA-946 (*Streptococcus pyogenes*)	Moderate Positive (~3X LoD)

Table 7. Summary of Reproducibility Results: % Agreement by Study Site/Operator

Sample	Site 1			Site 2			Site 3			% Total Agreement by Sample[a]
	Op 1	Op 2	Site	Op 1	Op 2	Site	Op 1	Op 2	Site	
Neg	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (144/144)
Low Pos	92% (22/24)	100% (24/24)	96% (46/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	98.6% (142/144)
Mod Pos	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (144/144)

[a] Eleven (11) indeterminate results were obtained over the course of the repeat study for an initial indeterminate rate of 2.5% (11/432). In all cases, the expected results were obtained upon retesting.

The reproducibility of the Xpert Xpress Strep A was also evaluated in terms of the fluorescence signal expressed in Ct values for each target detected. The mean, standard deviation (SD), and coefficient of variation (CV) between-sites, between-lots, between-days, between-operators and within-test for each panel member are presented in Table 8.

Table 8. Summary of Reproducibility Data

Sample	Assay Channel (Analyte)	N[a]	Mean Ct	Between-Site		Between-Lot		Between-Day		Between-Operator		Within-Test		Total	
				SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
Neg	SPC	144	34.7	0	0	1.9	5.3	0.3	1.0	0	0	1.3	3.7	2.3	6.6
Strep A Low Pos	SA	142	37.8	0.2	0.6	0	0	0.1	0.4	0.1	0.2	1.0	2.7	1.1	2.8
Strep A Mod Pos	SA	144	36.5	0	0	0.3	0.8	0	0	0.1	0.3	0.9	2.3	0.9	2.5

[a] Results with non-zero Ct values out of 144.

21 Analytical Performance

21.1 Analytical Sensitivity (Limit of Detection)

Studies were performed to determine the analytical sensitivity or Limit of Detection (LoD) of the Xpert Xpress Strep A using the ESwab collection kit (Copan P/N 480CE or 480C referred to in Section 8 as the “ESwab”). The limit of detection is the lowest concentration of sample (reported as CFU/mL in ESwab transport medium or CFU/test) that can be reproducibly distinguished from negative samples 95% of the time, or the lowest concentration of organisms at which 19 of 20 replicates were positive. This study determined the lowest concentration of *Streptococcus pyogenes* cells diluted into pooled clinical throat swab matrix that can be detected using the Xpert Xpress Strep A.

The analytical sensitivity of the Xpert Xpress Strep A was performed using two lots of reagents tested across three testing days with two *Streptococcus pyogenes* strains: ATCC BAA-946 and ATCC 19615.

The claimed LoD for each Strep A strain tested is summarized in Table 9.

Table 9. Strep A LoD

Strep A Strain	*emm* type	LoD (CFU/mL in ESwab transport medium)	LoD (CFU/test)
ATCC BAA-946	6	9	3
ATCC 19615	80	18	6

21.2 Analytical Reactivity (Inclusivity)

Twenty-four *Streptococcus pyogenes* strains were tested at 3X LoD using the Xpert Xpress Strep A in replicates of three. The strains tested included representative isolates of *emm* types 1, 3, 4, 6, 11, 12,18, 22, 25, 27, 38, 75, 77, 89, 94, 95. The list of strains tested in ESwab medium containing simulated throat swab matrix is shown in Table 10. All 24 strains were correctly reported as **Strep A DETECTED** with the Xpert Xpress Strep A.

Table 10. Analytical Reactivity (Inclusivity) of Xpert Xpress Strep A

Strep A Strain ID	*emm* type	Strain
ATCC 12202	1	NCTC 8370
ATCC 12344	1	T1
ATCC 700294	1	SF370
ATCC 12383	3	D58X
ATCC 12384	3	C203
ATCC 12385	4	J17A4
ATCC 12203	6	NCTC 8709
ATCC 12352	11	T11
ATCC BAA-1065	12	MGAS 2096
ATCC BAA-1315	12	MGAS9429
ATCC 12357	18	J17C
ATCC 10403	22	T22
ATCC 12204	25	A25
ATCC 8135	27	T27
ATCC 12365	38	C107
ATCC 12370	38	C94
ATCC 700497	75	CDC-SS-1147
ATCC 700499	77	CDC-SS-1149
ATCC 700949	89	CDC-SS-1397
ATCC BAA-355	94	N/A
ATCC BAA-356	95	N/A
ATCC 14289	M protein deficient *S.pyogenes*	C203 S
ATCC 49399	*emm* type not available	QC A62
ATCC 51339	*emm* type not available	1805

21.3 Analytical Specificity (Exclusivity)

The analytical specificity of the Xpert Xpress Strep A was evaluated by testing a panel of 70 potentially cross-reactive microorganisms, including species that are phylogenetically related to *Streptococcus pyogenes* and members of the throat commensal microflora (e.g., other bacteria, viruses, and yeast). The 70 organisms tested were identified as either Gram-positive (27), Gram-negative (33), or Gram-indeterminate (3), yeast (1), and viruses (6). *Streptococcus* Group B, *Streptococcus* Group C, and *Streptococcus* Group G strains were also included in this study. All strains were tested in triplicate in ESwab transport medium containing simulated throat swab matrix at $\geq 10^6$ CFU/mL for bacteria and yeast and $\geq 10^5$ $TCID_{50}$/mL for viruses. All three replicates of all 70 organisms were reported as **Strep A NOT DETECTED** by the Xpert Xpress Strep A (Table 11). The analytical specificity of the Xpert Xpress Strep A was 100%.

Table 11. Analytical Specificity of Xpert Xpress Strep A

Organism	Results
Acinetobacter baumannii	Strep A NOT DETECTED
Arcanobacterium haemolyticum	Strep A NOT DETECTED
Adenovirus, Type 1	Strep A NOT DETECTED
Adenovirus, Type 7	Strep A NOT DETECTED
Bacillus cereus	Strep A NOT DETECTED
Bordetella bronchiseptica	Strep A NOT DETECTED
Bordetella parapertussis	Strep A NOT DETECTED
Bordetella pertussis	Strep A NOT DETECTED
Burkholderia cepacia	Strep A NOT DETECTED
Campylobacter rectus	Strep A NOT DETECTED
Candida albicans	Strep A NOT DETECTED
Corynebacterium diphtheriae	Strep A NOT DETECTED
Corynebacterium pseudodiphtheriticum	Strep A NOT DETECTED
Cytomegalovirus AD-169	Strep A NOT DETECTED
Enterococcus faecalis	Strep A NOT DETECTED
Enterococcus faecium	Strep A NOT DETECTED
Epstein-Barr Virus 4	Strep A NOT DETECTED
Escherichia coli	Strep A NOT DETECTED
Fusobacterium necrophorum	Strep A NOT DETECTED
Haemophilus influenzae type A	Strep A NOT DETECTED
Haemophilus parahaemolyticus	Strep A NOT DETECTED
Haemophilus parainfluenzae	Strep A NOT DETECTED
Hepatitis B Virus	Strep A NOT DETECTED
Herpes Simplex Virus	Strep A NOT DETECTED
Klebsiella pneumoniae	Strep A NOT DETECTED
Lactobacillus acidophilus	Strep A NOT DETECTED
Lactococcus lactis subsp. *lactis*	Strep A NOT DETECTED
Legionella jordanis	Strep A NOT DETECTED
Legionella micdadei	Strep A NOT DETECTED

Organism	Results
Legionella pneumophila	Strep A NOT DETECTED
Listeria monocytogenes	Strep A NOT DETECTED
Moraxella catarrhalis (two strains)	Strep A NOT DETECTED
Moraxella lacunata	Strep A NOT DETECTED
Mycoplasma pneumoniae	Strep A NOT DETECTED
Neisseria gonorrhoeae	Strep A NOT DETECTED
Neisseria lactamica	Strep A NOT DETECTED
Neisseria meningitidis	Strep A NOT DETECTED
Neisseria mucosa	Strep A NOT DETECTED
Neisseria sicca	Strep A NOT DETECTED
Neisseria subflava	Strep A NOT DETECTED
Peptostreptococcus micros	Strep A NOT DETECTED
Prevotella (Bacteroides) oralis	Strep A NOT DETECTED
Proteus mirabilis	Strep A NOT DETECTED
Proteus vulgaris	Strep A NOT DETECTED
Pseudomonas aeruginosa	Strep A NOT DETECTED
Pseudomonas fluorescens	Strep A NOT DETECTED
Serratia marcescens	Strep A NOT DETECTED
Staphylococcus aureus	Strep A NOT DETECTED
Staphylococcus epidermidis	Strep A NOT DETECTED
Staphylococcus haemolyticus	Strep A NOT DETECTED
Stenotrophomonas maltophilia	Strep A NOT DETECTED
Streptococcus agalactiae	Strep A NOT DETECTED
Streptococcus anginosus	Strep A NOT DETECTED
Streptococcus bovis	Strep A NOT DETECTED
Streptococcus canis	Strep A NOT DETECTED
Streptococcus constellatus	Strep A NOT DETECTED
Streptococcus dysgalactiae	Strep A NOT DETECTED
Streptococcus equi	Strep A NOT DETECTED
Streptococcus gallolyticus	Strep A NOT DETECTED
Streptococcus intermedius	Strep A NOT DETECTED
Streptococcus mitis	Strep A NOT DETECTED
Streptococcus mutans	Strep A NOT DETECTED
Streptococcus oralis	Strep A NOT DETECTED
Streptococcus pneumoniae	Strep A NOT DETECTED
Streptococcus salivarius	Strep A NOT DETECTED
Streptococcus sanguinus	Strep A NOT DETECTED

Organism	Results
Treponema denticola	Strep A NOT DETECTED
Veillonella parvula	Strep A NOT DETECTED
Yersinia enterocolitica	Strep A NOT DETECTED

21.4 Carry-over Contamination

A study was conducted to demonstrate that single-use, self-contained GeneXpert cartridges prevent specimen and amplicon carry-over contamination from very high titer positive samples (*S. pyogenes*) into successively run negative samples when processed in the same GeneXpert module. The study consisted of a negative sample processed in the same GeneXpert module immediately after processing a very high titer positive sample at a concentration ≥ 1 X 10^6 CFU/mL in ESwab transport medium containing simulated throat swab matrix. The testing scheme was repeated 40 times between 2 GeneXpert instruments (one module per instrument) for a total of 41 runs per instrument (20 high positive samples per instrument and 21 negative samples per instrument). There was no evidence of any carry-over contamination. All 42 negative samples were correctly reported as **Strep A NOT DETECTED**. All 40 positive samples were correctly reported as **Strep A DETECTED**.

21.5 Potentially Interfering Substances

Ten potentially interfering substances that may be present in clinical throat specimens with the potential to interfere with the performance of the Xpert Xpress Strep A were evaluated. The potentially interfering substances included blood, mucus, human saliva, sugar-containing cold and flu remedies, cough medicine, antiseptic, salt-modifying remedies, pH-modifying remedies, antacids, and foods or drinks that increase salivary viscosity. The substances, active ingredients, and concentrations tested are listed in Table 12. Medically and/or physiologically relevant concentrations of potential interferents were tested in simulated throat swab matrix in the presence and absence of Strep A at 3X LoD.

There was no test interference in the presence of the substances at the concentrations tested in this study. All positive and negative samples were correctly identified using the Xpert Xpress Strep A.

Table 12. Potential Interfering Substances Tested

Substance/Class	Description/Active Ingredient	Concentration Tested
Saliva	100% Human Saliva	6.5% (v/v)
Mucin	Bound sialic acid, 0.5-1.5%	2.5% (w/v)
Blood	Whole human blood	5.0% (v/v)
Antiseptic	0.092% Eucalyptol, 0.042% menthol, 0.060% methyl salicylate, 0.064% thymol	6.5% (v/v)[a]
Cough Medicine	Dextromethorphan HBr USP 10 mg, Guaifenesin USP 200 mg	5 mg/mL
Sugar-containing cold and flu remedies	Acetaminophen 650 mg, Dextromethorphan HBr 20 mg, Doxylamine Succinate 12.5 mg, Phenylephrine HCl 10 mg	6.5% (v/v)
Salt-modifying remedies	Sodium Chloride (0.65%)	6.5% (v/v)
Foods/drinks that increase salivary viscosity	Milk	6.5% (v/v)

Substance/Class	Description/Active Ingredient	Concentration Tested
pH Modifying Remedies	100% Orange juice	6.5% (v/v)
Antacids	Aluminum Hydroxide 400 mg (equivalent to dried gel, USP) – antacid, Magnesium Hydroxide 400 mg – antacid, Simethicone 40 mg – antigas	6.5% (v/v)

[a] Although all samples were reported appropriately as positive or negative, reduced fluorescent signal for the *S. pyogenes* target was observed in the presence of antiseptic mouthwash at 6.5% v/v.

21.6 Microbial Interference

An interfering microorganism study was performed to assess the inhibitory effects of commensal microorganisms in throat swab samples on the performance of the Xpert Xpress Strep A. Twenty-seven microorganisms were tested for potential interference with Strep A detection (Table 13). The microorganisms were tested at ≥10^6 CFU/mL in the presence of Strep A at 3X LoD concentration in ESwab medium containing simulated throat swab matrix. The results showed that the presence of the tested microorganisms did not interfere with the detection of Strep A target DNA.

Table 13. Commensal Microorganisms Tested

Organism		
Acinetobacter baumannii	*Staphylococcus epidermidis*	*Streptococcus intermedius*
Candida albicans	*Streptococcus agalactiae*	*Streptococcus mitis*
Enterococcus faecalis	*Streptococcus anginosus*	*Streptococcus mutans*
Fusobacterium necrophorum	*Streptococcus bovis*	*Streptococcus oralis*
Haemophilus influenzae type A	*Streptococcus canis*	*Streptococcus pneumoniae*
Lactobacillus acidophilus	*Streptococcus constellatus*	*Streptococcus salivarius*
Neisseria lactamica[a]	*Streptococcus dysgalactiae*	*Streptococcus sanguinus*
Peptostreptococcus micros	*Streptococcus equi*	*Treponema denticola*
Prevotella (Bacteroides) oralis	*Streptococcus gallolyticus*	*Veillonella parvula*

[a] Although all samples were reported appropriately as positive, reduced fluorescent signal was observed for the S. pyogenes target in the presence of high concentrations of N. lactamica.

22 References

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6. Occupational Safety and Health Standards, Hazard Communication, Toxic and Hazard Substances (March 26, 2012) (29 C.F.R., pt. 1910, subpt. Z).

23 Cepheid Headquarters Locations

Corporate Headquarters

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Telephone: + 1 408 541 4191
Fax: + 1 408 541 4192
www.cepheid.com

European Headquarters

Cepheid Europe SAS
Vira Solelh
81470 Maurens-Scopont
France

Telephone: + 33 563 825 300
Fax: + 33 563 825 301
www.cepheidinternational.com

24 Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Lot number
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag number

United States Technical Support

Telephone: + 1 888 838 3222
Email: techsupport@cepheid.com

France Technical Support

Telephone: + 33 563 825 319
Email: support@cepheideurope.com

Contact information for all Cepheid Technical Support offices is available on our website: www.cepheid.com/en/support/contact-us.

25 Table of Symbols

Symbol	Meaning
REF	Catalog number
IVD	*In vitro* diagnostic medical device
	Do not reuse
LOT	Batch code
	Consult instructions for use
	Caution
	Manufacturer
CC	Country of manufacture
Σ	Contains sufficient for *n* tests
CONTROL	Control
	Expiration date
	Temperature limitation
	Biological risks
	Warning
Rx only	For prescription use only

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Telephone: + 1 408 541 4191
Fax: + 1 408 541 4192

www.cepheid.com

IVD

26 Revision History

Description of Changes: 301-6574 Rev. E to Rev. F

Purpose: To add new pipette procedure

Section	Description of Change
Throughout	“Assay” changed to “test” and “package insert” changed to “Instructions for Use (IFU)”. General formatting changes made and minor updates.
Preparing the Cartridge	Updated to include steps for two types of pipettes.
Revision History	Added revision history table