510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K173398

B. Purpose for Submission:

To obtain a Substantial Equivalence determination for the for the Xpert Xpress Strep A test performed on the GeneXpert Xpress System.

C. Measurand:

Conserved DNA sequence of the *Streptococcus pyogenes* bacterial genome

D. Type of Test:

Qualitative real-time Polymerase Chain Reaction (PCR)

E. Applicant:

Cepheid

F. Proprietary and Established Names:

Xpert Xpress Strep A

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.2680: *Streptococcus* spp. nucleic acid-based assay

2. Classification:

   Class II

3. Product code(s):

   PGX: Groups A, C and G β-Hemolytic *Streptococcus* Nucleic Acid Amplification System
   OOI: Instrumentation for clinical multiplex test systems

4. Panel:

   Microbiology (83)

H. Intended Use:

1. Intended use(s):

   The Xpert Xpress Strep A test, performed on the GeneXpert Xpress 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 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 assay 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.

2. Indication(s) for use:
   Same as Intended Use

3. Special conditions for use statement(s):

   For prescription use only.

   The following Limitations have been added to the labeling:

   a. Additional follow-up testing by culture is required if the Xpert Xpress Strep A test result is negative and clinical symptoms persist, or in the event of an outbreak of acute rheumatic fever (ARF).
   b. The performance of the Xpert Xpress Strep A test was evaluated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the test.
   c. The Xpert Xpress Strep A test has been validated only with Copan Liquid Amies Elution Swab (ESwab) Collection Kit (Copan 480C or Copan 480CE).

4. Special instrument requirements:

   GeneXpert Xpress System (The GeneXpert Xpress II and GeneXpert Xpress IV instruments)

I. Device Description:

The Cepheid Xpert Xpress Strep A test is an automated real-time polymerase chain reaction (PCR) *in vitro* diagnostic test for qualitative detection of *Streptococcus pyogenes* DNA directly from throat swab specimens from patients with signs and symptoms of pharyngitis.

Throat swab specimen are collected using the Copan Liquid Amies Elution Swab (ESwab) collection medium. The sample is mixed by shaking and 300ul of is added to the Xpert Xpress Strep A cartridge using a disposable transfer pipette. Once the cartridge is loaded into a GeneXpert Xpress module and the test is initiated by the operator, all the steps associated with sample processing, PCR amplification/detection and result interpretation occur automatically.

The Xpert Xpress Strep A Assay is performed on the Cepheid GeneXpert Xpress System that automates sample preparation, DNA amplification and real-time detection in single-use, disposable cartridges.

The Xpert Xpress Strep A test cartridge contains a pair of PCR primers and a hydrolysis probe that enable detection of a conserved DNA sequence within the *S. pyogenes* genome. The assay also incorporates a Sample Processing Control (SPC) and a Probe Check Control (PCC) to monitor the integrity of the reagents and process workflow.

The GeneXpert Xpress System, which uses the GeneXpert Xpress II and IV instruments, performs separate sample preparation and real-time PCR and RT-PCR tests. Each module contains a syringe pump drive for dispensing fluids, an ultrasonic horn for lysing cells, a valve drive that rotates the cartridge valve body to address the different cartridge chambers for sample movement, and a thermocycler unit for performing real-time PCR and RT-PCR and detection.

The Xpert Xpress Strep A results are interpreted by the GeneXpert Xpress software from measured fluorescent signals and are shown in the "Test Result" screen. The final result report can be viewed on-screen and/or printed.

The single-use, multi-chambered fluidic cartridges are designed to complete sample preparation and real-time PCR for the detection of genomic DNA *S. pyogenes* in approximately 24 minutes or less.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Liat Strep A Assay

2. Predicate 510(k) number(s):

   K141338

3. Comparison with predicate:

Table 1. Comparison of the Xpert Xpress Strep A with the Predicate Device

Similarities		
Item	**Device (K173398)**	**Predicate (K141338)**
	Xpert Xpress Strep A Assay	**Liat Strep A Assay**
Regulation	21 CFR 866.2680	Same
Product Code	PGX	Same
Device Class	Class II	Same
Intended Use	The Xpert Xpress Strep A test, performed on the GeneXpert Xpress 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 assay 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.	The Liat Strep A Assay, performed on the Liat Analyzer, 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 Liat 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.
Analyte	Group A *Streptococcus*	Same
Measurand	Conserved region of *S. pyogenes* DNA	Same
Specimen Type	Throat swab in liquid Amies medium	Same
Reagent Format	Unitized ready for use	Same
Assay Format	Automated DNA extraction, amplification and detection	Same
Process Control	Cell-based	Same
External Controls	Available	Same
Detection Technique	Different reporter dyes for target and Internal Control	Same
Assay Result	Qualitative	Same

Differences		
Item	**Device (K173398)**	**Predicate (K141338)**
	Xpert Xpress Strep A	**Liat Strep A Assay**
Instrument System	GeneXpert Xpress, GeneXpert Dx, GeneXpert Infinity-48s or GeneXpert Infinity-80 instrument systems	Liat Analyzer
Bacterial Lysis	Mechanical (sonication)	Chaotrope and enzymatic digestion
Time-to-result	~24 minutes without early assay termination; ~18 minutes with early assay termination for positive samples	~15 minutes
Early Assay termination function	Yes (for positive samples)	No

K. Standard/Guidance Document Referenced (if applicable):

1. Guidance for Industry, FDA Reviewers and Compliance on: Off-the-Shelf Software Use in Medical Devices; September 9, 1999.
2. General Principles of Software Validation; Final Guidance for Industry and FDA Staff; January 11, 2002.
3. Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software; January 14, 2005.
4. Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document - Instrumentation for Clinical Multiplex Test Systems; March 10, 2005.
5. Guidance for Industry and FDA Staff: Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices; May 11, 2005.
6. Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s; August 12, 2005.
7. Guidance for Sponsors, Institutional Review Boards, Clinical Investigators and FDA Staff: Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable; April 25, 2006.
8. Guidance for Industry and FDA Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; October 2, 2014.

L. Test Principle:

The Xpert Xpress Strep A is performed on the GeneXpert XpressSystem (GeneXpert Xpress II and IV instruments) that automate nucleic acid extraction, amplification and detection in single-use, disposable cartridges. Each cartridge contains primers and probes for detection of the targeted region of the *S. pyogenes* chromosome (if present) and a Sample Processing Control (SPC). The SPC and a separate Probe Check Control (PCC) are used by the GeneXpert systems to monitor reagent and process integrity.

Throat swab specimens for testing with the Xpert Xpress Strep A Assay are collected using

the Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System. Upon receipt in the testing laboratory, the ESwab tube is mixed by shaking and 300µL of the transport medium is added to an Xpert Xpress Strep A Assay cartridge using a disposable transfer pipette. The operator then initiates the test from the operator interface and loads the cartridge into the GeneXpert instrument, after which all process steps are performed automatically.

Once complete, the final result report can be viewed on-screen and/or printed. Results are reported as *Strep A DETECTED, Strep A NOT DETECTED, , INSTRUMENT ERROR* or *NO RESULT-REPEAT TEST* (If the result is NO RESULT-REPEAT TEST, then retest with a new cartridge. If the retest is NO RESULT-REPEAT TEST, call Cepheid Technical Support).). Instructions for retesting are provided for samples with indeterminate results.

The Xpert Xpress Strep A Assay has an Early Termination Feature whereby results for samples that are strongly positive for *S. pyogenes* are reported prior to completion of the full number of PCR cycles designated in the assay definition file.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

Analytical studies for the Xpert Xpress Strep A Assay were described in submission K172126 that was cleared on September 25, 2017. All testing was performed using the same assay in this submission. No changes have been made to the design of the Xpert Xpress Strep A Assay since the 510(k) clearance of K172126. For this submission the data from all analytical studies (except Reproducibility study) is identical to those conducted in support of K172126 clearance. All analytical data was generated with GeneXpert Dx software using the GeneXpert Dx (GX-IV and GX-XVI) instrument and reanalyzed with GeneXpert Xpress software 5.0 The data re-analyzed with GeneXpert Xpress software 5.0 provided identical results to those original analysis with GeneXpert Dx software 4.7b.

a. Precision/Reproducibility:

A multi-center study was conducted at three sites with three operators at each site. Each operator tested four-member panel comprised of positive samples with varying concentrations of *Streptoccoccus pyogenes* ATCC BAA-946 at three target concentrations levels and a negative sample (No *Streptococcus pyogenes*) in a liquid Amies media containing simulated throat swab matrix (Table 2). Each operator tested blinded panel twice per day over 5 testing days (3 operators x 2 times/day x 5 days x 3 sites=90 results). Three lots of Xpress Strep A Assay reagent were used in this study but only two lots of reagents were used at each testing site. All sites used the GeneXpert Xpress IV instrument. Samples were stored at 2-8°C until testing The data was generated with Xpress software 4.7c and re-analyzed with GeneXpert Dx 5.0 software. The Reproducibility data re-analysis, with GeneXpert Dx 5.0 software provided results identical to the original analysis, with GeneXpert Xpress software 4.7c. A summary of the reproducibility panel members is outlined in Table2.

Table 2. Summary of Reproducibility Study panel members

S. pyogenes Strain	Analyte Level	Multiple of LoD	CFU/mL[1]
Not applicable[2]	Negative	Not applicable	0
ATCC BAA-946	High negative	~0.05X LOD	~0.5
	Low Positive	~ 1X	~10
	Moderate Positive	~3X	~30

ATCC: American Type Culture Collection; LoD: Limit of Detection

[1] CFU per mL of ESwab transport medium

[2] No *Streptococcus pyogenes* in a liquid Amies media containing simulated throat swab matrix.

Xpert Xpress A assays for 96.4% (347/360) of samples were successful on the first attempt. The indeterminate cases included 12 NO RESULT-REPEAT TEST results and one INSTRUMENT ERROR results. All of the 13 initially indeterminate cases were retested (per the assay instruction) and yielded valid results upon repeat testing. The overall rate of success was 100% (360/360). Reproducibility results are shown in detail in Table 3.

Table 3. Reproducibility Results Data

Sample	Site 1				Site 2				Site 3				% Total Agreement by Sample[a, b]
	Op 1	Op 2	Op 3	Site	Op 1	Op 2	Op 3	Site	Op 1	Op 2	Op 3	Site	
Neg	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)	100% (90/90)
Strep A High Neg	70% (7/10)	100% (10/10)	100% (10/10)	90.0% (27/30)	80.0% (8/10)	100% (10/10)	100% (10/10)	93.0% (27/30)	90.0% (9/10)	100% (10/10)	80% (8/9)	90% (27/30)	91.0% (82/90)
Strep A Low Pos	100% (10/10)	100% (10/10)	90.0% (9/10)	97.0% (29/30)	100% (10/10)	90% (9/10)	100% (10/10)	97.0% (29/30)	100% (10/10)	100% (10/10)	90% (9/10)	97.0% (29/30)	97% (87/90)
Strep A Mod Pos	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)	100% (90/90)

[a] Agreement based on expected result: Neg and High Neg=expected negative; Low Pos and Mod Pos=expected positive

[b] Thirteen (13) indeterminate (12 NO RESULT-REPEAT TEST and 1 INSTRUMENT ERROR) results were obtained over the course of the study for an initial indeterminate rate of 3.6% (13/360). In all cases, the expected results were obtained upon retesting.

- A total of 100% of all negative samples produced a negative result (90/90).
- A total of 91% of high negative produced negative results (82/90)
- A total of 97% of the low positive produced positive results (87/90)
- A total of 100% of all moderate positive samples produced a positive result (90/90).

ANOVA (Analysis Of Variance) was also performed to assess the variance components of the Ct values for the *S. pyogenes* and SPC targets (Table 4). The total variation for all targets was between 1 and 1.9 Ct (2.6-5.5%).

Table 4. Summary of Ct variance components observed in the Reproducibility Study

Sample	Target	N[2]	Ct											
			Mean	Between Site		Between Lot		Between Day		Between Operator		Within Assay		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative	SPC[*]	90	33.5	0.3	0.9	1.0	3.0	0.3	0.9	0	0	1.5	4.5	1.9	5.5
High Negative	SPC	82[4]	33.6	0.4	1.2	1.1	3.2	0	0	0	0	1.3	3.9	1.7	5.2
Low Positive	SA [1]	87[3]	38.6	0	0	0.4	0.9	0	0	0	0	1.3	3.4	1.3	3.5
Moderate Positive	SA [1]	90	37.2	0	0	0.1	0.3	0.2	0.5	0.2	0.5	0.9	2.4	1.0	2.6

[*] SPC: Sample Processing Control
[1] SA=Strep A
[2] Results with non-zero Ct values out of 90
[3] Three (3) samples gave negative results for Group A *Streptococcus*
[4] Eight (8) samples gave negative results for Group A *Streptococcus*

The Xpert Xpress Strep A test demonstrated acceptable reproducibility across sites, lot, operators and panel members.

b. Linearity/assay reportable range:
Not applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

No additional studies were performed. All data for these studies were supported by the prior clearance. For studies and performance of the following, please refer to submission K172126: Traceability, Calibrator, Controls and Carry Over.

Additional information was provided for Specimen Stability, Reagent Stability and Cartridge Hold Time
Stability:
Stability studies have been performed in K172126 to support the following claims:

Specimen Stability:
The following specimen stability claims are supported by study data from K172126. :

- Room temperature (15-30°C) for up to 48 hours
- Refrigerated (2-8°C) for up to six days

Reagent Stability:
The following kit stability claims are supported by study data from K172126 with the following changes:

- Lot #0061 currently have twelve months of real-time stability data and nine months of real-time stability data for lots#0092 and #1002 at 2-28°C.

- The shipping simulation data product configuration for Xpert Xpress Strep A (120-test kit).

Cartridge Hold Time:
The following stability claim for prepared samples tested with the Xpert Xpress Strep A Assay on the GeneXpert Infinity System are supported by study data from K172126:

- Up to 4.5 hours at room temperature is recommended.

d. Detection limit:

For detection limit and Analytical Reactivity/Inclusivity studies, please refer to submission K172126.

e. Analytical specificity:

For analytical specificity and Carry-over Contamination studies, please refer to submission K172126.

f. Assay cut-off:

Please refer to submission K172126.

g. Assay interference:

For Interfering Substances Microbial Interference studies, please refer to submission K172126.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable.

b. Matrix comparison:

For Comparison of Fresh versus. Frozen Cell Stock Equivalency and Comparison of Performance of Natural versus Simulated Matrices studies, please refer to submission K172126.

3. Clinical Studies:

a. Clinical Sensitivity and Specificity:

The performance of the Xpert Xpress Strep A Assay was conducted at a total of nine (9) clinical sites in the U.S. that were selected to be representative of the CLIA Waived testing environment (including emergency departments, urgent care centers, physician's offices and a walk-in clinic). The GeneXpert Operators who performed the Xpert Xpress Strep A Assay at each site were non-laboratory healthcare personnel, with no experience with either the Cepheid CW or moderately complex assays.

Throat swab specimen were prospectively collected in Liquid Amies medium (ESwab) from consented subjects presenting signs and symptoms of pharyngitis following collection of standard of care (SOC) swab specimens. Specimen were stored at 2-8°C until all testing was completed. The performance of the Xpert Xpress Strep A Assay was determined relative to the reference culture. Xpert Xpress Strep A Assay testing and the reference culture method were performed within 48 hours of specimen collection. Isolated colonies that exhibited β-hemolysis were typed by latex agglutination (Remel Streptex). Culture plates that did not exhibit β-hemolytic colonies after 48 hours were recorded as negative for Group A *Streptococcus*. The study was performed with the GeneXpert Xpress system (GeneXpert II and IV instrument). The data was generated with GeneXpert Xpress software 4.7c and reanalyzed with GeneXpert Xpress software 5.0.

A total of 666 specimens were collected from individual subjects initially enrolled in this clinical study. Of the 666 specimen, 43 specimen were excluded because of: lack of consent documents (10), previously enrolled subject (1), delay in shipment for reference culture testing (27), indeterminate culture results (4), and incorrect specimen type (1).Of the 623 eligible specimens, 4.7% (29/623) produced "NO RESULT-REPEAT TEST" and 0.6% (4/623) produced an "INSTRUMENT ERROR" with the Xpert Xpress Strep A test. Twenty eight out of twenty nine samples with NO RESULT-REPEAT test were retested and twenty five samples yielded valid results. Three out of four samples with INSTRUMENT ERROR were retested and three samples have yielded valid results. A total of 618 specimens were therefore included in the final evaluable data for analysis of performance. Specimens were prospectively collected. The results were compared to culture and latex agglutination for Strep A typing (Table 5).

Table 5 . Expert Xpress Strep A Assay Clinical Performance vs Reference Culture

		Reference Culture		
		Positive	**Negative**	**Total**
Xpert Xpress Strep A	**Positive**	157	27[1]	**184**
	Negative	1[3]	433	**434**
	Total	**158**	**460**	**618**[2]
Sensitivity		99.4% (157/158); (95% CI: 96.5-99.9%)		
Specificity		94.1% (433/460); (95% CI: 91.6-95.9%)		
Positive Predictive Value		85.3%(157/184) (95% CI: 79.5-89.7%)		
Negative Predictive Value		99.8%(433/434) (95% CI: 98.7-100%)		
Prevalence		25.6% (158/618)		

95% CI: Two-sided 95% score confidence interval

[1] 27 specimens were tested by an alternative PCR assay with bi-directional sequencing of the amplified products; 10/27 were positive for *S. pyogenes* and 5 out of these 10 positives were also positive by a rapid antigen test method used as the standard of care; 13/27 specimens were negative by the alternative PCR assay, but 1 out of these 13 was also positive by a rapid antigen test used as standard of care; 4/27 produced inconclusive results, and all four were also negative by rapid antigen testing.

[2] On initial testing, 33/623 specimens (5.3%) produced indeterminate results (NO RESULT REPEAT TEST: 29/623; INSTRUMENT ERROR: 4/623)

The performance of the Xpert Xpress Strep A Assay stratified by clinical site is outlined in Table 6. These results are acceptable.

Table 6 . Xpert Xpress Strep A performance stratified by site

Site	Culture Positive (%)	Xpert Xpress Strep A (%; 95% Confidence Interval)	
		Sensitivity	Specificity [1, 2]
1	1/5 (20.0)	1/1 (100; 20.7-100)	4/4 (100; 51.0-100)
2	8/22 (36.4)	8/8 (100; 67.6-100)	14/14 (100; 78.5-100)
3	9/24 (37.5)	9/9 (100; 70.1-100)	15/15 (100; 79.6-100)
4	19/36 (52.8)	19/19 (100; 83.2-100)	18/19 (94.7; 75.4-99.1)
5	3/25 (12.0)	3/3 (100; 43.9-100)	21/22 (95.5; 78.2-99.2)
6	6/24 (25.0)	5/6 (83.3; 43.7-97.0)	17/18 (94.4; 74.2-99.0)
7	53/218 (24.3)	53/53 (100; 93.2-100)	145/165 (87.9; 82.0-92.0)
8	24/97 (24.7)	24/24 (100; 86.2-100)	72/73 (98.6; 92.6-99.8)
9	35/165 (21.2)	35/35 (100; 90.1-100)	127/130 (97.7; 93.4-99.2)
Total	**158/618 (25.6)**	**157/158 (99.4; 96.5-100)**	**433/460 (94.1; 91.6-95.9)**

[1] 27 specimen were tested by an alternative PCR assay with bi-directional sequencing of the amplified products; 10/27 were positive for S. pyogenes

[2] 6/27 specimen (22.2) were positive by a rapid antigen test method used as the standard of care, which in 4 cases included culture.

b. Clinical specificity:

Refer to **Section M(3)(a)**, above.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The performance of the Xpert Xpress Strep A Assay was evaluated in a Clinical Study conducted at multiple sites in the US (**Section M(3)(a)**). The total of 618 specimens included in the analysis of performance included 53.2% (329/618) male subject, and 46.7% (289/618) female subject.

The overall percentage of positive results for *S. pyogenes* (Group A *Streptococcus*) in throat swab specimens was 29.8% as determined by the Xpert Xpress Strep A assay and 25.6% as determined by culture. The positivity rate of Group A *Streptococcus* as determined by the Xpert Xpress Strep A assay is outlined in Table 7, stratified by the age and gender of the subjects.

Table 7. Prevalence of *S. pyogenes* positive subjects by age and gender

Age/Gender	Number	Xpert Xpress Strep A Positive	% Positivity [1]
0 to 1 years	6	1	16.7
2-5 years	91	32	35.2
6-12 years	336	129	38.4
13-21 years	150	18	12.0
>22-65 years	34	5	14.7
>65 years	1	0	0.0
Male	329	89	27.1
Female	289	95	32.9
Total	**618**	**184**	**29.8**

[1] As determined by the Xpert Xpress Strep A Assay

N. Instrument Name:

GeneXpert Xpress system (GeneXpert II and IV instrument) with GeneXpert Xpress software version 5.

Please refer to K172126 for other instrument systems that were cleared with Xpert Xpress Strep A Assay.

O. System Descriptions:

1. System Description:

   The GeneXpert Xpress System automates and integrates sample purification, nucleic acid amplification and detection of target sequences within compatible, assay-specific, single-use cartridges. The instrument systems each contain a computer and preloaded software for running tests and viewing the results.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X___ or No _____

3. Level of Concern:

   Moderate

4. Specimen Identification:

   Barcode scan or manual entry.

5. Specimen Sampling and Handling:

   Throat swab samples are collected using the Copan Liquid Amies Elution Swab (ESwab) and transported to the testing laboratory. The test operator briefly shakes the ESwab tube containing the swab to elute the sample and adds 300µL of the transport medium to an Xpert Xpress Strep A Assay cartridge using a transfer pipette. The operator then loads the cartridge into the GeneXpert System and initiates the run from the operator interface.

6. Calibration:

   No calibration by the operator is required.

7. Quality Control:

   Refer to K172126 for information on internal and external controls.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports substantial equivalence decision.