CLIA Waiver by Application

Approval Determination Decision Summary

A. Document Number

CW170005

B. Parent Document Number

K171552

C. Purpose of the Submission

This submission is a Dual 510(k) and CLIA Waiver by Application (Dual Submission) tracked as K171552 and CW170005. CW170005 was submitted to obtain CLIA Waiver of the Xpert Xpress Flu Assay performed on the Cepheid Gene Xpert Xpress System for nasal swab and nasopharyngeal swab specimens.

D. Measurand (analyte)

Influenza A and influenza B viral RNA

E. Sample Type

Direct nasal and nasopharyngeal swabs

F. Type of Test

This assay is a multiplex nucleic acid assay that detects and differentiates influenza A and influenza B through nucleic acid extraction, amplification, and detection using real-time RT-PCR. All steps of the assay are automated, after sample addition, and performed in a single container.

G. Applicant

Cepheid

H. Proprietary and Established Names

Xpert Xpress Flu
Xpert Xpress Flu Assay

I. Test System Description

1. Overview

This assay uses nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection. Viral nucleic acid is extracted from the sample and the influenza A and/or influenza B viral RNA is amplified and detected through real-time reverse transcription polymerase chain reaction (RT-PCR). Detection and differentiation of influenza A and influenza B is reported to the user.

The assay uses a single use disposable cartridge that has a separate section for specimen loading. The cartridge also contains all PCR reagents and is where the PCR reaction takes place. The GeneXpert Xpress System performs all assay steps from clinical sample to reporting assay results automatically. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge. The SPC is present to control for adequate processing of the target viruses and to monitor the presence of inhibitors in the PCR reaction. The Probe Check Control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability.

The GeneXpert Xpress System iscomprised of the GeneXpert Dx System GX-II, which has two modules capable of performing separate sample preparation and real-time PCR and RT-PCR tests, and the GX-IV which has four modules. Each module contains a syringe drive for dispensing fluids (i.e., the syringe drive activates the plunger that works in concert with the rotary valve in the cartridge to move fluids between chambers), an ultrasonic horn for lysing cells, and a proprietary thermocycler for performing real-time PCR and RT-PCR and detection.

Turnaround time for analysis of a sample is approximately 30 minutes or less. The assay results are automatically generated at the end of the process and provided in a report that can be viewed and printed.

2. Results Interpretation

A positive result for either analyte is determined by detection of a fluorescent signal generated from sequence specific probes to influenza A, influenza B, and signal processing control targets at levels above a signal threshold and within a defined cycle range. The diagnostic algorithm in the assay software contains all the fixed criteria to determine the correct result. These criteria cannot be modified by the end user. At the end of the assay the result is reported on the tablet screen to the user.

There are five possible results: (1) positive for influenza A; (2) positive for influenza B; (3) negative for both influenza A and B; (4) Instrument Error-Repeat Test and (5) No Result-Repeat Test. Due to the early assay termination feature of this test some Influenza A and B dual positive results may not be detected by this assay. If an invalid test result is reported, the test should be repeated with a new patient sample and a new test cartridge.

The results are displayed on the instrument screen. The results can also be printed on an integrated printer if this option is selected.

The kit contains the following test components:

- 10 Xpert Xpress Flu Assay Cartridges with Integrated Reaction Tubes individually Packaged Test Cartridges
- 12 disposable 300µL fixed volume Transfer Pipettes
- CD containing assay Software

Sample collection kits, Gene Xpert Xpress System and Instruments, and Positive and Negative controls are not included with the assay kit.

J. Demonstrating "Simple"

The Xpert Xpress Flu Assay on the GeneXpert Xpress System was designed to be simple and easy to use by incorporating the following features:

- The test uses direct unprocessed nasopharyngeal swab specimens.
- The test requires basic, non-technique dependent specimen handling to obtain accurate test results.
- There is no reagent handling, all reagents are inside the single use cartridge.
- Fixed volume pipettes are provided for sample addition.
- The test cartridges are unitized and contain all the reagents required for analysis.
- The test does not require any operator intervention during the analysis step.
- The test cartridges are keyed and can be inserted into the analyzer in only one direction.
- The GeneXpert Xpress System performs automated analysis of test results and eliminates subjectivity associated with visual reading of results by the end-user.
- The results are reported on a touchscreen as positive and negative results and require no interpretation
- The Gene Xpert Xpress System uses a touchscreen and is designed for ease of use and features a color display that facilitates easy-to-read messages.
- Technical or specialized training is not required for troubleshooting or error code interpretation. If an error code is shown, simple on screen instructions are provided to the user.
- Error messages are unambiguous and include easy-to-interpret solutions.
- The Gene Xpert Xpress System offers a video that the user can watch that demonstrates how to prepare a sample, add the sample to the cartridge and load the cartridge into the instrument.
- Recommended maintenance tasks are simple. The user conducts basic cleaning procedures. A simple system check is also performed annually for calibration.
- System Control Checks are in place for temperature to ensure the instrument is operating within validated heating and cooling specifications.

- The test procedure, and the entire Quick Reference Guide is written at a 7th grade comprehension level.

K. Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-safe Mechanisms

1. Risk Assessment

A risk analysis for the Xpert Xpress Flu Assay and GeneXpert Xpress System for risks associated with hazards and hazardous situations due to user skills, human factors and foreseeable misuse has been performed. The risk management has been performed per ISO 14971 and Cepheid's internal procedure for risk management. The sponsor utilized the Device Hazard Analysis and the Failure Mode Effects Analysis (FMEA) methods to assess the risks of failure that may occur during use or misuse of the device. The FMEA includes potential failure modes and effect of the failure, potential causes, built in design controls and evaluation of severity, frequency of occurrence, and ability to detect the failure. The elements considered include the intended user, environment, human factors/potential human errors, and historical field data from similar devices.

Potential sources of errors that could adversely affect system performance were identified and mitigated first through system design and then through additional cautions in the labeling. The identified risks which could result in erroneous test results were evaluated in flex studies that stressed the functional limits of the test system (see below).

The sponsor provided detailed software validation and verification documentation, including requirements related to assay performance of the Xpert Xpress Flu Assay on the GeneXpert Xpress System. The instrument software was reviewed under the parent 510(k) submissions (K162456 and K171552).

2. Fail-safe and Failure Alert Mechanisms

The Xpert Xpress Flu Assay and the GeneXpert Xpress System was designed to include numerous features and "lockouts" built into the hardware and software to prevent erroneous results.

- Module door will not latch if tube is positioned incorrectly. Incorrect positioning when inserting the cassette can also be detected by force increase and assay will not run. The assay will also not run without a cartridge inserted.
- Module door closes before assay start to block external light, there is also a signal check for light leak.
- Self-check performed by software before assay include: thermal checks for temperature out of range, ultrasonic instrument, cooling rate, heating rate, force sensor for cartridge loading, optics check, syringe drive and valve checks.
- Temperature sensor is designed to prevent the test from proceeding when the ambient temperature is too high, or if the system cannot reach a programmed temperature.

- Calibration is performed by the manufacturer before shipment. The user is directed to run the Xpert Check to determine if any calibration or preventative maintenance needs to be scheduled to be performed by Cepheid service personnel.
- The assay barcode is read once the cartridge is placed inside the instrument:
  - The instrument will not proceed if the assay cartridge has previously been used
  - The instrument will not allow the same sample ID to be entered more than once
  - The instrument will not proceed if the assay cartridge is expired
  - The instrument will not proceed if the assay reagent lot and assay definition file (assay selected) do not match
  - The instrument will not proceed if the assay cartridge used does not exactly match the assay selected on the instrument touchscreen.
- All assay results are locked and cannot be changed by the user. All information about the assay run is automatically saved at the start of the test.
- Only one assay can be started at a time.
- The software provides an instructional video on the procedure for the user to watch.

External Controls

External controls are not provided with this kit. External controls from ZeptoMetrix (catalog #NATCXVA9-6C (Coxsackie virus) as an external negative control, and catalog # NATFLUAB-6C (NATtrol Influenza A/B) as an external positive control) are recommended in the Package Insert.

In-test Controls

- The assay includes a Sample Processing Control (SPC) which ensures the sample was processed correctly. It is composed of Armored RNA and verifies the release of RNA during the extraction procedure and can detect inhibition in the RT-PCR and PCR reactions.
- The assay also includes a Probe Check Control (PCC) which checks the fluorescence signal from the probes before the PCR reaction is started. This monitors bead rehydration, reaction tube filling, probe integrity and dye stability.

Self-checks

The GeneXpert Xpress has an internal function for on-going internal performance monitoring, and if the data indicate that maintenance is required the user will be instructed to contact Cepheid Technical Support, in which case the company will send a support technician to the user.

The functionality of Fail-Safe mechanisms built into the software of the Xpert Xpress Flu Assay on the GeneXpert Xpress System was demonstrated in testing performed and described below.

Table 1. Fail-Safe Mechanisms for Xpert Xpress Flu Assay and GeneXpert Xpress Instrument

	User Action	Expected Results
1	Ambient temperature outside of the instrument specifications (below and above the range limits)	The testing module icon will be greyed out and cannot be selected, indicating that tests cannot be performed. Testing does not proceed
2	Test was stopped before results were obtained.	Test results were reported as "ERROR"
3	User turned off instrument before test was completed and tried to resume the test once the instrument was back on.	Error message: "Cartridge serial number… for assay with product code… lot… has already been used. Cartridges can only be used once. Select a new cartridge." Testing does not proceed
4	User attempted to test a cartridge on an instrument that was past its calibration check.	Expected results obtained.
5	Cartridge reaction tube is missing.	Testing proceeds but "No Result" is obtained.
6	Cartridge reaction tube is broken (not missing).	Testing proceeds but "No Result" is obtained.
7	Non-CLIA-Waived cartridge is used.	Error message: "The … assay is not CLIA-Waived and cannot be run on this system. Select a correct CLIA-Waived cartridge."
8	Incorrect assay definition file (ADF) is loaded on the GeneXpert Xpress tablet.	Error Message: "No assays found for product code. Import assay definition file." Testing does not proceed.
9	Place Sample ID/Patient ID label on top of the cartridge blocking the plunger.	Expected results obtained
10	Cartridge lid not fully closed	Expected results obtained
11	Shake cartridge before opening lid and adding sample.	Expected results obtained
12	Shake cartridge after adding sample.	Expected results obtained
13	Try to start a test using a cartridge that has already been used	Error message: "Cartridge serial number… for assay with product code… lot… has already been used. Cartridges can only be used once. Select a new cartridge." Testing does not proceed
14	Move the GeneXpert Xpress instrument by tilting the instrument during the test.	Expected results obtained

All studies generated the expected error messages or produced valid results confirming the effectiveness of the fail-safe mechanisms built into the analyzer's software.

3. Flex Studies

The operational limits of the device were evaluated in a series of experiments under "stress" conditions of use.

Contrived test samples were used in the flex studies for the Xpert Xpress Flu Assay. Negative samples consisted of one nasal swab added to the Cepheid Transport Medium. Positive samples consist of a combination of Flu A (A/Victoria/361/2011) and Flu B (B/Wisconsin/01/11) viruses at 2X LoD spiked into one nasal swab specimen. The results from each of the flex studies were compared to negative and positive controls in which all cartridges were prepared correctly. All test samples (Negative, Low Positive Flu A, and Low Positive Flu B) were blinded and randomized and tested in five replicates per condition.

The effect of the following conditions on the performance of the assay was evaluated:

Human Factors/Operator Errors

a. Non-level positioning of the GeneXpert Xpress instrument

Three instruments were tilted on a benchtopat <15° and each sample was tested in five individual replicates at each position. No failures were observed and all samples generated expected results.

b. Mishandling of the test cartridge

This study evaluated the potential of invisible damage to the test cartridge when inadvertently dropped or knocked over during the procedure both before and after sample addition to the cartridge.

i. Cartridges were dropped from workbench height onto the floor prior to sample addition. After dropping, each cartridge was tested and all expected results were obtained. There were no false positive or false negative results observed.

ii. Cartridges were dropped from workbench height onto the floor after sample addition. After dropping, each cartridge was tested and all expected results were obtained. There were no false positive or false negative results observed.

c. Varying the sample volume applied to the test strip

This study evaluated the effect of varied sample volume (outside of the 300 µL delivered with the fixed-volume transfer pipette) on the performance of the assay. Seven different volumes were evaluated, ranging from 50 µL to 900 µL. The data

showed that 300 µL to 900 µL sample volumes generate expected results. At the low volume of 50µL (and no sample added) no result was reported and an error message was displayed. At 100µL, for the positive swabs, there was 1/5 negative, 2/5 positive and 2/5 invalid, all negative swabs were invalid. At 150 µL, for the positive swabs, there was 1/5 negative, 2/5 positive and 2/5 invalid, all negative swabs were negative. The likelihood of this error is minimized by the fixed volume pipette that is included with the kit.

d. Improper mixing of the sample

This study evaluated the effect of improper mixing on the performance of the assay. The proper mixing procedure is inversion of the viral transport media tube 5 times. Six different improper mixing techniques were tested: no mixing of the tube, shaking the tube 1,3,7, and 10 times and vortexing the tube for 5 seconds at maximum speed. All samples generated expected results.

e. Incorrect timing of cartridge preparation

The test directions instruct the user to start the test within 30 minutes of adding the sample. Testing was conducted at 60 minutes after adding the sample. All tests generated expected results.

f. Conducting testing with and without nitrile or latex gloves (touchscreen functionality)

Operators attempted to conduct testing and use the instrument touchscreen with no gloves, single or triple layers of either nitrile or latex gloves. All users could easily use the touchscreen and all tests generated expected results.

g. Testing by multiple operators with multiple assays on one GeneXpert Xpress Instrument

A separate field study was conducted using a 4-module instrument with four untrained, inexperienced operators and two different assays. Testing was performed by alternating operators who followed the assay instructions provided in the quick reference instructions. Each operator could run all tests assigned to them and all test runs obtained the expected results.

Specimen Integrity and Handling

h. Incorrect sample storage

Testing was conducted with specimens stored outside the defined temperature conditions and for a longer than recommended storage time. The following conditions were tested: 14 days at -20°C, 48 hours at 35°C, 14 days at 2-8°C, 48

hours at room temperature, 7 days at -20°C and 24 hours at 35°C. All tests generated expected results.

Environmental Factors

a. Operational temperature and humidity

This study was conducted as part of product development testing. The study was designed to evaluate the effect of temperature and humidity outside of the expected normal conditions of use. Temperatures of 20°C and 36°C with humidity up to 95% RH (relative humidity) were examined. The cartridges and instruments were equilibrated to the specified conditions for 2 hours before testing for conditions a and b below. The instrument was abruptly transitioned to the conditions for c and d. The effect of the temperature and humidity was evaluated in different combinations:

a. 95% Relative humidity (RH) at 20°C, 2 hour acclimation
b. 95% Relative humidity (RH) at 36°C, 2 hour acclimation
c. 95% Relative humidity (RH) at 20°C, abrupt transition
d. 95% Relative humidity (RH) at 36°C, abrupt transition

When the instrument could stabilize for 2 hours before testing, all expected results were obtained although there was a 17% increase in time to result. Abrupt transition or exposure to high humidity produced an instrument error where the user could not select a module to start testing, this is part of the Fail-safe mechanisms for this instrument. Once the instrument acclimates the module will be available for testing.

The conducted flex studies demonstrated that the system is robust and is not sensitive to user errors or environmental stresses. The combination of built in fail-safe mechanisms and explicit cautions in the labeling provide adequate controls to ensure that improper use of the device is not likely to yield erroneous results.

L. Demonstrating "Insignificant Risk of an Erroneous Result" - Accuracy

1. Clinical Performance of the Xpert Xpress Flu Assay on the GeneXpert Xpress instrument

The clinical study was conducted in CLIA-Waiver like sites in a Point of Care setting. Each location was assessed by Cepheid to confirm that all testing sites saw patients in the same location where the testing for the study would take place. The operators at each site provided their education level, employment status, years of employment, job title and a summary of daily duties. Personnel who were selected to participate in the study had no professional CLIA moderate or high complexity laboratory work experience. The operators had also never used a Cepheid instrument before this study and received no training on how to set up the instrument or perform the assay. Reasons for personnel not selected to participate in the study were provided. Fourteen (14) sites (12 Emergency Departments and 2 Urgent Care Clinic/Primary Care Offices) were included in the clinical study with 35 users, 25 of which observed at least five positive and five negative samples.

A total of 3610 specimens were enrolled in this clinical study, 29 specimens were ineligible for inclusion because of improper consent documents, 4 previously enrolled subjects and1 subject deemed ineligible by the institutional review board (patient was an employee of the testing site). Of the 3576 eligible specimens, there were 1784 nasal swabs (NS) and 1792 nasopharyngeal (NP) swabs. Each patient provided either an NS specimen or NP swab specimen. For nasal swab specimens, one swab was used to swab both nostrils, only one nostril was swabbed for the NP swab specimen. Specimens were prospectively collected fresh and tested as soon as possible after collection and within 24 hours.

A total of 297 samples were excluded for the following reasons; 235 unresolved comparator result, 6 with invalid comparator assay controls, 17 specimens frozen, 14 shipping problem, 9 incorrect specimen collection, 8 not tested with GX system, 4 run on incorrect assay, and 4 not tested within protocol specified time period. There were a series of samples (47) that had invalid controls for the Xpert Xpress Flu Assay. This occurred when users did not conduct the external controls as directed (each day prior to specimen runs and for each new lot). It was determined that this scenario is reflective of the CLIA-Waived environment and therefore these specimens were not excluded but included in the performance analysis.

There were 3279 eligible specimens evaluated which resulted in 61 indeterminate results (33 NO RESULT and 28 INSTRUMENT ERROR), 59 of those were re-tested to yield 54 valid results from repeat testing. The final indeterminate rate was 0.2% (7/3279).

The total number of eligible samples with valid results was 3272; 54.8% from female subjects and 45.2% from male subjects. The table below shows the distribution of patients by age group and the number of positives for Flu A and Flu B.

Table 2. Number and Percent of Positive Specimens by Age Range[a]

Age Group	Number of Patients	% of Total	Flu A		Flu B	
			Number of Positives	Percent Positive	Number of Positives	Percent Positive
≤5 years	1288	39.4%	141	10.9%	58	4.5%
6-21 years	518	15.8%	133	25.7%	54	10.4%
22-59 years	1142	34.9%	122	10.7%	37	3.2%
≥60 years	324	9.9%	56	17.3%	5	1.5%
Total	3272	100%	452	13.8%	154	4.7%

[a]Six subjects had multi-infections by the Xpert Xpress Flu Assay and are therefore counted more than once in this table. Of the 6 subjects with multi-infections, 1 sample Flu A and Flu B POS by comparator assay; 5 samples NEG for both targets by comparator assay.

Performance with Nasal Swabs and Nasopharyngeal Swabs

Table 3. Clinical Performance for Influenza A, Nasal Swabs

Nasal Swab Specimens (1602 specimens)		Comparator Result	
		Positive	Negative
Xpert Xpress Flu Assay	Positive	186	37
	Negative	2	1377

PPA: 98.9% (95% CI: 96.2%-99.7%)
NPA: 97.4% (95%CI: 96.4%-98.1%)

Table 4. Clinical Performance for Influenza A, Nasopharyngeal Swabs

Nasopharyngeal Swab Specimens (1670 specimens)		Comparator Result	
		Positive	Negative
Xpert Xpress Flu Assay	Positive	200	29
	Negative	5	1436

PPA: 97.6% (95% CI: 94.4%-99.0%)
NPA: 98.0% (95%CI: 97.1%-98.6%)

Table 5. Clinical Performance for Influenza B, Nasal Swabs

Nasal Swab Specimens (1602 specimens)		Comparator Result	
		Positive	Negative
Xpert Xpress Flu Assay	Positive	63	12
	Negative	1	1526

PPA: 98.4% (95% CI: 91.7%-99.7%)
NPA: 99.2% (95%CI: 98.6%-99.6%)

Table. 6. Clinical Performance for Influenza B, Nasopharyngeal Swabs

Nasopharyngeal Swab Specimens (1670 specimens)		Comparator Result	
		Positive	Negative
Xpert Xpress Flu Assay	Positive	71	8
	Negative	2	1589

PPA: 97.3% (95% CI: 90.6%-99.2%)
NPA: 99.5% (95%CI: 99.0%-99.7%)

Table 7. Clinical Performance for Influenza A, All Swabs Combined

Combined Swabs (3272 specimens)		Comparator Result	
		Positive	Negative
Xpert Xpress Flu Assay	Positive	386	66
	Negative	7	2813

PPA: 98.2% (95% CI: 96.4% -99.1%)
NPA: 97.7% (95% CI: 97.1% -98.2%)

Table 8. Clinical Performance for Influenza B, All Swabs Combined

Combined Swabs (3272 specimens)		Comparator Result	
		Positive	Negative
Xpert Xpress Flu Assay	Positive	134	20
	Negative	3	3115

PPA: 97.8% (95% CI: 93.8% -99.3%)
NPA: 99.4% (95% CI: 99.0% -99.6%)

2. Performance with Analyte Concentrations Near the Assay Cutoff:

A study was conducted at three geographically diverse CLIA waived healthcare provider sites. The study was designed to evaluate the ability of untrained operators in CLIA waived settings to obtain accurate results with weakly positive samples when testing with the Xpert Xpress Flu Assay on the GeneXpert Xpress instrument. A total of 9 operators participated in the study (3 operators each at three sites) none of which had previous laboratory experience. The study was conducted over a period of eleven days.

The operators were non-laboratorian personnel and included research assistants, coding specialist and research coordinator. The work experience of the operators ranged from <0.5 years to 5 years and their education level ranged from high school to college; none of the operators had experience with diagnostic testing other than simple CLIA waived tests. The operators performed the testing using the Quick Reference Instructions; no additional training was provided to the operators.

Each operator tested a coded panel of individual samples contrived at virus concentrations near the assay cutoff. The test samples were contrived by spiking inactivated strains of influenza A and influenza B into negative simulated clinical matrix. The selected virus strains were diluted with the simulated clinical matrix to concentrations targeting the LoD of the assay. Five samples were prepared: a low positive sample for influenza A, a low positive sample for influenza B, a moderate positive sample for influenza A, a moderate positive sample for influenza B, and a negative sample which consisted of the unspiked simulated clinical matrix.

All samples were coded and the operators at each site tested 30 replicates of each sample (a total of 90 samples per level across the 3 sites). The samples were blinded and randomized and the testing was incorporated into the daily workflow of each testing site.

Testing of 9 samples was repeated due to invalid results; 8 samples generated a valid result on the repeat testing and are included in the calculations of agreement with expected results.

Table 10: Performance of the Xpert Xpress Flu Assay Testing Samples at Virus Concentrations Near the Assay Cutoff

Percent Agreement with Expected Results					
Sample Type	**Site 1**	**Site 2**	**Site 3**	**Overall**	**Overall 95% CI**
Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.1% - 100%
Influenza A Low Positive	96.7% (29/30)	90% (27/30)	86.2% (25/29)	91.0% (81/89)	86.3% -95.4 %
Influenza A Moderate Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.1% - 100%
Influenza B Low Positive	93.3% (28/30)	96.7% (29/30)	90.0% (27/30)	93.3% (84/90)	86.2% - 96.9%
Influenza B Moderate Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.1% - 100%

There were no significant differences in the observed positivity of the device with weakly positive samples between operators, between sites and between the two operational modes. All negative samples yielded expected results at all three sites for all operators. The study results demonstrated that untrained operators could perform the test correctly and the test provided the expected results for samples with virus concentrations near the assay cutoff. It is acceptable that there was not >95% agreement with expected results for the low positive samples because the LoD of this assay is at least 10X below the virus titer that is seen in clinical specimens.

3. Quick Reference Instructions (QRI)

The QRI was reviewed in detail to ensure that the directions are clear and easy to understand and that all precautions are included as appropriate. The QRI for the use of the test with either one of the instruments is written in simple language (at 7th grade reading level) and contains pictorial descriptions of the individual steps. Additionally, the instrument software gives the user the option to watch an instructional video on how to prepare the sample and perform the test. The interpretation of results is simple and easy to understand. The results are reported in different colors (red for positive and green for negative) to make the display and results interpretation more user-friendly.

4. Operator Questionnaire Results:

   At the end of the study each operator was given an operator questionnaire to provide feedback on the ease of use of the GeneXpert Xpress instrument and the Xpert Xpress Assay. All but two operators took the survey. The two operators who did not take the survey left employment at the site before the end of the study. Based on the operator feedback, they found the on-screen instructions and initiating a test easy and simple. Users also found the Quick Reference Instructions and package insert easy to understand and follow.

M. Conclusion:

The submitted information in this CLIA waiver application supports a CLIA Waiver approval decision.