DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 13, 2017

Cepheid
Jim Kelly, PhD
Executive Director, Regulatory Affairs
904 Caribbean Drive
Sunnyvale, CA 94089

Re: K162456
Trade/Device Name: Xpert® Xpress Flu Assay
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: II
Product Code: OCC, OOI, JSM
Dated: January 10, 2017
Received: January 11, 2017

Dear Dr. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Steven R. Gitterman -S

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162456

Device Name

Xpert Xpress Flu

Indications for Use *(Describe)*

The Cepheid Xpert® Xpress Flu Assay, performed on the GeneXpert® Instrument Systems, is an automated, multiplex real-time, reverse transcriptase polymerase chain reaction (RT-PCR) assay intended for the *in vitro* qualitative detection and differentiation of influenza A and influenza B viral RNA. The Xpert Xpress Flu Assay uses nasopharyngeal (NP) swab specimens collected from patients with signs and symptoms of respiratory infection. The Xpert Xpress Flu Assay is intended as an aid in the diagnosis of influenza infections in conjunction with clinical and epidemiological risk factors.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2015-2016 influenza season. When other novel influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Ancillary Collection Kit Indications for Use:

The Xpert® Nasopharyngeal Sample Collection Kit is designed to collect, preserve, and transport nasopharyngeal swab specimens and to preserve and transport nasal aspirate/wash specimens containing viruses from patients with signs and symptoms of respiratory infection prior to analysis with the Xpert Flu Assay or the Xpert Flu/RSV XC Assay.

The Xpert® Nasopharyngeal Sample Collection Kit is designed to collect, preserve, and transport nasopharyngeal swab specimens containing viruses from patients with signs and symptoms of respiratory infection prior to analysis with the Xpert Flu+RSV Xpress Assay, Xpert Xpress Flu/RSV Assay or the Xpert Xpress Flu Assay.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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8.0 510(k) Summary

As required by 21 CFR Section 807.92(c).

Submitted by:	Cepheid 904 Caribbean Drive Sunnyvale, CA 90489 Phone number: (847) 228-3299 Fax number: (847) 890-6589
Contact:	Scott A. Campbell, PhD, MBA
Date of Preparation:	September 01, 2016
Device:	
Trade name:	Xpert® Xpress Flu
Common name:	Xpert Xpress Flu Assay
Type of Test:	Automated, multiplex real-time reverse transcription-polymerase chain reaction (RT-PCR) assay intended for the *in vitro* qualitative detection and differentiation of influenza A and influenza B viral RNA.
Regulation number/ Classification name/ Product code:	866.3980/Respiratory viral panel multiplex nucleic acid assay/OCC 866.2570/Instrumentation for clinical multiplex test systems/OOI 866.2390/Culture Media, Non-Propagating Transport
Classification Advisory Panel	Class II Microbiology (83)
Prescription Use	Yes
Predicate Devices Assay:	1) *For the detection and differentiation of influenza A, influenza B, and RSV A/B viral RNA in nasopharyngeal swab specimens:* Xpert® Flu/RSV XC Assay [510(k) #K142045] 2) *For the Sample Collection Kits:* Cepheid Xpert® Nasopharyngeal Sample Collection Kit [510(k) # K151226]

Device Description:

The Xpert Xpress Flu Assay is a rapid, automated *in vitro* diagnostic test for qualitative detection and differentiation of influenza A (Flu A) and influenza B (Flu B) viral RNA directly from nasopharyngeal (NP) swab specimens. The assay is performed on the Cepheid GeneXpert® Instrument Systems.

The Xpert Xpress Flu Assay includes reagents for the simultaneous detection and differentiation of the target viruses. The primers and probes in the Xpert Xpress Flu Assay detect the presence of nucleic acid sequences for Flu A and Flu B directly from NP swab specimens collected from patients with signs and symptoms of respiratory infection. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are internal controls utilized by the GeneXpert Instrument System platform. The SPC is present in every assay to control for adequate processing of the target viruses and to monitor for the presence of inhibitor(s) in the PCR assay to avoid false-negative results. The PCC verifies reagent rehydration, real-time PCR tube filling in the cartridge, probe integrity, and dye stability.

The specimens are collected in viral transport medium and transported to the GeneXpert area. The specimen is prepared according to package insert instructions and transferred to the sample chamber (large opening) of the Xpert Xpress Flu Assay cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off automated sample processing and real-time RT-PCR for detection of Flu viral RNA. Summary and detailed test results are obtained in approximately 30 minutes or less. The results are automatically generated at the end of the process in a report that can be viewed and printed.

Device Intended Use:

The Cepheid Xpert® Xpress Flu Assay, performed on the GeneXpert® Instrument Systems, is an automated, multiplex real-time, reverse transcriptase polymerase chain reaction (RT-PCR) assay intended for the *in vitro* qualitative detection and differentiation of influenza A and influenza B viral RNA. The Xpert Xpress Flu Assay uses nasopharyngeal (NP) swab specimens collected from patients with signs and symptoms of respiratory infection. The Xpert Xpress Flu Assay is intended as an aid in the diagnosis of influenza infections in conjunction with clinical and epidemiological risk factors.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2015-2016 influenza season. When other novel influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Ancillary Specimen Collection Kit

The Xpert® Nasopharyngeal Sample Collection Kit is designed to collect, preserve, and transport nasopharyngeal swab specimens and to preserve and transport nasal aspirate/wash specimens containing viruses from patients with signs and symptoms of

respiratory infection prior to analysis with the Xpert Flu Assay or the Xpert Flu/RSV XC Assay.

The Xpert® Nasopharyngeal Sample Collection Kit is designed to collect, preserve, and transport nasopharyngeal swab specimens containing viruses from patients with signs and symptoms of respiratory infection prior to analysis with the Xpert Flu+RSV Xpress Assay, Xpert Xpress Flu/RSV Assay or the Xpert Xpress Flu Assay.

Substantial Equivalence**:**

The Xpert Xpress Flu Assay is substantially equivalent to the current Xpert® Flu/RSV XC Assay [510(k) #K142045]. The Xpert Xpress Flu Assay detects influenza A and influenza B from nasopharyngeal (NP) swab specimens and the Xpert® Flu/RSV XC Assay detects influenza A, influenza B, and RSV from both NP swab specimens and nasal aspirate/wash (NA/W) specimens. Both assays utilize the same technology by determining the presence of the target organisms through real-time RT-PCR amplification and fluorogenic target-specific hybridization detection. A multi-center clinical study was conducted and obtained data using the Xpert Xpress Flu/RSV Assay which was then reanalyzed with the Xpert Xpress Flu Assay Definition File (ADF). The reanalyzed data was used to determine the performance characteristics of the Xpert Xpress Flu Assay relative to the predicate device, which has been FDA cleared for NP swab and NA/W specimens. Discordant results between the Xpert Xpress Flu Assay and the reference method Prodesse ProFlu+ Assay [510(k) #K132129] were analyzed by bi-directional sequencing using primers different from those used in the Xpert Xpress Flu Assay. The study results showed that the Xpert Xpress Flu Assay is substantially equivalent to the predicate device.

Table 8-1 shows the similarities and differences between the Xpert Xpress Flu Assay and the predicate device.

Table 8-1: Comparison of Similarities and Differences of the Xpert Xpress Flu Assay with the Predicate Device

Similarities		
	Device	**Predicate**
Item	**Cepheid Xpert® Xpress Flu**	**Cepheid Xpert® Flu/RSV XC 510(k)# K142045**
Regulation	866.3980	Same
Product Code	OCC, OOI	Same
Device Class	II	Same
Technology Principle of Operation	Multiplex real time RT-PCR	Same
Intended Use	The Cepheid Xpert® Xpress Flu Assay, performed on the GeneXpert® Instrument Systems, is an automated, multiplex real-time, reverse transcriptase polymerase chain reaction (RT-PCR) assay intended for the *in vitro* qualitative detection and differentiation of influenza A and influenza B viral RNA. The Xpert Xpress Flu Assay uses nasopharyngeal (NP) swab specimens collected from patients with signs and symptoms of respiratory infection. The Xpert Xpress Flu Assay is intended as an aid in the diagnosis of influenza infections in conjunction with clinical and epidemiological risk factors. Negative results do not preclude influenza virus infection and should not be	The Cepheid Xpert® Flu/RSV XC Assay is an automated, multiplex real-time, reverse transcriptase polymerase chain reaction (RT-PCR) assay intended for the *in vitro* qualitative detection and differentiation of influenza A, influenza B, and respiratory syncytial virus (RSV) viral RNA. The Xpert Flu/RSV XC Assay uses nasopharyngeal swab and nasal aspirate/wash specimens collected from patients with signs and symptoms of respiratory infection. The Xpert Flu/RSV XC Assay is intended as an aid in the diagnosis of influenza and respiratory syncytial virus infections in conjunction with clinical and epidemiological risk factors. Negative results do not

Similarities		
	Device	**Predicate**
Item	**Cepheid Xpert® Xpress Flu**	**Cepheid Xpert® Flu/RSV XC 510(k)# K142045**
	used as the sole basis for treatment or other patient management decisions. Performance characteristics for influenza A were established during the 2015-2016 influenza season. When other novel influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	preclude influenza virus or respiratory syncytial virus infection and should not be used as the sole basis for treatment or other patient management decisions. Performance characteristics for influenza A were established during the 2013-2014 influenza season. When other novel influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Similarities		
	Device	**Predicate**
Item	**Cepheid Xpert® Xpress Flu**	**Cepheid Xpert® Flu/RSV XC 510(k)# K142045**
Indications for Use	Patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors	Same
Nucleic Acid Extraction	Yes	Same
Extraction Methods	Sample preparation integrated in GeneXpert Cartridge and GeneXpert Instrumentation System	Same
Assay Results	Qualitative	Same
Instrument System	Cepheid GeneXpert Instrument Systems; same Cepheid I-core technology	Same
Primers and probes	Primers and probes to detect the presence of nucleic acid sequences of influenza A, influenza B, and RSV. Only results for influenza A and influenza B are reported.	Primers and probes to detect the presence of influenza A, influenza A subtype H7N9, influenza B and RSV. Results for influenza A, influenza B and RSV analytes are reported.
Laboratory Users	Laboratory users in moderate and high complexity laboratory settings.	Same
Sample Preparation	Self-contained and automated after mixed specimen is added to cartridge. All other reagents are contained in the cartridge.	Same

Similarities		
	Device	**Predicate**
Item	**Cepheid Xpert® Xpress Flu**	**Cepheid Xpert® Flu/RSV XC 510(k)# K142045**
Primers and probes for influenza A, influenza B	Primers and probes to detect the presence of nucleic acid sequences of influenza A, influenza B, and RSV A/B. The Xpert Xpress Flu Assay contains primers and probes to detect additional RNA segments in order to protect the assay sensitivity and specificity from mutations in the influenza genome due to antigenic drifts and shifts. Only results for influenza A and influenza B are reported.	Primers and probes to detect the presence of nucleic acid sequences of influenza A, influenza B, and RSV A/B. The Xpert Flu/RSV XC Assay contains primers and probes to detect additional RNA segments in order to protect the assay sensitivity and specificity from mutations in the influenza genome due to antigenic drifts and shifts.
Target Sequences	Influenza A: Matrix protein (MP),basic polymerase (PB2) and acidic protein (PA) Influenza B: Matrix protein (MP) and Non-structural proteins (NS 1 and NS 2) RSV A and RSV B: Nucleocapsid protein Only results for influenza A and influenza B are reported.	Influenza A: Matrix protein (MP),basic polymerase (PB2) and acidic protein (PA) Influenza B: Matrix protein (MP) and Non-structural proteins (NS 1 and NS 2) RSV A and RSV B: Nucleocapsid protein
Internal Controls	Sample processing control (SPC) and probe check control (PCC).	Same
Early assay termination function	Yes	Yes

Differences		
	Device	**Predicate**
Item	**Cepheid Xpert® Xpress Flu**	**Cepheid Xpert® Flu/RSV XC**
Assay Targets	Influenza A Virus and Influenza B Virus viral RNA	Influenza A Virus, Influenza B Virus, and RSV viral RNA
Specimen Types	Nasopharyngeal (NP) swab specimens	Nasal aspirate/wash (NA/W) specimens and Nasopharyngeal (NP) swab specimens
Assay Controls	Encapsulated (armored) RNA pseudovirus as a sample processing control. Available but not provided are inactivated virus controls for influenza A/B as external positive controls, and Coxsackie virus as an external negative control.	Encapsulated (armored) RNA pseudovirus as a sample processing control. Available but not provided are inactivated virus controls for influenza A/B and RSV as external positive controls, and Coxsackie virus as an external negative control.
Time to obtain test results	Approximately 30 minutes or less for sample preparation and RT-PCR	Approximately 60 minutes or less for sample preparation and RT-PCR
Combinatorial Assay Selections	Not applicable	Yes, user may select combined assay with all targets or a Flu only assay or a RSV only assay.

The Xpert Xpress Flu Assay and the predicate device have the same general intended use and technological characteristics, and both detect influenza A and influenza B viral RNA from NP swab specimens. The clinical study demonstrates that the Xpert Xpress Flu Assay is substantially equivalent to the predicate device.

The predicate device for the ancillary specimen collection kit, the Xpert® Nasopharyngeal Sample Collection Kit is the Cepheid Nasopharyngeal Sample Collection Kit, [510(k) # K151226]. The similarities and differences are shown in Table 8-2.

Table 8-2: Comparison of Similarities and Differences of the Xpert Nasopharyngeal Sample Collection Kit with the Predicate Device

Similarities		
	Device	**Predicate**
Item	**Xpert® Nasopharyngeal Sample Collection Kit**	**Xpert® Nasopharyngeal Sample Collection Kit 510(k)# K151226**
Intended Use	The Xpert® Nasopharyngeal Sample Collection Kit is designed to collect, preserve, and transport nasopharyngeal swab specimens and to preserve and transport nasal aspirate/wash specimens containing viruses from patients with signs and symptoms of respiratory infection prior to analysis with the Xpert Flu Assay or the Xpert Flu/RSV XC Assay. The Xpert® Nasopharyngeal Sample Collection Kit is designed to collect, preserve, and transport nasopharyngeal swab specimens containing viruses from patients with signs and symptoms of respiratory infection prior to analysis with the Xpert Flu+RSV Xpress Assay, Xpert Xpress Flu/RSV Assay or the Xpert Xpress Flu Assay.	The Xpert® Nasopharyngeal Sample Collection Kit is designed to collect, preserve, and transport nasopharyngeal swab specimens and to preserve and transport nasal aspirate/wash specimens containing viruses from patients with signs and symptoms of respiratory infection prior to analysis with the Xpert Flu Assay or the Xpert Flu/RSV XC Assay. The Xpert® Nasopharyngeal Sample Collection Kit is designed to collect, preserve, and transport nasopharyngeal swab specimens containing viruses from patients with signs and symptoms of respiratory infection prior to analysis with the Xpert Flu+RSV Xpress Assay.
Single-use Device	Yes	Same

Similarities		
	Device	**Predicate**
Item	**Xpert® Nasopharyngeal Sample Collection Kit**	**Xpert® Nasopharyngeal Sample Collection Kit 510(k)# K151226**
Transport Medium Formulation	Hank's Balanced Salt Solution Bovine Serum Albumin L-cysteine Gelatin Sucrose L-glutamic acid HEPES buffer Vancomycin Amphotericin B Colistin Phenol red	Same
pH	7.3 $\pm$ 0.2	Same
Storage Temperature	2 - 25^{o}C (refrigerated and room temperature)	Same
Volume	3 ml	Same
Glass Beads	3 x 3 mm	Same
Container	Plastic (medical-grade polypropylene)	Same
Product Configuration	Medium Tube in Kit with individually-wrapped sterile swab.	Same

Differences		
	Device	**Predicate**
Item	**Xpert® Nasopharyngeal Sample Collection Kit**	**Xpert® Nasopharyngeal Sample Collection Kit 510(k)# K151226**
Intended Use	For collection, preservation and transport of nasopharyngeal swab specimens and to preserve and transport nasal aspirate/wash specimens containing viruses from patients with signs and symptoms of respiratory infection prior to analysis with the Xpert Flu Assay, Xpert Flu/RSV XC Assay, Xpert Flu+RSV Xpress Assay, Xpert Xpress Flu/RSV Assay and Xpert Xpress Flu Assay.	For collection, preservation and transport of nasopharyngeal swab specimens and to preserve and transport nasal aspirate/wash specimens containing viruses from patients with signs and symptoms of respiratory infection prior to analysis with the Xpert Flu Assay, Xpert Flu/RSV XC Assay and Xpert Flu+RSV Xpress Assay.

The proposed collection kit and predicate collection kit have the same general intended use and the same technology to collect, store and transport clinical specimens, including viruses, to the laboratory for further testing. The prospective component of the multi-center clinical study of the Xpert Xpress Flu Assay was conducted using Xpert Nasopharyngeal Sample Collection Kit [510(k) # K151226] demonstrating that the Xpert Nasopharyngeal Sample Collection Kit is substantially equivalent to the predicate device.

Non-Clinical Studies:

Analytical Sensitivity (Limit of Detection)

Studies were performed to determine the analytical limit of detection (LoD) of the Xpert Xpress Flu Assay with two lots of reagents across three testing days. The higher LoD

observed per strain and per lot as determined by probit analysis was selected for verification. Verification of the estimated LoD claim was performed on one reagent lot across a minimum of three testing days. LoD was established using two influenza A H3N2 strains, two influenza A 2009 H1N1 strains and two influenza B strains. Viruses were diluted into negative pooled NP swab clinical matrix for testing. The LoD is defined as the lowest concentration (tissue culture infective dose, $TCID_{50}$/mL) per sample that can be reproducibly distinguished from negative samples with 95% confidence or the lowest concentration at which 19 of 20 replicates were positive. Each strain was tested in replicates of 20 per concentration of virus. The LoD values for each strain tested are summarized in Tables 8-3 – 8-5.

Table 8-3 Confirmed LoD (TCID50/mL): Influenza A 2009 H1N1

Virus Strain	Confirmed LoD ($TCID_{50}$/mL)
Influenza A/California/7/2009	0.02
Influenza A/Florida/27/2011	0.04

Table 8-4 Confirmed LoD ($TCID_{50}$/mL): Influenza A H3N2

Virus Strain	Confirmed LoD ($TCID_{50}$/mL)
Influenza A/Perth/16/2009	0.01
Influenza A/Victoria/361/2011	0.75

Table 8-5 Confirmed LoD ($TCID_{50}$/mL): Influenza B

Virus Strain	Confirmed LoD ($TCID_{50}$/mL)
Influenza B/Mass/2/2012	0.40
Influenza B/Wisconsin/01/2011	0.19

Analytical Specificity (Exclusivity)

The analytical specificity of the Xpert Xpress Flu Assay was evaluated by testing a panel of 44 cultures consisting of 16 viral, 26 bacterial, and two yeast strains representing common respiratory pathogens or those potentially encountered in the nasopharynx. Three replicates of each bacterial and yeast strain were tested at concentrations of $\geq 1 \times 10^6$ CFU/mL with the exception of one strain that was tested at 1×10^5 CFU/mL (*Chlamydia pneumoniae*). Three replicates of each virus were tested at concentrations of $\geq 1 \times 10^5$ $TCID_{50}$/mL. The analytical specificity was 100%. Results are shown in Table 8-6.

Table 8-6 Analytical Specificity of the Xpert Xpress Flu Assay

Organism	Concentration (per cartridge)	Result	
		Influenza A	Influenza B
No Template Control	N/A	NEG	NEG
Adenovirus Type 1	1.12E+06 $TCID_{50}$/mL	NEG	NEG
Adenovirus Type 7	1.87E+05 $TCID_{50}$/mL	NEG	NEG
Human coronavirus OC43	2.85E+05 $TCID_{50}$/mL	NEG	NEG
Human coronavirus 229E	1.00E+05 $TCID_{50}$/mL	NEG	NEG
Cytomegalovirus	1.00E+05 $TCID_{50}$/mL	NEG	NEG
Echovirus	3.31E+07 $TCID_{50}$/mL	NEG	NEG
Enterovirus	3.55E+05 $TCID_{50}$/mL	NEG	NEG
Epstein Barr Virus	7.16E+07 $TCID_{50}$/mL	NEG	NEG
HSV	8.90E+05 $TCID_{50}$/mL	NEG	NEG
Measles	6.31E+05 $TCID_{50}$/mL	NEG	NEG
Human metapneumovirus	1.00E+05 $TCID_{50}$/mL	NEG	NEG
Mumps virus	6.31E+06 $TCID_{50}$/mL	NEG	NEG
Human parainfluenza Type 1	1.15E+06 $TCID_{50}$/mL	NEG	NEG
Human parainfluenza Type 2	6.31E+05 $TCID_{50}$/mL	NEG	NEG
Human parainfluenza Type 3	3.55E+06 $TCID_{50}$/mL	NEG	NEG
Rhinovirus Type 1A	1.26E+05 $TCID_{50}$/mL	NEG	NEG
Acinetobacter baumannii	1.00E+06 CFU/mL	NEG	NEG
Burkholderia cepacia	3.30E+06 CFU/mL	NEG	NEG
Candida albicans	3.20E+06 CFU/mL	NEG	NEG
Candida parapsilosis	3.00E+06 CFU/mL	NEG	NEG
Bordetella pertussis	3.30E+06 CFU/mL	NEG	NEG
Chlamydia pneumoniae	1.00E+05 CFU/mL	NEG	NEG
Citrobacter freundii	3.30E+06 CFU/mL	NEG	NEG
Corynebacterium sp.	3.30E+06 CFU/mL	NEG	NEG
Escherichia coli	1.00E+07 CFU/mL	NEG	NEG
Enterococcus faecalis	1.30E+06 CFU/mL	NEG	NEG
Haemophilus influenzae	1.00E+06 CFU/mL	NEG	NEG
Lactobacillus reuteri	1.00E+06 CFU/mL	NEG	NEG
Legionella spp.	1.00E+06 CFU/mL	NEG	NEG
Moraxella catarrhalis	1.00E+07 CFU/mL	NEG	NEG

Organism	Concentration (per cartridge)	Result	
		Influenza A	Influenza B
Mycobacterium tuberculosis (avirulent)	1.00E+06 CFU/mL	NEG	NEG
Mycoplasma pneumoniae	1.00E+06 CFU/mL	NEG	NEG
Neisseria meningitidis	2.15E+06 CFU/mL	NEG	NEG
Neisseria mucosa	1.00E+07 CFU/mL	NEG	NEG
Propionibacterium acnes	2.40E+07 CFU/mL	NEG	NEG
Pseudomonas aeruginosa	3.70E+06 CFU/mL	NEG	NEG
*Staphylococcus aureus (*protein A producer)	2.20E+06 CFU/mL	NEG	NEG
Staphylococcus epidermidis	3.40E+06 CFU/mL	NEG	NEG
Staphyloccus haemolyticus	4.00E+06 CFU/mL	NEG	NEG
Streptococcus agalactiae	3.50E+06 CFU/mL	NEG	NEG
Streptococcus pneumoniae	1.00E+06 CFU/mL	NEG	NEG
Streptococcus pyogenes	1.00E+07 CFU/mL	NEG	NEG
Streptococcus salivarius	1.00E+07 CFU/mL	NEG	NEG
Streptococcus sanguinis	3.10E+06 CFU/mL	NEG	NEG

Analytical Reactivity (Inclusivity)

The analytical reactivity of the Xpert Xpress Flu Assay was evaluated against multiple strains of influenza A H1N1 (seasonal pre-2009), influenza A H1N1 (pandemic 2009), influenza A H3N2 (seasonal), avian influenza A (H5N1, H5N2, H6N2, H7N2, H7N3, H2N2, H7N9, and H9N2) and influenza B (representing strains from both Victoria and Yamagata lineages) at levels near the analytical LoD. A total of 48 strains comprised of 35 influenza A and 13 Influenza B strains were tested in this study with the Xpert Xpress Flu Assay. Three replicates were tested for each strain. All Flu strains tested positive in all three replicates, except for one Flu A H1N1 strain (A/New Jersey/8/76), which tested positive in 2 of 3 replicates at 0.1 $TCID_{50}$/mL. Results are shown in Table 8-7.

Further *in silico* analysis was conducted to determine the predicted cross reactivity of additional influenza A 2009 H1N1-like strains. The results showed 100% sequence homology for all primer target nucleotide sequences analyzed.

Table 8-7 Analytical Reactivity (Inclusivity) of the Xpert Xpress Flu Assay

Virus	Strain	Target Concentration	Result	
			Flu A	Flu B
No Template Control		n/a	NEG	NEG
Influenza A H1N1 (pre-2009)	A/swine/Iowa/15/30	0.1 $TCID_{50}$/mL	POS	NEG
	A/WS/33	0.1 $TCID_{50}$/mL	POS	NEG
	A/PR/8/34	0.1 $TCID_{50}$/mL	POS	NEG
	A/Mal/302/54	0.1 $TCID_{50}$/mL	POS	NEG
	A/Denver/1/57	0.1 $TCID_{50}$/mL	POS	NEG
	A/New Jersey/8/76	0.1 $TCID_{50}$/mL	POS	NEG
	A/New Caledonia/20/1999	0.1 $TCID_{50}$/mL	POS	NEG
	A/New York/55/2004	0.1 $TCID_{50}$/mL	POS	NEG
	A/Soloman Island/3/2006	0.1 $TCID_{50}$/mL	POS	NEG
	A/Taiwan/42/06	0.1 $TCID_{50}$/mL	POS	NEG
	A/Brisbane/59/2007	0.1 $TCID_{50}$/mL	POS	NEG
Influenza A H1N1 (pdm2009)	A/swine/NY/02/2009	0.1 $TCID_{50}$/mL	POS	NEG
	A/Colorado/14/2012	0.1 $TCID_{50}$/mL	POS	NEG
	A/Washington/24/2012	0.1 $TCID_{50}$/mL	POS	NEG
Influenza A H3N2 (Seasonal)	A/Aichi/2/68	2.0 $TCID_{50}$/mL	POS	NEG
	A/HongKong/8/68	2.0 $TCID_{50}$/mL	POS	NEG
	A/Port Chalmers/1/73	2.0 $TCID_{50}$/mL	POS	NEG
	A/Hawaii/15/2001	2.0 $TCID_{50}$/mL	POS	NEG
	A/Wisconsin/67/05	2.0 $TCID_{50}$/mL	POS	NEG
	A/Brisbane/10/2007	2.0 $TCID_{50}$/mL	POS	NEG
	A/Minnesota/11/2010 (H3N2)v	2.0 $TCID_{50}$/mL	POS	NEG
	A/Indiana/08/2011 (H3N2)v	2.0 $TCID_{50}$/mL	POS	NEG
	A/Texas/50/2012	2.0 $TCID_{50}$/mL	POS	NEG

Virus	Strain	Target Concentration	Result	
			Flu A	Flu B
Avian influenza A	A/duck/Hunan/795/2002 (H5N1)	≤ 1ρg/μL[a]	POS	NEG
	A/chicken/Hubei/327/2004 (H5N1)	≤ 1ρg/μL[a]	POS	NEG
	A/Anhui/01/2005 (H5N1)	≤ 1ρg/μL[a]	POS	NEG
	A/Japanese white eye/ HongKong/ 1038/2006 (H5N1)	≤ 1ρg/μL[a]	POS	NEG
	A/mallard/WI/34/75 (H5N2)	≤ 1ρg/μL[a]	POS	NEG
	A/chicken/CA431/00 (H6N2)	≤ 1ρg/μL[a]	POS	NEG
	A/duck/LTC-10-82743/1943 (H7N2)	≤ 1ρg/μL[a]	POS	NEG
	A/chicken/NJ/15086-3/94 (H7N3)	≤ 1ρg/μL[a]	POS	NEG
	A/Anhui/1/2013 (H7N9)	N/A[b]	POS	NEG
	A/Shanghai/1/2013 (H7N9)	N/A[b]	POS	NEG
	A/chicken/Korea/38349-p96323/ 1996 (H9N2)	≤ 1ρg/μL[a]	POS	NEG
	A/Mallard/NY/6750/78 (H2N2)	≤ 1ρg/μL[a]	POS	NEG
Influenza B	B/Lee/40	1.0 $TCID_{50}$/mL	NEG	POS
	B/Allen/45	1.0 $TCID_{50}$/mL	NEG	POS
	B/GL/1739/54	1.0 $TCID_{50}$/mL	NEG	POS
	B/Maryland/1/59	1.0 $TCID_{50}$/mL	NEG	POS
	B/Panama/45/90[c]	1.0 $TCID_{50}$/mL	NEG	POS
	B/Florida/07/2004[d]	1.0 $TCID_{50}$/mL	NEG	POS
	B/Florida/02/06[c]	1.0 $TCID_{50}$/mL	NEG	POS
	B/Florida/04/06[d]	1.0 $TCID_{50}$/mL	NEG	POS
	B/Hong Kong/5/72	1.0 $TCID_{50}$/mL	NEG	POS
	B/Wisconsin/01/2010[d]	1.0 $TCID_{50}$/mL	NEG	POS
	B/Malaysia/2506/04[c]	1.0 $TCID_{50}$/mL	NEG	POS
	B/Taiwan/2/62	1.0 $TCID_{50}$/mL	NEG	POS
	B/Brisbane/60/2008[c]	1.0 $TCID_{50}$/mL	NEG	POS

a. Purified viral RNA in simulated background matrix was used for avian influenza A viruses due to biosafety regulations.
b. Inactivated avian influenza A (H7N9) viruses without viral titer was diluted 100,000 fold in simulated background matrix and tested due to biosafety regulations.
c. Known Victoria lineage.
d. Known Yamagata lineage.

Potentially Interfering Substances

In a non-clinical study, potentially interfering substances that may be present in the nasopharynx were evaluated directly relative to the performance of the Xpert Xpress Flu Assay. Potentially interfering substances in the nasopharynx may include, but are not limited to: blood, nasal secretions or mucus, and nasal and throat medications used to relieve congestion, nasal dryness, irritation, or asthma and allergy symptoms, as well as antibiotics and antivirals. Negative samples (n = 8) were tested per each substance to determine the effect on the performance of the sample processing control (SPC). Positive samples (n = 8) were tested per substance with six influenza (four influenza A and two influenza B) strains spiked at 3X the analytical LoD determined for each strain. All results were compared to positive and negative simulated nasal matrix controls. The simulated nasal matrix consisted of 2.5% (w/v) porcine mucin, 1% (v/v) human whole blood in 0.85% sodium chloride (NaCl) formulated in 1x PBS solution with 15% glycerol, which was then diluted 1:5 in UTM.

The evaluated substances are listed in Table 8-8 with active ingredients and concentrations tested shown. None of the substances caused interference of the assay at the concentrations tested in this study. All positive and negative replicates were identified correctly using the Xpert Xpress Flu Assay.

Table 8-8 Potentially Interfering Substances in the Xpert Xpress Flu Assay

Substance/Class	Description/Active Ingredient	Concentration Tested
Control	Simulated nasal matrix	100% (v/v)
Beta-adrenergic bronchodilator	Albuterol Sulfate	0.83 mg/mL (equivalent to 1 dose per day)
Blood	Blood (Human)	2% (v/v)
BD™ Universal Viral Transport System	Transport Media	100% (v/v)
Remel M4®	Transport Media	100% (v/v)
Remel M4RT®	Transport Media	100% (v/v)
Remel M5®	Transport Media	100% (v/v)
Remel M6®	Transport Media	100% (v/v)
Throat lozenges, oral anesthetic and analgesic	Benzocaine, Menthol	1.7 mg/mL
Mucin	Purified Mucin protein (Bovine or porcine submaxillary gland)	2.5% (w/v)
Antibiotic, nasal ointment	Mupirocin	10 mg/mL
Saline Nasal Spray	Sodium Chloride (0.65%)	15% (v/v)
Anefrin Nasal Spray	Oxymetazoline, 0.05%	15% (v/v)
PHNY Nasal Drops	Phenylephrine, 0.5%	15% (v/v)
Tamiflu Anti-viral drugs	Zanamivir	7.5 mg/mL
Antibacterial, systemic	Tobramycin	4 µg/mL
Zicam Nasal Gel	Luffa opperculata, Galphimia glauca, Histaminum hydrochloricum Sulfur	15% (w/v)
Nasal corticosteroid	Fluticasone Propionate	5 µg/mL

Carry-Over Contamination

A study was conducted to demonstrate that single-use, self-contained GeneXpert cartridges prevent carry-over contamination of negative samples when followed by very high positive samples in the same GeneXpert module. The study consisted of a negative sample processed in the same GeneXpert module immediately followed by a very high influenza A sample (A/Victoria/361/2011, $2x10^7$ $TCID_{50}$/mL) spiked into a simulated nasal matrix. This testing scheme was repeated 20 times for a total of 41 runs resulting in 20 positive and 21 negative specimens for each virus type. All 20 positive samples were correctly reported as Flu A POSITIVE; Flu B NEGATIVE. All 21 negative samples were correctly reported as Flu A NEGATIVE; Flu B NEGATIVE.

Fresh vs. Frozen Sample Equivalency Study

Fresh and frozen specimen equivalency in the Xpert Xpress Flu Assay was evaluated by testing individual influenza strains at three different concentrations representing low positives (2X LoD), moderate positives (5X LoD), and high positives (10X LoD) in pooled negative NP swab clinical matrix. Negative samples consisted of pooled negative NP swab clinical matrix only. Fresh and frozen specimen equivalency was determined using one seasonal Flu A H3N2 strain (A/Victoria/361/2011) and one Flu B strain (B/Mass/2/2012). Replicates of 20 were tested for each specimen type and concentration. All positive and negative specimens were tested fresh, after one freeze-thaw cycle, and after two freeze-thaw cycles. There was no difference in the performance of the Xpert Xpress Flu Assay between fresh virus dilutions and two sequential freeze thaw cycles for positive and negative samples. All positive and negative replicates were correctly identified using the Xpert Xpress Flu Assay.

Competitive Interference Study

Competitive interference of the assay caused by the presence of two targets in the Xpert Xpress Flu Assay was evaluated by testing individual influenza strains near the LoD in the presence of different influenza strains at a higher concentration in a simulated nasal matrix. Analytical competitive interference was assessed using one (1) seasonal Flu A H3 strain (H3/Victoria/361/2011) at 0.8 $TCID_{50}$/mL and one (1) Flu B strain (B/Mass/2/2012) at 0.45 $TCID_{50}$/mL; the strains were tested at in the presence of competing strains at either 1 x 10^2 $TCID_{50}$/mL or 1 x 10^3 $TCID_{50}$/mL. Replicates of 20 were tested for each target strain and each competitive strain combination. The normal binomial distribution with 20 replicate samples at LoD is between 17 and 20 positive results based on the binomial distribution with N=20, p=0.95 (X~Bin(20,0.95)). Therefore, sets of 20 with 16 or less positives would be rare and an indication of a competitive inhibitory effect due to high levels of a competing analyte.

With Flu A/Victoria/361/2011 at a concentration of 0.8 $TCID_{50}$/mL no competitive inhibitory effects were observed in the presence of $1x10^3$ $TCID_{50}$/mL of Flu B/Mass/2/2012.

With Flu B/Mass/2/2012 at a concentration of 0.45 $TCID_{50}$/mL competitive inhibitory effects were observed in the presence of $1x10^3$ $TCID_{50}$/mL of Flu A/Victoria/361/2011. No competitive inhibitory effects were observed in the presence of $1x10^2$ $TCID_{50}$/mL of Flu A/Victoria/361/2011.

Under the conditions of this study, internal competitive inhibitory effects were observed on the targets (Flu A and Flu B) in the presence of two targets for the Xpert Xpress Flu Assay. The competitive inhibitory effect on the Xpert Xpress Flu targets is addressed in the Limitations section of the package insert.

Clinical Studies

Clinical Comparison Study

Performance characteristics of the Xpert Xpress Flu Assay were evaluated at eleven institutions in the U.S. during the 2015-2016 influenza season. Due to the low prevalence of influenza viruses and the difficulty in obtaining fresh influenza specimens, the specimen population for this study was supplemented with consecutively collected, frozen specimens.

Specimens were collected from the following:

- Individuals exhibiting signs and symptoms of respiratory infection who provided informed consent for the collection of a NP swab specimen.
- Individuals with signs and symptoms of respiratory infection and whose routine care called for collection of NP swab specimens for influenza testing. For eligible subjects, aliquots of leftover specimens were obtained for testing with the Xpert Xpress Flu Assay and reference testing, and patient management continued at the site per their standard practice.

The Xpert Xpress Flu Assay performance was compared to FDA-cleared molecular comparator assay. Bi- directional sequencing was performed on specimens where the Xpert Xpress Flu Assay and the comparator assay were discrepant, and is provided for informational purposes only.

Overall Results – NP Swab Specimens

A total of 2065 NP swab specimens were tested for influenza A and influenza B by the Xpert Xpress Flu Assay and the comparator assay. Of the 2065 NP swab specimens, 1142 were fresh, prospectively collected and 923 were consecutively collected, frozen specimens.

For the fresh, prospectively collected NP swab specimens, the Xpert Xpress Flu Assay demonstrated a PPA and NPA of 94.6% and 99.3% for the detection of influenza A and 100% and 99.2% for influenza B, respectively (Table 8-9).

For the consecutively collected, frozen NP swab specimens, the Xpert Xpress Flu Assay demonstrated a PPA and NPA of 100% and 97.2% for the detection of influenza A, respectively; 100% and 98.2% for influenza B, respectively (Table 8-9).

For the combined dataset, the Xpert Xpress Flu Assay demonstrated a PPA and NPA of 98.1% and 98.4% for the detection of influenza A and 100% and 98.7% for influenza B, respectively (Table 8-9).

Table 8-9 Xpert Xpress Flu Assay Performance on NP Swab Specimens

Specimen Type	Target	n	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)
Fresh, prospectively collected	Flu A	1142	35	8[a]	1097	2[b]	94.6% (CI:82.3-98.5)	99.3% (CI:98.6-99.6)
	Flu B	1142	42	9[c]	1091	0	100.0% (CI:91.6-100.0)	99.2% (CI:98.5-99.6)
Frozen, consecutively collected	Flu A	923	69	24[d]	830	0	100.0% (CI:94.7-100.0)	97.2% (CI:95.9-98.1)
	Flu B	923	36	16[e]	871	0	100.0% (CI:90.4-100.0)	98.2% (CI:97.1-98.9)
Combined[1]	Flu A	2065	104	32[f]	1927	2[b]	98.1% (CI:93.4-99.5)	98.4% (CI:97.7-98.8)
	Flu B	2065	78	25[g]	1962	0	100.0% (CI:95.3-100.0)	98.7% (CI:98.1-99.1)

a. Testing results by sequencing: 3 of 8 were Flu A Positive; 4 of 8 were Flu A Negative; 1 of 8 insufficient specimen.
b. Testing results by sequencing: 2 of 2 were Flu A Negative.
c. Testing results by sequencing: 6 of 9 were Flu B Positive; 2 of 9 were Flu B Negative; 1 of 9 insufficient specimen.
d. Testing results by sequencing: 8 of 24 were Flu A Positive; 11 of 24 were Flu A Negative; 5 of 24 insufficient specimen.
e. Testing results by sequencing: 7 of 16 were Flu B Positive; 3 of 16 were Flu B Negative; 6 of 16 insufficient specimen.
f. Testing results by sequencing: 11 of 32 were Flu A Positive; 15 of 32 were Flu A Negative; 6 of 32 insufficient specimen.
g. Testing results by sequencing: 13 of 25 were Flu B Positive; 5 of 25 were Flu B Negative; 7 of 25 insufficient specimen.
1. Seven specimens (6 Flu A FP; 7 Flu B FP) were positive for all three targets.

Of the Xpert Xpress Flu Assay runs performed with eligible specimens, 98.4% (2038/2071) of these specimens were successful on the first attempt. The remaining 33 gave indeterminate results on the first attempt (20 **ERROR**, 10 **INVALID,** and 3 **NO RESULT**). The initial indeterminate rate was 1.59% (33/2071) with the 95% CI 1.14-2.23%. Thirty of the 33 indeterminate cases were retested, of which 27 yielded valid results upon repeat testing; three specimens were not retested.

The overall rate of assay success was 99.7% (2065/2071). The overall indeterminate rate after retesting was 0.3% (6/2071) with 95% CI 0.13- 0.63%.

In addition, there were 102 pre-selected frozen NP swab specimens tested. The results of this testing were analyzed separately and are as follows; the Xpert Xpress Flu Assay demonstrated a PPA and NPA of 100% and 95.8%, for influenza A, respectively; and 100% and 94.5% for influenza B, respectively.

Reproducibility Study

Reproducibility was established in a multi-center, blinded study using a 5-member specimen panel consisting of a negative control and two each of simulated nasal matrix spiked with influenza A, or influenza B at 1X (low pos) and 2-3X (mod pos) the respective LODs. Testing was performed at three sites (one internal, two external) using the GeneXpert Dx system, the Infinity-48 system, and the Infinity-80 system. Two operators at each site tested one panel in duplicate two times per day (equivalent to four replicates per day) over six, not necessarily consecutive days. Three lots of Xpert Xpress Flu cartridges were used, with each lot representing approximately two days of testing. Results are summarized in Table 8-10.

Table 8-10 Summary of Reproducibility Results

Sample ID	Site 1/Infinity-80			Site 2/DX			Site 3/Infinity-48			% Total Agreement by Sample[a]
	Op 1	Op 2	Site	Op 1	Op 2	Site	Op 1	Op 2	Site	
Negative	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)
Flu A-Low Pos	87.5% (21/24)	95.8% (23/24)	91.7% (44/48)	95.7% (22/23)	91.7% (22/24)	93.6% (44/47)	100% (24/24)	91.7% (22/24)	95.8% (46/48)	93.7% (134/143)[b]
Flu A-Mod Pos	100% (24/24)	100% (24/24)	100% (48/48)	100% (23/23)	100% (23/23)	100% (46/46)	100% (24/24)	100% (24/24)	100% (48/48)	100% (142/142)[b]
Flu B-Low Pos	95.8% (23/24)	95.8% (23/24)	95.8% (46/48)	95.8% (23/24)	95.8% (23/24)	95.8% (46/48)	95.8% (23/24)	91.7% (22/24)	93.8% (45/48)	95.1% (137/144)
Flu B-Mod Pos	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	95.8% (23/24)	97.9% (47/48)	99.3% (143/144)[c]

a. Agreement calculated based on expected result: Negative for Negative (targeted positivity: 0%); Positive for Low Pos (targeted positivity: 95%) and Mod Pos (targeted positivity: 100%) samples.
b. Three samples 2x indeterminate [Flu A Low Pos (1); Flu A Mod Pos (2)]
c. One Flu B Mod Pos sample was positive for both targets

The reproducibility of the Xpert Xpress Flu Assay 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- days, between-lots and between-operators for each panel member are presented in Table 8-11.

Table 8-11 Summary of Reproducibility Data

Sample	Assay Channel (Analyte)	N[a]	Mean Ct	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	144	32.3	0	0	0.7	2.1	0	0	0.2	0.5	0.6	1.8	0.9	2.8
Flu A-Low Pos	FluA1	134	35.3	0	0	0.4	1.1	0.6	1.8	0.1	0.4	0.9	2.5	1.2	3.3
Flu A-Mod Pos	FluA1	142	33.1	0	0	0.1	0.4	0.1	0.4	0	0	0.6	1.9	0.7	2.0
Flu B-Low Pos	FluB	137	34.6	0	0	0	0	0.4	1.3	0	0	1.4	4.1	1.5	4.3
Flu B-Mod Pos	FluB	144	32.2	0.2	0.5	0.2	0.7	0	0	0.2	0.7	1.0	3.1	1.1	3.3

a. Results with non-zero Ct values of 144.

Conclusions

The results of the nonclinical analytical and clinical performance studies summarized above demonstrate that the Xpert Xpress Flu Assay is substantially equivalent to the predicate device.