March 14, 2025

Centers for Disease Control and Prevention
Melissa Ivey
Regulatory Affairs Specialist
1600 Clifton Rd
Atlanta, Georgia 30329

Re: K243931
Trade/Device Name: CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel: Influenza A/B Typing Kit (VER 2); Influenza A Subtyping Kit (VER 4); Influenza B Lineage Genotyping Kit (VER 1.1 and 2); and Influenza A/H5 Subtyping Kit (VER 4)
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay
Regulatory Class: Class II
Product Code: OZE
Dated: December 16, 2024
Received: December 20, 2024

Dear Melissa Ivey:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anna M. Mielech -S

Anna Mielech, PhD.
Deputy Branch Chief (Acting)
Viral Respiratory and HPV Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243931

Device Name
CDC Human Influenza Real-Time RT-PCR Diagnostic Panel:Influenza A/B Typing Kit (VER 2), Influenza A Subtyping Kit (VER 4), Influenza B Lineage Genotyping Kit (VER 1.1 and 2), and Influenza A/H5 Subtyping Kit (VER 4)

Indications for Use *(Describe)*

CDC Human Influenza Real-Time RT-PCR Diagnostic Panel: Influenza A/B Typing Kit (VER 2)

The Influenza A/B Typing Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an in vitro diagnostic real-time PCR instrument that has been FDA-cleared for use with this kit in conjunction with clinical and epidemiological information:

• For qualitative detection of influenza virus type A or B viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) and lower respiratory tract specimens (including bronchoalveolar lavage [BAL], bronchial wash [BW], tracheal aspirate [TA], sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture.

• To provide epidemiological information for surveillance of circulating influenza viruses.

Performance characteristics for influenza were established during a season when seasonal influenza viruses A(H1N1) and A(H3N2) were the predominant influenza A viruses in circulation and during a season when the A(H1N1)pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses.
Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

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 department for testing. Viral culture should not be attempted unless a BSL 3E facility is available to receive and culture specimens.

All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

CDC Human Influenza Real-Time RT-PCR Diagnostic Panel: Influenza A Subtyping Kit (VER 4)

The Influenza A Subtyping Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an in vitro diagnostic real-time PCR instrument that has been FDA-cleared for use with this kit in conjunction with clinical and epidemiological information:

• For determination of the subtype of seasonal human influenza A viruses as seasonal A(H3) and/or A(H1)pdm09 from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) and lower

respiratory tract specimens (including bronchoalveolar lavage [BAL], bronchial wash [BW], tracheal aspirate [TA], sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture;

• To provide epidemiological information for surveillance of circulating influenza viruses.

Performance characteristics for influenza were established during a season when seasonal influenza viruses A(H1N1) and A(H3N2) were the predominant influenza A viruses in circulation and during a season when the A(H1N1)pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses.
Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

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 department for testing. Viral culture should not be attempted unless a BSL 3E facility is available to receive and culture specimens.

All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza B Lineage Genotyping Kit (VER 1.1 and 2)

The Influenza B Lineage Genotyping Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an in vitro diagnostic real-time PCR instrument that has been FDA-cleared for use with this kit in conjunction with clinical and epidemiological information:

• For the determination of the genetic lineage of human influenza B viruses as B/Victoria or B/Yamagata lineage from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) from human patients with signs and symptoms of respiratory infection and/or from viral culture;

• To provide epidemiologic information for surveillance of circulating influenza viruses.
Performance characteristics for influenza B lineage genotyping were established during a season when influenza B/Victoria and B/Yamagata lineages were in circulation.
Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza A/H5 Subtyping Kit (VER 4)

The Influenza A/H5 Subtyping Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an in vitro diagnostic real-time PCR instrument that has been FDA-cleared for use with this kit in conjunction with clinical and epidemiological information:

• For the presumptive identification of virus in patients who may be infected with influenza A subtype A(H5) (Asian lineage) from viral RNA in human respiratory specimens, conjunctival swabs, and viral culture in conjunction with clinical and epidemiological risk factors;

• To provide epidemiologic information for surveillance of circulating influenza viruses.

Performance characteristics for influenza were established during a season when seasonal influenza viruses A(H1N1) and A(H3N2) were the predominant influenza A viruses in circulation and during a season when the A(H1N1)pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses.

Testing with the influenza H5a and H5b primer and probe sets should not be performed unless the patient meets the most current U.S.Department of Health and Human Services (DHHS) clinical and epidemiologic criteria for testing suspect A(H5) specimens. The definitive identification of influenza A(H5) (Asian lineage) either directly from patient specimens or from virus cultures requires additional laboratory testing, along with clinical and epidemiological assessment in consultation with national influenza surveillance experts.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
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 department for testing. Viral culture should not be attempted unless a BSL 3E facility is available to receive and culture specimens.

All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. GENERAL INFORMATION

Submitter
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, GA 30329

Contact Person
Marie Kirby
Lead, Genomics and Diagnostics Team
Virology, Surveillance and Diagnostic Branch, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
mkirby@cdc.gov
(404)718-7689

Date Prepared: December 16, 2024

II. DEVICE INFORMATION

Proprietary Name:	CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza A/B Typing Kit (VER 2), Influenza A Subtyping Kit (VER 4), Influenza B Lineage Genotyping Kit (VER 1.1 and 2), and Influenza A/H5 Subtyping Kit (VER 4)
Common Name:	CDC Flu rRT-PCR Dx Panel: Influenza A/B Typing Kit, Influenza A Subtyping Kit, Influenza B Lineage Genotyping Kit, and Influenza A/H5 Subtyping Kit
Regulation Section:	866.3980-Respiratory viral panel multiplex nucleic acid assay

Device Classification: Class II

Product Code: OZE

Panel: Microbiology

III. PREDICATE DEVICES

K190302 - CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel: Influenza A/B Typing Kit, Influenza A Subtyping Kit (VER 2), Influenza B Lineage Genotyping Kit (VER 1.1 and 2), and Influenza A/H5 Subtyping Kit (VER 3)

IV. DEVICE DESCRIPTION

The CDC Human Influenza Real-Time RT-PCR Diagnostic Panel consists of four real-time RT-PCR (rRT-PCR) assays used on IVD-labeled real-time PCR instruments that has been FDA-cleared for use with this device. The panel is configured in four separate kits: Influenza A/B Typing kit, Influenza A Subtyping kit, Influenza A/H5 Subtyping kit, and Influenza B Genotyping kit. Each kit consists of oligonucleotide primers, fluorescently labeled hydrolysis probes, and controls which are used in rRT-PCR assays for the in vitro qualitative detection and characterization of influenza virus RNA in respiratory and conjunctival specimens from patients presenting with influenza-like illness (ILI). Oligonucleotide primers and probes for detection of influenza A, influenza B, and 2009 influenza A (swine origin) were selected from highly conserved regions of the matrix (M), non-structural (NS), and nucleoprotein (NP) genes, respectively. Oligonucleotide primers and probes for characterization and differentiation of influenza A(H3) and A(H1)pdm09 viruses, genetic lineages of influenza B, and avian influenza A(H5) viruses were selected from highly conserved regions of their HA genes. Oligonucleotide primers and probes to detect the human RNase P gene (RP) in control samples and clinical specimens are also included in the panel.

V. INTENDED USE

Influenza A/B Typing Kit (VER 2)
The Influenza A/B Typing Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an in vitro diagnostic real-time PCR instrument that has been FDA-cleared for use with this kit in conjunction with clinical and epidemiological information:

• For qualitative detection of influenza virus type A or B viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) and lower respiratory tract specimens (including bronchoalveolar lavage [BAL], bronchial wash [BW], tracheal aspirate [TA], sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture.

• To provide epidemiological information for surveillance of circulating influenza viruses.

Performance characteristics for influenza were established during a season when seasonal influenza viruses A(H1N1) and A(H3N2) were the predominant influenza A viruses in circulation and during a season when the A(H1N1)pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses.
Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

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 department for testing. Viral culture should not be attempted unless a BSL 3E facility is available to receive and culture specimens.

All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

Influenza A Subtyping Kit (VER 4)
The Influenza A Subtyping Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an in vitro diagnostic real-time PCR instrument that has been FDA-cleared for use with this kit in conjunction with clinical and epidemiological information:

• For determination of the subtype of seasonal human influenza A viruses as seasonal A(H3) and/or A(H1)pdm09 from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) and lower respiratory tract specimens (including bronchoalveolar lavage [BAL], bronchial wash [BW], tracheal aspirate [TA], sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture;

• To provide epidemiological information for surveillance of circulating influenza viruses.

Performance characteristics for influenza were established during a season when seasonal influenza viruses A(H1N1) and A(H3N2) were the predominant influenza A viruses in circulation and during a season when the A(H1N1)pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses.
Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

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 department for testing. Viral culture should not be attempted unless a BSL 3E facility is available to receive and culture specimens.

All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

Influenza B Genotyping Kit (VER 1.1 and 2)
The Influenza B Lineage Genotyping Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an in vitro diagnostic real-time PCR instrument that has been FDA-cleared for use with this kit in conjunction with clinical and epidemiological information:

• For the determination of the genetic lineage of human influenza B viruses as B/Victoria or B/Yamagata lineage from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) from human patients with signs and symptoms of respiratory infection and/or from viral culture;

• To provide epidemiologic information for surveillance of circulating influenza viruses.

Performance characteristics for influenza B lineage genotyping were established during a season when influenza B/Victoria and B/Yamagata lineages were in circulation.
Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

Influenza A/H5 Subtyping Kit (VER 4)
The Influenza A/H5 Subtyping Kit contains reagents and controls of the Centers for Disease Control and Prevention (CDC) Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an in vitro diagnostic real-time PCR instrument that has been FDA-cleared for use with this kit in conjunction with clinical and epidemiological information:

• For the presumptive identification of virus in patients who may be infected with influenza A subtype A(H5) (Asian lineage) from viral RNA in human respiratory specimens, conjunctival swabs and viral culture in conjunction with clinical and epidemiological risk factors;

• To provide epidemiologic information for surveillance of circulating influenza viruses.

Performance characteristics for influenza were established during a season when seasonal influenza viruses A(H1N1) and A(H3N2) were the predominant influenza A viruses in circulation and during a season when the A(H1N1)pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses.

Testing with the influenza H5a and H5b primer and probe sets should not be performed unless the patient meets the most current U.S. Department of Health and Human Services (DHHS) clinical and epidemiologic criteria for testing suspect A(H5) specimens. The definitive identification of influenza A(H5) (Asian lineage) either directly from patient specimens or from virus cultures requires additional laboratory testing, along with clinical and epidemiological assessment in consultation with national influenza surveillance experts.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

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 department for testing. Viral culture should not be attempted unless a BSL 3E facility is available to receive and culture specimens.

All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

VI. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel remains the same as the predicate device.

VII. SUBSTANTIAL EQUIVALENCE COMPARISON

	CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza A/B Typing Kit (K190302)	**CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza A/B Typing Kit (VER 2) (K243931)**
General Device Characteristic Similarities		
Intended Use	The Influenza A/B Typing Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an in vitro diagnostic real-time PCR instrument that has been FDA-cleared for use with this kit in conjunction with clinical and epidemiological information: • For qualitative detection of influenza virus type A or B viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) and lower respiratory tract specimens (including bronchoalveolar lavage [BAL], bronchial wash [BW], tracheal aspirate [TA], sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture. • To provide epidemiological information for surveillance	Same

	of circulating influenza viruses. Performance characteristics for influenza were established during a season when seasonal influenza viruses A(H1N1) and A(H3N2) were the predominant influenza A viruses in circulation and during a season when the A(H1N1)pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. 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 department for testing. Viral culture should not be attempted unless a BSL 3E facility is available to receive and culture specimens. [black box: All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.]	

Specimen Types	Upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) and lower respiratory tract specimens (including bronchoalveolar lavage [BAL], bronchial wash [BW], tracheal aspirate [TA], sputum, and lung tissue), and/or viral culture	Same
Organisms Detected	Influenza A and Influenza B	Same
Analytes	RNA- InfA, InfB, RP	Same
Technological Principles	Real-time RT-PCR	Same
Instrumentation	Applied Biosystems 7500 Fast Dx Real-time PCR system with SDS software version 1.4 Applied Biosystems QuantStudio Dx with version 1.0.3 software QIAGEN Rotor-Gene Q MDx with AssayManager 1.0.4.1 and Epsilon version 1.0.1 software	Same
Enzyme Master Mix	Invitrogen SuperScript III Platinum One-Step Quantitative RT-PCR Kit (with or without ROX) Quanta BioSciences qScript One-Step qRT PCR Kit, Low ROX	Same
Nucleic Acid Extraction	QIAamp DSP Viral RNA Mini Kit, QIAGEN MagNA Pure Compact – Nucleic Acid Isolation Kit I, Roche MagNA Pure Compact – RNA Isolation Kit, Roche	Same

	MagNA Pure LC – Total Nucleic Acid Kit, Roche MagNA Pure 96 - DNA and Viral NA Small Volume Kit, Roche QIAcube – QIAamp DSP Viral RNA Mini Kit, QIAGEN NucliSENS easyMAG, bioMérieux EMAG, bioMérieux* EZ1 Advanced XL – EZ1 DSP Virus Kit and EZ1 RNA Tissue Mini Kit, QIAGEN	
	CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza A Subtyping Kit (VER 2) (K190302)	**CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza A Subtyping Kit (VER 4) (K243931)**
General Device Characteristic Similarities		
Intended Use	The Influenza A Subtyping Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an in vitro diagnostic real-time PCR instrument that has been FDA-cleared for use with this kit in conjunction with clinical and epidemiological information: • For determination of the subtype of seasonal human influenza A viruses as seasonal A(H3), and/or A(H1)pdm09 from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) and lower respiratory tract specimens (including bronchoalveolar lavage [BAL],	Same

	bronchial wash [BW], tracheal aspirate [TA], sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture; • To provide epidemiologic information for surveillance of circulating influenza viruses. Performance characteristics for influenza were established during a season when seasonal influenza viruses A(H1N1) and A(H3N2) were the predominant influenza A viruses in circulation and during a season when the A(H1N1)pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. 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 department for testing. Viral culture should not be attempted unless a BSL 3E facility is available to receive and culture specimens. [black box: All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC	

	instructors or designees.]	
Specimen Types	Upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) and lower respiratory tract specimens (including bronchoalveolar lavage [BAL], bronchial wash [BW], tracheal aspirate [TA], sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture	Same
Organisms Detected	Influenza A viruses (animal and human), swine-origin influenza A viruses, influenza A subtypes: seasonal A(H3) and A(H1)pdm09	Same
Analytes	RNA- InfA, H3, pdmInfA, pdmH1 and RP	Same
Technological Principles	Real-time RT-PCR	Same
Instrumentation	Applied Biosystems 7500 Fast Dx Real-time PCR system with SDS software version 1.4 Applied Biosystems QuantStudio Dx with version 1.0.3 software QIAGEN Rotor-Gene Q MDx with AssayManager 1.0.4.1 and Epsilon version 1.0.1 software	Same
Enzyme Master Mix	Invitrogen SuperScript III Platinum One-Step Quantitative RT-PCR Kit (with or without ROX) Quanta BioSciences qScript One-Step qRT PCR Kit, Low ROX	Same
Nucleic Acid Extraction	QIAamp DSP Viral RNA Mini Kit, QIAGEN MagNA Pure Compact – Nucleic Acid Isolation Kit I, Roche	QIAamp DSP Viral RNA Mini Kit, QIAGEN MagNA Pure LC – Total Nucleic Acid Kit, Roche

	MagNA Pure Compact – RNA Isolation Kit, Roche MagNA Pure LC – Total Nucleic Acid Kit, Roche MagNA Pure 96 - DNA and Viral NA Small Volume Kit, Roche QIAcube – QIAamp DSP Viral RNA Mini Kit, QIAGEN NucliSENS easyMAG, bioMérieux EMAG, bioMérieux* EZ1 Advanced XL – EZ1 DSP Virus Kit and EZ1 RNA Tissue Mini Kit, QIAGEN	MagNA Pure 96 - DNA and Viral NA Small Volume Kit, Roche QIAcube – QIAamp DSP Viral RNA Mini Kit, QIAGEN NucliSENS easyMAG, bioMérieux EMAG, bioMérieux* EZ1 Advanced XL – EZ1 DSP Virus Kit and EZ1 RNA Tissue Mini Kit, QIAGEN
	CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza B Genotyping Kit (VER 1.1 and 2) (K190302)	**CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza B Genotyping Kit (VER 1.1 and 2) (K243931)**
General Device Characteristic Similarities		
Intended Use	The Influenza B Lineage Genotyping Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an in vitro diagnostic real-time PCR instrument that has been FDA-cleared for use with this kit in conjunction with clinical and epidemiological information: • For the determination of the genetic lineage of human influenza B viruses as B/Victoria or B/Yamagata lineage from viral RNA in 6 upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual	Same

	nasopharyngeal/throat swabs [NPS/TS]) from human patients with signs and symptoms of respiratory infection and/or from viral culture; • To provide epidemiologic information for surveillance of circulating influenza viruses. Performance characteristics for influenza B lineage genotyping were established during a season when influenza B/Victoria and B/Yamagata lineages were in circulation. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. [black box: All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.]	
Specimen Types	Upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) and/or viral culture	Same
Organism Detected	Influenza B	Same
Analytes	RNA- InfB, VIC, YAM, RP	Same

Technological Principles	Real-time RT-PCR	Same
Instrumentation	Applied Biosystems 7500 Fast Dx Real-time PCR system with SDS software version 1.4 Applied Biosystems QuantStudio Dx with version 1.0.3 software QIAGEN Rotor-Gene Q MDx with AssayManager 1.0.4.1 and Epsilon version 1.0.1 software	Same
Enzyme Master Mix	Invitrogen SuperScript III Platinum One-Step Quantitative RT-PCR Kit (with or without ROX) Quanta BioSciences qScript One-Step qRT PCR Kit, Low ROX	Same
Nucleic Acid Extraction	QIAamp DSP Viral RNA Mini Kit, QIAGEN MagNA Pure Compact – Nucleic Acid Isolation Kit I, Roche MagNA Pure Compact – RNA Isolation Kit, Roche MagNA Pure LC – Total Nucleic Acid Kit, Roche MagNA Pure 96 - DNA and Viral NA Small Volume Kit, Roche QIAcube – QIAamp DSP Viral RNA Mini Kit, QIAGEN NucliSENS easyMAG, bioMérieux EMAG, bioMérieux EZ1 Advanced XL – EZ1 DSP Virus Kit and EZ1 RNA Tissue Mini Kit, QIAGEN	Same

	CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza A/H5 Subtyping Kit (VER 3) (K190302)	CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza A/H5 Subtyping Kit (VER 4) (K243931)
General Device Characteristic Similarities		
Organisms Detected	Influenza A viruses (animal and human), Influenza A subtype A(H5) (Asian lineage)	Same
Analyte	RNA- InfA, H5a, H5b, RP	Same
Technological Principles	Real-time RT-PCR	Same
Instrumentation	Applied Biosystem 7500 Fast Dx Real-time PCR system with SDS software version 1.4 Applied Biosystems QuantStudio Dx with version 1.0.3 software QIAGEN Rotor-Gene Q MDx with AssayManager 1.0.4.1 and Epsilon version 1.0.1 software	Same
Enzyme Master Mix	Invitrogen SuperScript III Platinum One-Step Quantiative RT-PCR Kit (with or without ROX) Quanta BioSciences qScript One-Step qRT-PCR Kit, Low ROX	Same
Nucleic Acid Extraction	QIAamp DSP Viral RNA Mini Kit, QIAGEN MagNA Pure Compact – Nucleic Acid Isolation Kit I, Roche MagNA Pure Compact – RNA Isolation Kit, Roche MagNA Pure LC – Total Nucleic Acid Kit, Roche	Same

	MagNA Pure 96 - DNA and Viral NA Small Volume Kit, Roche QIAcube – QIAamp DSP Viral RNA Mini Kit, QIAGEN NucliSENS easyMAG, bioMérieux EMAG, bioMérieux* EZ1 Advanced XL – EZ1 DSP Virus Kit and EZ1 RNA Tissue Mini Kit, QIAGEN	
General Device Characteristic Differences		
Intended Use	The Influenza A/H5 Subtyping Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an in vitro diagnostic real-time PCR instrument that has been FDA-cleared for use with the CDC device in conjunction with clinical and epidemiological information: • For the presumptive identification of virus in patients who may be infected with influenza A subtype A(H5) (Asian lineage) from viral RNA in human respiratory specimens and viral culture in conjunction with clinical and epidemiological risk factors; • To provide epidemiologic information for surveillance of circulating influenza viruses. Performance characteristics for influenza were established during a season when seasonal influenza viruses A(H1N1)	The Influenza A/H5 Subtyping Kit contains reagents and controls of the Centers for Disease Control and Prevention (CDC) Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an *in vitro* diagnostic real-time PCR instrument that has been FDA-cleared for use with this kit in conjunction with clinical and epidemiological information: • For the presumptive identification of virus in patients who may be infected with influenza A subtype A(H5) (Asian lineage) from viral RNA in human respiratory specimens, conjunctival swabs and viral culture in conjunction with clinical and epidemiological risk factors; •To provide epidemiologic information for surveillance of circulating influenza viruses. Performance characteristics for influenza were established during a season when seasonal influenza viruses A(H1N1) and A(H3N2)

	and A(H3N2) were the predominant influenza A viruses in circulation and during a season when the A(H1N1)pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses. Testing with the influenza H5a and H5b primer and probe sets should not be performed unless the patient meets the most current U.S. Department of Health and Human Services (DHHS) clinical and epidemiologic criteria for testing suspect A(H5) specimens. The definitive identification of influenza A(H5) (Asian lineage) either directly from patient specimens or from virus cultures requires additional laboratory testing, along with clinical and epidemiological assessment in consultation with national influenza surveillance experts. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. 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 department for testing. Viral culture should not be attempted unless a BSL 3E facility is available to receive and culture specimens. [black box: All users, analysts, and any person reporting results from use of this device should be trained to perform	were the predominant influenza A viruses in circulation and during a season when the A(H1N1)pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses. Testing with the influenza H5a and H5b primer and probe sets should not be performed unless the patient meets the most current U.S. Department of Health and Human Services (DHHS) clinical and epidemiologic criteria for testing suspect A(H5) specimens. The definitive identification of influenza A(H5) (Asian lineage) either directly from patient specimens or from virus cultures requires additional laboratory testing, along with clinical and epidemiological assessment in consultation with national influenza surveillance experts. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. 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 department for testing. Viral culture should not be attempted unless a BSL 3E facility is available to receive and culture specimens. [black box: All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a

	and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.]	training course provided by CDC instructors or designees.]
Specimen Types	Human respiratory specimens and viral culture	Human respiratory specimens, conjunctival swabs, and viral culture

VIII. Analytical Performance Evaluation

Confirmation of Limit of Detection

To assess the Limit of Detection (LoD) of the Influenza A/H5 Subtyping Kit testing conjunctival swab collected in VTM/UTM specimens, an initial range-finding experiment using BPL inactivated A/American Wigeon/South Carolina/22-000345-001/2021 H5N1 was performed in a background of VTM + A549 human lung epithelial cells (a simulated respiratory VTM matrix). A 5-fold dilution series of the virus was prepared using this simulated matrix as the diluent. Each dilution step was tested in triplicate using the CDC Flu rRT-PCR Dx Panel Influenza A/H5 Subtyping assay. The range finding limit of detection was defined as the viral titer of the last dilution step demonstrating 100% positive results (3/3) in this experiment. Results demonstrated a preliminary LoD with an approximate titer of $10^{5.5}$ EID_{50}/ml.

Due to limited availability of negative conjunctival swab matrix material, the estimated LoD was confirmed by testing replicates at concentrations of 2x and 5x preliminary LoD using contrived specimens in either influenza A/H5 negative conjunctival swab matrix or simulated respiratory swabs collected in VTM matrix. Contrived specimens were spiked with BPL inactivated A/American Wigeon/South Carolina/22-000345-001/2021 H5N1 virus. Five replicates of each contrived specimen type at either 2x LoD or 5x preliminary LoD were tested along with 10 negatives for each matrix. Each specimen was extracted on the Qiagen EZ1 Advanced XL with the EZ1 DSP Virus kit, amplified by the Invitrogen SuperScript™ III Platinum® One-Step Quantitative RT-PCR System (without Rox) and run on the Applied Biosystems 7500 Fast Dx PCR platform. Detection levels and Ct values of the conjunctival swab matrix were similar to that observed in the simulated respiratory matrix in VTM at both the 2x and 5x preliminary LoD concentrations. Based on this data, the LoD for the conjunctival swab specimens was determined to be $10^{5.5}$ EID_{50}/ml.

Interfering Substances

Two studies were performed to evaluate the potential impact of exogenous interfering substances in conjunctival swab specimen matrix. Studies were conducted using two common over the counter eye drops containing olopatadine or naphazoline hydrocholoride.

For the first study, to evaluate the effect of eyedrops on the assay, a set of contrived specimens (N=5) was constructed with a measured volume of each eyedrop plus A/American Wigeon/South Carolina/22-000345-001/2021 H5N1 at 2x LoD in conjunctival swab matrix. An additional set of contrived specimens (N=5) was constructed with a measured volume of each eyedrop plus A/American Wigeon/South Carolina/22-000345-001/2021 H5N1 at 2x LoD in VTM + A549 cells (a simulated respiratory matrix). Each contrived specimen contained 2.31% ClearEye eyedrop (naphazoline hydrochloride as the main ingredient) and 2.08% Pataday eyedrop (olopatadine hydrochloride as the main ingredient), and was extracted on the Qiagen EZ1 Advanced XL with the EZ1 DSP Virus kit, amplified by the Invitrogen SuperScript™ III Platinum® One-Step Quantitative RT-PCR System (without Rox) and run on the Applied Biosystems 7500 Fast Dx PCR platform. Due to a lack of sufficient volume of natural conjunctival swabs, the study was conducted by mixing both the olopatadine and naphazoline hydrochloride into a single reaction. Cycle threshold (Ct) results were compared to contrived specimens tested at 2x LoD without the addition of eyedrops as the control condition.

No interference was seen with the addition of olopatadine and naphazoline hydrochloride in either the contrived specimens in conjunctival matrix or the contrived specimens in VTM + A549 cells matrix in this study.

The second study was performed by adding a measured amount of each eyedrop (2.22% Pataday and 2.46% Clear Eyes, respectively)) directly into the
RT-PCR enzyme master mix and tested in 20 replicates to evaluate the effect of the eyedrop chemistry to the A/H5 assay and determine if autofluorescence is produced due to the eyedrop additions that could generate a false positive A/H5 assay result. No false positive A/H5 assay result was seen when the eyedrops were added directly to the RT-PCR reaction in this study.

IX. Clinical Performance Evaluation

Human upper respiratory tract (URT) swab specimens, including nasopharyngeal swab (NPS) specimens, combined nasal swab (NS) and oropharyngeal swab (OS) specimens, NS and/or OS specimens, as well as human conjunctival swab (CS) specimens were collected by health care professionals (HCPs) as part of public health investigations into outbreaks of influenza A/H5 in dairy cows and poultry in the US from March to November 2024. All available URT specimens and CS specimens from individuals with either a presumptive influenza A/H5 positive laboratory result (in any specimen) at the state public health laboratories, or a strong epidemiological link and clinical suspicion that indicate suspected influenza A/H5 infection, were sent to the CDC laboratory in Atlanta for confirmatory testing and evaluation.

URT specimens and CS specimens collected from a total of 44 confirmed and 2 probable human cases of A/H5N1 were received and tested using the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel Influenza A/H5 Subtyping Kit (VER 4) (i.e., the CDC A/H5 assay). The influenza A/H5N1 confirmed or probable case status for each case was adjudicated based on the criteria described in the current Council of State and Territory Epidemiologists (CSTE) document 24-ID-09.

Of the 44 confirmed human cases and 2 probable cases, 42 (95.5%) and 2 (100%), respectively, reported conjunctivitis symptoms. While 28 confirmed cases and 1 probable case reported both respiratory and/or systemic symptoms and conjunctivitis symptoms, 16 confirmed cases and 1 probable case reported conjunctivitis symptoms only. The mean age of the 46 confirmed and probable cases was 36.5 years (range: 18-57 years); 87.0% were male and 13.0% were female.

Due to a field correction regarding the H5b component assay reagents required for testing and result interpretation using the CDC A/H5 assay, clinical specimens from 9 of the 44 confirmed cases were tested without the H5b component assay reagents. As a result, clinical specimens from these 9 confirmed cases were excluded from the performance assessment (i.e., 35 confirmed cases and 2 probable cases were assessed).

Of the 35 confirmed cases assessed, 33/35 (94.3%) reported conjunctivitis symptoms. Of those 33 cases, 26/33 (78.8%) tested positive and 3/33 (9.1%) tested inconclusive for A/H5 on CS specimens using the CDC A/H5 assay. Four (4) of the 33 confirmed cases with conjunctivitis symptoms (15.2%) tested positive for A/H5 on URT specimens only using the CDC A/H5 assay.

Of the 2 confirmed cases without conjunctivitis symptoms reported, 1/2 (50%) tested positive for A/H5 on a CS specimen, and 1/2 (50%) tested positive for A/H5 on a URT specimen only using the CDC A/H5 assay.

Of the 2 probable cases with conjunctivitis symptoms reported, 2/2 (100%) tested negative on CS specimens using the CDC A/H5 assay.

Subject matched paired URT swab specimens and CS specimens were available for testing in 32 out of 35 confirmed cases and 1 of the probable cases. For 3 of the 35 confirmed cases and 1 of the 2 probable cases, only CS specimens were available for testing.

Of the subject matched paired URT and CS specimens from 32 confirmed human cases, 10/32 (31.3%) were positive on at least one URT and the CS specimens;15/32 (46.9%) were positive in CS specimens only and 4/32 (12.5%) were positive in at least one URT specimen only. For 3/32 (9.4%) confirmed human cases the CS specimens tested inconclusive and URT specimens tested negative.

Of the subject matched paired URT and CS specimens from 1 probable human case, all URT and the CS specimen tested negative.

For 3 of the 35 confirmed cases where only CS specimens were available for testing, the CS specimens tested positive in 2 cases, and inconclusive in 1 case.

For 1 of the 2 probable cases where only a CS specimen was available for testing, the result was negative.

X. Conclusion

Validation data demonstrates that the modification of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel to add conjunctival swabs for use with the Influenza A/H5 Subtyping Kit, which is one of the four component assay kits of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel, is substantially equivalent to the predicate device.