

JAN 17 2014

8. **510(k) Summary**

CDC hereby submits this Special 510(k) in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter

Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30333
Establishment Registration: 1050190

Contact Person

CAPT Hye-Joo Kim, Pharm.D.
Associate Director for Regulatory Affairs
Office of the Director
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE, MS C-18
Atlanta, GA 30333
(404) 639-4643 (office)
(404) 639-1275 (fax)
hek6@cdc.gov

Proprietary Name

CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel, Influenza A/B Typing Kit

Common or Usual Name

Influenza A/B Typing Kit

Regulatory Information

Classification Regulation Section: 866.3980- Respiratory viral panel multiplex nucleic acid assay
Classification: Class II Classification Product
Code: OZE
Subsequent Product Codes: NSU
Panel: Microbiology

Predicate Device

CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel (K132508)

Device Description

The Influenza A/B Typing Kit contains components of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel that is used in real-time RT-PCR (rRT-PCR) assays on the ABI 7500 Fast Dx Real-Time PCR Instrument. The Influenza A/B Typing Kit consists of oligonucleotide primers and dual-labeled hydrolysis (TaqMan®) probes to be used in rRT-PCR for the *in vitro* qualitative

detection and characterization of human influenza viruses from viral RNA in respiratory specimens from patients presenting with influenza-like illness (ILI).

The Influenza A/B Typing Kit is based on technology which is used in many molecular diagnostic assays. rRT-PCR assays are one-tube assays that first reverse-transcribe specific regions of RNA into cDNA copies. The cDNA then serves as a template for a polymerase chain reaction that utilizes a thermocyclic heating and cooling of the reaction to logarithmically amplify a specific region of DNA. The probe anneals to a specific internal target sequence located between the target loci of the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades any probe molecules hybridized to amplified target sequence, causing the reporter dye to separate from the quencher dye, and generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle. Amplification of targets is reflected by logarithmic increase in fluorescence over time in comparison to the background signal.

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 Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR instrument in conjunction with clinical and epidemiological information:

- For qualitative detection of influenza virus type A or B 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 epidemiologic information for surveillance of circulating influenza viruses.

Performance characteristics for influenza were established during a season when seasonal influenza viruses A/H1 and A/H3 were the predominant influenza A viruses in circulation and during a season when the A/H1pdm09 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 3+ 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.

Technological Characteristics

The changes proposed to the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel subject to this special 510(k) are for labeling purposes only and will not alter the technological attributes of the device.

Substantial Equivalence Comparison

The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (K132508) will serve as the predicate for the intended change. Please see Table 1 for a detailed comparison.

Table 1: Device Comparison

	CDC Human Influenza Virus Real-time PCR Diagnostic Panel (K132508)	Influenza A/B Typing Kit
	<p>The CDC Human Influenza Virus Real-Time PCR Diagnostic Panel is intended for use in Real-time RT-PCR assays on an Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument in conjunction with clinical and epidemiological information:</p> <ul style="list-style-type: none"> For qualitative detection of influenza virus type A or B from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes and dual nasopharyngeal/throat swabs), and lower respiratory tract specimens (including bronchoalveolar lavages, bronchial washes, tracheal aspirates, sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture; For determination of the subtype of seasonal human influenza A virus as seasonal A/H1, A/H3, and/or A/H1pdm09 from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes and dual nasopharyngeal/throat swabs), and lower respiratory tract specimens (including bronchoalveolar lavages, bronchial washes, tracheal aspirates, sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture; 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 NPS, NS, TS, NA, NW, and NPS/TS) from human patients with signs and symptoms of respiratory infection and/or from viral culture; 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 the circulating influenza viruses. <p>Performance characteristics for influenza were established during a season when seasonal influenza A viruses in circulation and during a season when the A/H1pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses.</p> <p>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.</p> <p>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 3+ facility is available to receive and culture specimens.</p>	<p>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 assays on an Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument in conjunction with clinical and epidemiological information:</p> <ul style="list-style-type: none"> For qualitative detection of influenza virus type A or B from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes and dual nasopharyngeal/throat swabs), and lower respiratory tract specimens (including bronchoalveolar lavages, bronchial washes, tracheal aspirates, 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 the circulating influenza viruses. <p>Performance characteristics for influenza were established during a season when seasonal influenza viruses A/H1 and A/H3 were the predominant influenza A viruses in circulation and during a season when the A/H1pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses.</p> <p>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.</p> <p>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 3+ facility is available to receive and culture specimens.</p>
Intended Use		

CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel, Influenza A/B Typing Kit

Specimen Types	Nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes and dual nasopharyngeal/throat swabs, bronchoalveolar lavages, bronchial aspirates, bronchial washes, tracheal aspirates, sputum, and lung tissue. Only upper respiratory specimens for influenza B genetic lineage determination	Same
Technology	Real-time RT-PCR	Same
Required Instrumentation	Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS software version 1.4	Same
Organism Detected	Universal influenza A viruses (animal and human), Swine-origin influenza A viruses, Influenza B viruses, Influenza A subtypes: seasonal A/H1, A/H3, A/H1pdm09, and A/H5, Influenza B/Yamagata and B/Victoria lineages	Universal influenza A viruses (animal and human), Influenza B viruses
Nucleic Acid Extraction	Yes	Same

Risk Analysis

The Influenza A/B Typing Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel. A risk analysis of the labeling modification to create a separate Package Insert for the Influenza A/B Typing Kit was performed to verify that the change in the package insert did not present increased or new risks to the user. No new significant risks were identified as a result of the proposed modification.

Substantial Equivalence Conclusion

The changes proposed to the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel do not alter the device's design or technological attributes. In addition, the indications for use and intended use of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel will remain the same. The modification to the package insert included with the Influenza A/B Typing Kit made available to users retains all required label information, and is determined to be substantially equivalent to the predicate.



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

CENTERS FOR DISEASE CONTROL AND PREVENTION
CAPT. HYE-JOO KIM, PHARMA D.,
ASSOCIATE DIRECTOR FOR REGULATORY AFFAIRS, NCEZID
1600 CLIFTON ROAD, MSC-C18
ATLANTA, GA 30333

January 17, 2014

Re: K133869

Trade/Device Name: CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel,
Influenza A/B Typing Kit

Regulation Number: 21 CFR 866.3980

Regulation Name: Respiratory viral panel multiplex nucleic acid assay

Regulatory Class: II

Product Code: OZE, NXD, NSU

Dated: December 19, 2013

Received: December 20, 2013

Dear Dr. Kim:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Uwe Scherf -S for

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

Enclosure

Indications for Use

510(k) Number (if known): K133869

Device Name: CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel, Influenza A/B Typing Kit

Indications For 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 Applied Biosystems (ABI) 7500 Fast Dx Real Time PCR Instrument in conjunction with clinical and epidemiological information:

- For qualitative detection of influenza virus type A or B 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 epidemiologic information for surveillance of circulating influenza viruses.

Performance characteristics for influenza were established during a season when seasonal influenza viruses A/H1 and A/H3 were the predominant influenza A viruses in circulation and during a season when the A/H1pdm09 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 3+ 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.

Prescription Use <u> X </u> (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)
--	--------	--

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Tamara V. Feldblyum -S
2014.01.16 14:14:46 -05'00'