K130551

510(k) Summary

MAY 2 2 2013

Submitted By
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Proprietary Name
CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel

Common or Usual Name

Human Influenza Virus Real-Time RT-PCR Diagnostic Panel

Regulatory Information
Classification Regulation Section: 866.3332- Reagents for detection of specific novel influenza A viruses
Subsequent Regulation Sections: 866.3980- Respiratory viral panel multiplex nucleic acid assay
862.2570- Instrumentation for clinical multiplex test systems
Classification: Class II
Classification Product Code: OQW
Subsequent Product Codes: NSU, NXD, OEP
Panel: Microbiology

Predicate Device
CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (K111507)

Device Description
The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel is used in real-time RT-PCR assays (rRT-PCR) on the ABI 7500 Fast Dx Real-Time PCR Instrument. The device 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 CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel 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 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' exonuclease 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. The amplification of each target is reflected by a logarithmic increase in fluorescence in comparison to the background signal.

Intended Use

The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel is intended for use in rRT-PCR assays on an 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 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.

- For determination of the subtype of seasonal human influenza A viruses as seasonal A/H1, A/H3, and/or A/H1pdm09 from viral RNA in upper respiratory tract clinical specimens (including NPS, NS, TS, NA, NW, and NPS/TS) and lower respiratory tract specimens (including BAL, BW, TA, sputum and lung tissue) 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 epidemiological 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.

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 epidemiological 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 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.

Indications for Use

The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel 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;
- For determination of the subtype of seasonal human influenza A viruses as seasonal A/H1, A/H3, and/or A/H1pdm09 from viral RNA in upper respiratory tract clinical specimens (including NPS, NS, TS, NA, NW and NPS/TS) and lower respiratory tract specimens (including BAL, BW, TA, sputum and lung tissue) 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 epidemiological information for surveillance of circulating influenza viruses.

Technological Characteristics

The changes proposed to the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel subject to this 510(k) do not change the device's design or technological attributes.

Substantial Equivalence Comparison

The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (K111507) will serve as the predicate for the intended change. See Table 8-1 for a detailed comparison.

Table 8-1: Device Comparison

	CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (K111507)	CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (used with the Quanta BioSciences qScript™ One-Step qRT-PCR Kit, Low ROX)
Intended Use	The CDC Human Influenza Virus Real-Time RT-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: • 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 viruses 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 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 epidemiological information for surveillance of the circulating influenza viruses.	Same
Organism Detected	Universal influenza A viruses (animal and human), Swine-origin influenza A viruses, Influenza B viruses, and Influenza A subtypes: seasonal A/H1, A/H3, A/H1pdm09 , and A/H5	Same
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 and virus culture.	Same
Nucleic Acid Extraction	Yes	Same

Extraction Method	• QIAamp® Viral RNA Mini Kit, Qiagen Inc. • MagNA Pure Compact -Total Nucleic Acid Kit, Roche Applied Science • MagNA Pure Compact – RNA Isolation Kit, Roche Applied Science • MagNA Pure LC - RNA Isolation Kit II, Roche Applied Science • Qiagen QIAcube with QIAamp® Viral RNA Mini Kit, Qiagen Inc. • NucliSENS® easyMAG®, bioMerieux	Same
Enzyme Master Mix	Invitrogen SuperScript™ III Platinum® One-Step Quantitative RT-PCR Kits (with or without ROX)	Invitrogen SuperScript™ III Platinum® One-Step Quantitative RT-PCR Kit (with or without ROX) **OR** Quanta BioSciences qScript™ One-Step qRT-PCR Kit, Low ROX

The intended change will add another enzyme kit option for users of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel. The new enzyme kit option, Quanta BioSciences qScript™ One-Step qRT-PCR Kit, Low ROX functions in the same manner as the current enzyme kit used with the CDC device. A summary of the characteristics of the two enzyme kits is provided in Table 8-2 for comparison.

Table 8-2: Enzyme Comparison

	Quanta BioSciences qScript™ One-Step qRT-PCR Kit, Low ROX	**Invitrogen SuperScript™ III Platinum® One-Step Quantitative RT-PCR Kit (with or without ROX)**
FDA Regulatory Status	RUO	RUO
Manufactured Under GMPs	No	No
Type of Kit	One-Step RT-PCR	One-Step RT-PCR
cDNA synthesis & PCR	Both reactions take place in one tube	Both reactions take place in one tube
cDNA Synthesis Temperature	48°-50°C	42°-60°C
Compatible Real-Time PCR Systems	Multiple, including the ABI 7500 Fast Dx Real-Time PCR Instrument	Multiple, including the ABI 7500 Fast Dx Real-Time PCR Instrument
Reverse Transcriptase	Optimized 50X formulation of recombinant MMLV reverse transcriptase	Recombinant MMLV that has been engineered to reduce RNase H activity and provide increased thermal stability
Taq polymerase	AccuStart™ Taq DNA polymerase; a recombinant Taq DNA polymerase preparation which contains monoclonal antibodies that bind to the polymerase and keep it inactive before PCR thermal cycling. Activated AccuStart Taq DNA polymerase possesses 5'→3' DNA polymerase activity and a double-strand specific 5'→3' exonuclease. The polymerase does not have 3'-exonuclease activity and is free of any contaminating endo or exonuclease activities.	Platinum® Taq DNA polymerase; Recombinant Taq DNA polymerase that is complexed with a proprietary antibody that blocks polymerase activity at ambient temperatures. Activity is restored during the PCR denaturation step, providing a "hot start" PCR that increases sensitivity, specificity, and yield.
Storage & Stability	Stable for 1 year when stored in a constant temperature freezer at -20°C.	Components must be stored at -20°C. Manufacturer has not established a shelf life for the product.
Hybridization probe detection chemistries	Dual-labeled fluorogenic oligonucleotide probes	Dual-labeled fluorogenic oligonucleotide probes

Each enzyme product name will hereafter be abbreviated; Quanta BioSciences qScript™ One-Step qRT-PCR Kit, Low ROX (Quanta qScript™) and Invitrogen SuperScript™ III Platinum® One-Step Quantitative RT-PCR Kit (with or without ROX) (Invitrogen SuperScript™).

Analytical Performance Evaluation

Analytical Sensitivity - Limit of Detection Study (LOD)

Analytical sensitivity was demonstrated by determining the LOD of each primer and probe set in the CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel using Quanta qScript™ to demonstrate equivalency to the LOD using Invitrogen SuperScript™. Serial dilutions of two different influenza virus strains representing influenza B, A/H1, A/H3, A/H5 and A/H1pdm09 were tested to identify an end-point for detection using both enzymes. RNA was purified from each of the characterized viruses using one of the cleared extraction procedures. The LOD for each primer and probe set was calculated to indicate the range of the lowest detectable concentration of influenza virus (EID_{50} /mL or $TCID_{50}$ /mL) at which ≥ 95% of all replicates tested positive. The lowest concentration of influenza virus detected determined the end-point concentration where both the type and subtype primer and probe sets had uniform detection. If the two endpoints differed in concentration, the lowest

concentration where the endpoints had uniform detection was reported as the LOD. In all cases, the resulting LOD was either the same or within one 5-fold dilution of the comparator (Invitrogen SuperScript™). The results are summarized in Table 8-3.

Table 8-3: LOD Summary Comparison Table

Influenza Virus Type/Subtype	Influenza Virus	LOD (EID_{50}/mL)	
		Invitrogen SuperScript™	Quanta qScript™
A/H1N1	A/Brisbane/59/2007	$10^{2.3}$	$10^{2.3}$
	A/Fujian Gulou/1896/2009	$10^{2.7}$	$10^{2.7}$
A/H1pdm09	A/California/07/2009	$10^{1.6}$	$10^{3.0}$
	A/South Carolina/2/2010	$10^{2.1}$	$10^{2.8}$
A/H3N2	A/Perth/16/2009	$10^{2.8}$	$10^{2.8}$
	A/Victoria/361/2011	$10^{2.8}$	$10^{2.8}$
A/H5N1	A/Vietnam/1203/2004-PR8/CDC-RG	$10^{1.2}$	$10^{1.2}$
	A/Anhui/01/2005-PR8-IBCDC-RG6	$10^{1.7}$	$10^{2.4}$
B	B/Wisconsin/01/2010	$10^{2.1}$	$10^{2.8}$
	B/Nevada/01/2011	$10^{1.4}$	$10^{0.7}$

Analytical Sensitivity - Inclusivity Testing

The inclusivity of the CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel using Quanta qScript™ was examined by testing two influenza viruses of each type and subtype against the corresponding target assay within the panel at concentrations at or near the established LOD. Virus RNA was isolated using one of the cleared extraction chemistries and serially diluted to approximately 10^2 EID_{50} /mL. The performance of Quanta qScript™ was compared to Invitrogen SuperScript™ by testing each virus RNA preparation in triplicate with the CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel.

Table 8-4 summarizes the results of the inclusivity testing of the CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel with both the investigational (Quanta qScript™) and comparator (Invitrogen SuperScript™) enzyme systems. The average Ct value of the three replicates is presented for each assay.

Table 8-4: Inclusivity Results Summary

Virus Type/Subtype	Strain Designation	Titer	InfA (Avg[1] Ct)		H1 (Avg Ct)		H3 (Avg Ct)		pdm InfA (Avg Ct)		H1pdm (Avg Ct)		H5a (Avg Ct)		H5b (Avg Ct)		B (Avg Ct)	
		(EID_{50}/mL)	INV[2]	QUA[2]	INV	QUA	INV	QUA	INV	QUA	INV	QUA	INV	QUA	INV	QUA	INV	QUA
A/H1N1	A/Brisbane/59/07	$10^{2.4}$	34.3	34.1	34.5	34.9												
A/H1N1	A/Fujian Gulou/1896/2009	$10^{2.7}$	33.8	32.8	33.3	33.3												
A/H3N2	A/Perth/16/2009	$10^{2.8}$	33.7	35.0			35.5	35.1										
A/H3N2	A/Rhode Island/01/2010	$10^{2.9}$	30.2	29.9			34.3	30.3										
A/H1N1pdm09	A/California/07/09	$10^{2.3}$	33.0	33.0					31.1	35.8	34.5	36.5						
A/H1N1pdm09	A/South Carolina/2/2010	$10^{2.1}$	35.7	32.6					34.5	33.5	34.4	36.1						
A/H5N1	A/Anhui/01/2005 – PR8-IBCDC-RG6	$10^{2.5}$	34.4	32.5									33.9	34.0	37.9	34.2		
A/H5N1	A/Vietnam/1203/2004 – PR8/CDC-RG	$10^{2.0}$	31.3	29.7									34.9	33.6	34.3	35.4		
B	B/Texas/06/2011	$10^{2.9}$															35.0	32.2
B	B/Brisbane/60/2008	$10^{2.5}$															32.9	31.9

[1] Avg = average. The average of 3 replicates is represented.
[2] INV = Invitrogen SuperScript™; QUA = Quanta qScript™

The results of the inclusivity testing with the CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel using Quanta qScript™ were 100% concordant with the predicate.

Clinical Performance Evaluation

A prospective clinical study was conducted during the 2011-2012 influenza season to compare the performance of the CDC Human Influenza rRT-PCR Diagnostic Panel using Quanta qScript™ and Invitrogen Superscript™. Residual material from a total of 1,002 respiratory specimens from patients who were symptomatic for influenza-like illness (ILI) was collected and tested at 6 clinical sites. Nine hundred thirty-one specimens were included in the data analysis after exclusion of samples with inconclusive results (42), technician or instrument error (25), or unspecified specimen type (4).

The study population and specimen types are summarized by age range and specimen type in Table 8-5.

Table 8-5: Study Population and Specimen Type Summary

	Number of Clinical Specimens by Type							
Age Range	NA	NW	NS	NPS	NPS/TS	TS	LR	Unknown
0-16	10	15	51	337	14	2	3	2
17-54	2	6	37	263	14	2	2	2
≥ 55	1	2	25	175	9	4	0	0
Unknown	0	1	0	23	0	0	0	0
Totals	13	24	113	798	37	8	5	4

NA=nasal aspirate, NW=nasal wash, NS=nasal swab, NPS=nasopharyngeal swab, NPS/TS=dual nasopharyngeal and throat swab, TS=throat swab, LR=lower respiratory specimens including bronchoalveolar lavage, bronchial wash, tracheal aspirate, sputum, or lung tissue.

Expected Values

During February 25, 2012 to May 19, 2012, World Health Organization and National Respiratory and Enteric Virus Surveillance System (NREVSS) collaborating laboratories in the United States tested 47,281 respiratory specimens for influenza viruses. Of these, 9,415 (19.9%) were positive: 85% of the positive specimens were positive for influenza A viruses and 15% were positive for influenza B viruses. Among the 5,071 influenza A viruses for which subtyping was performed, 3,680 (72.6%) were influenza A/H3 viruses and 1,391 (27.4%) were 2009 H1N1 influenza viruses.

Prospective Study Comparison

The performance of each assay within the panel, with the exception of the H5a and H5b assays, was demonstrated at each clinical site using both enzymes. The results from the prospective study are summarized in Table 8-6 showing the percent sensitivity or specificity with the two-sided 95% confidence interval.

Table 8-6: Summary Comparison

Assay Result	# of Positives[1]	% Positive Agreement (95% CI)	# of Negatives[1]	% Negative Agreement (95% CI)
InfB	77/80	96.3 (89.5 – 98.7)	851/851	100.0 (99.6 – 100.0)
A/H1	0	NA[2]	931/931	100.0 (99.6 – 100.0)
A/H3	331/335	98.8 (97.0 – 99.5)	595/596	99.8 (99.1 – 100.0)
A/H1pdm09	43/43	100.0 (91.8 – 100.0)	888/888	100.0 (99.6 – 100.0)

[1]Proportion of true positives or true negatives correctly identified versus the comparator
[2]NA = not applicable

Retrospective Study Comparison

Due to the absence of seasonal influenza A/H1N1, retrospective specimens from a previous clinical study conducted during the 2006-2007 influenza season were used to supplement the clinical evaluation. The study director used historical study results to select specimens containing varying concentrations of seasonal influenza A/H1N1. No negative specimens were selected since the prospective study provided sufficient numbers of negative specimens for comparing the specificity of the investigational enzyme with the A/H1 marker assay. The results of the retrospective specimen testing are summarized in Table 8-7.

Table 8-7: A/H1 Comparison

Assay Result	# of Positives[1]	% Positive Agreement (95% CI)	# of Negatives[1]	% Negative Agreement (95% CI)
A/H1	30/30	100.0 (88.7 – 100.0)	0	NA[2]

[1]Proportion of true positives or true negatives correctly identified versus the comparator
[2]NA = not applicable

Due to the lack of available clinical specimens containing influenza A/H5N1, evaluation of the performance of the H5a and H5b primer and probe sets was addressed with an alternative approach. Samples for the retrospective study were prepared according to a method using a characterized and titered stock of influenza A/H5N1 virus and human A549 cells (Lednicky et al.). The stock virus was added to the A549 cell suspension in high, moderate, and low concentrations with 12 samples at each concentration. The low virus concentration was prepared to approximate the LOD of the A/H5 assay. Test results of simulated A/H5N1 samples are summarized in Tables 8-8 to 8-10.

Table 8-8: A/H5 Comparison High Virus Concentration

		Invitrogen SuperScript™			
		Positive	Negative	Inconclusive	Total
Quanta qScript™	Positive	12	0	0	12
	Negative	0	0	0	0
	Inconclusive	0	0	0	0
	Total	12	0	0	12

Table 8-9: A/H5 Comparison Moderate Virus Concentration

		Invitrogen SuperScript™			
		Positive	Negative	Inconclusive	Total
Quanta qScript™	Positive	12	0	0	12
	Negative	0	0	0	0
	Inconclusive	0	0	0	0
	Total	12	0	0	12

Table 8-10: A/H5 Comparison Low Virus Concentration

		Invitrogen SuperScript™			
		Positive	Negative	Inconclusive	Total
Quanta qScript™	Positive	1	0	1	2
	Negative	0	0	0	0
	Inconclusive	2	0	8	10
	Total	3	0	9	12

Fifty negative specimens were obtained from a previous clinical study conducted during the 2006-2007 influenza season wherein respiratory specimens were collected and stored under the same conditions and acceptance criteria as the prospective study. The results with the negative specimens showed 100% agreement with a 95% confidence interval of 92.9-100.0.

Conclusion

Analytical and clinical data demonstrate that the performance of the CDC Human Influenza Virus rRT-PCR Diagnostic Panel with Quanta qScript™ is substantially equivalent to that with Invitrogen Superscript™.

References

Lednicky JA, Villanueva JM, Burke SA, Shively R, Shaw MW, Daniels DE, Hamilton SB, Donis RO. 2010. Validation of a method for preparing influenza H5N1 simulated samples. J Virol Methods. 2010 Aug;167(2):125-31.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center – WO66-G609
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May 22, 2013

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Re: K130551
Trade/Device Name: CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel
Regulation Number: 21 CFR 866.3332
Regulation Name: Reagents for detection of specific novel influenza A viruses
Regulatory Class: II
Product Code: OQW, NSU, NXD, OEP
Dated: March 01, 2013
Received: March 04, 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,

Sally A. Hojvat -S

Sally Hojvat
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Intended Use

510(k) Number (if known): K130551

Device Name: **CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel**

Intended Use:
The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel 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;
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- 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 epidemiological 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.

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 epidemiological 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 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 ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Tamara V. Feldblyum -S
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