

SPECIAL 510(k): Device Modification
OIR Review Memorandum (Decision Making Document is Attached)

To: Centers for Disease Control and Prevention

RE: K140857

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
 CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel
 510(k): K132508
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**:
 The modification presented in this special 510(k) consisted of a revised package insert for the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel, Influenza B Lineage Genotyping Kit. Recently, additional assays have been included in the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and cleared by FDA to accommodate the new influenza virus subtypes. The consumption of the various assays within the panel may be different since the prevalence of influenza virus types and subtypes vary from season to season. To address the consequent variation in consumption, CDC plans to provide the users with an option to order different configurations of specific components of the panel (including the Influenza B Lineage Genotyping Kit in this special 510(k)) so that their supply of reagents can be managed efficiently, minimizing the waste. The different components of CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel will be accompanied by revised labeling (package inserts) and the current submission is to clear another component, i.e., Influenza B Genotyping.
4. The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
5. **Comparison Information:** (similarities and differences)

	CDC Human Influenza Virus Real-time PCR Diagnostic Panel (K132508)	Influenza A Lineage Genotyping Kit (K140857)
Intended Use	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: For qualitative detection of influenza virus type A or B from viral RNA in upper	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 assays on an Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument in conjunction with clinical and epidemiological information: For the determination of the genetic lineage of human

	<p>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;</p> <p>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;</p> <p>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</p>	<p>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;</p> <p>To provide epidemiologic information for surveillance of the circulating influenza viruses.</p> <p>Performance characteristics for influenza B lineage genotyping were established during a season when influenza B/Victoria and B/Yamagata lineages were found in approximately equal proportion.</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>
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	<p>symptoms of respiratory infection and/or from viral culture;</p> <p>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;</p> <p>To provide epidemiologic information for surveillance of the circulating influenza viruses.</p> <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>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</p>	
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	<p>assessment in consultation with national influenza surveillance experts.</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>	
Specimen Type	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	Only upper respiratory specimens for influenza B genetic lineage determination. Nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes and dual nasopharyngeal/throat swabs.
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	Influenza B/Yamagata and B/Victoria lineages

	B/Yamagata and B/Victoria lineages	
Nucleic Acid Extraction	Yes	Same

6. A Design Control Activities Summary which includes:

A “Declaration of Conformity” statement was submitted for the verification activities, and the manufacturing facility. The statement was signed by the Acting Branch Chief of the Virus Surveillance and Diagnostic Branch, CDC, and the Deputy Branch Chief, Division of Scientific Resources, CDC. The statement indicates:

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis for the modification, were performed by the designated individual(s) and the results demonstrate the predetermined acceptance criteria were met.

Manufacturing Facility

The CDC Division of Scientific Resources manufacturing facility is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

In conclusion, the modified labeling is truthful and accurate. The changes do not affect the performance of the test and it is therefore substantially equivalent to the current cleared test.

7. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter’s description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.