The information previously contained on these webpages were authorized under the 2009 H1N1 Influenza Emergency Use Authorizations (EUAs). As of June 23, 2010, the EUAs have been terminated and this information is no longer current.

ATTACHMENT 3

******DO NOT DISCARD: Important product-specific information ******

CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (NPS, NS, TS, NPS/TS, NA) and Viral Culture

Expanded Intended Use to Include Additional Specimen Types and AgPath-ID RT-PCR System

CATALOG: KT0096
LOT:
EXPIRATION DATE:

Components of the rRT-PCR Flu Panel are essential to testing with the rRT-PCR Swine Flu Panel authorized for use under the Emergency Use Authorization Act. The rRT-PCR Flu Panel is utilized in conjunction with or as the first tier test for patient specimens with suspected 2009 A/H1N1 swine flu virus. The 510(k) device is an integral component of the testing algorithm for the rRT-PCR Swine Flu Panel.

This EUA is intended to use the AgPath-ID™ One-Step RT-PCR Kit with the rRT-PCR Flu Panel (IVD) to detect seasonal influenza A/H1, A/H3, A/H5 (Asian lineage) from viral RNA in nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, dual naso-pharyngeal/throat swabs, and isolates from human respiratory specimens.

INTENDED USE:
The CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (NPS, NS, TS, NPS/TS, NA) and Viral Culture (rRT-PCR Flu Panel) is intended for use in Real-time RT-PCR assays on an ABI 7500 Fast Dx Real-time PCR instrument in conjunction with clinical and epidemiological information:

- For the qualitative detection of swine-like 2009 A/H1N1 influenza virus type A in symptomatic patients from viral RNA in nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, dual naso-pharyngeal/throat swabs, and isolates specimens,
- for qualitative detection of influenza virus type A or B in symptomatic patients from viral RNA in nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, dual naso-pharyngeal/throat swabs, and isolates specimens,
- for determination of the subtype of seasonal human influenza A virus, as seasonal A/H1 or A/H3, if present, from viral RNA in nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, dual naso-pharyngeal/throat swabs, and isolates,
- for 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, and
- to provide epidemiologic information for surveillance for influenza viruses.

Performance characteristics for influenza A were established when influenza A/H3 and A/H1 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

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.

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

REAGENTS
Probe contains 6-FAM reporter and BHQ1 quencher. Approximate number of tests per kit: 1,000.

ANCILLARY REAGENTS REQUIRED BUT NOT PROVIDED
Specific lots for the AgPath-ID™ One-Step RT-PCR Kit will be qualified for use with the CDC rRT-PCR Flu Panel by CDC Influenza Division quality control testing and lot qualification program.

The rRT-PCR Flu Panel test performance requires that only qualified ancillary reagent lots be used with the device. Any lots not specifically qualified by the CDC Influenza Division for use with the rRT-PCR Flu Panel are not valid for use with this device, and may affect device performance.

PRECAUTIONS:
Reagents used for testing nasal aspirates, throat swabs, dual nasopharyngeal/throat swabs, and isolates are for use under emergency authorization only.

REHYDRATION
Rehydrate each tube with 0.5 ml (500 µl) of 10 mM Tris, pH 7.4 to 8.2 or PCR water. Dispense into aliquots.

STORAGE INSTRUCTIONS:
Prior to rehydration, store kits at 2-8°C. Store rehydrated aliquots of primers and probes at -20°C or below. Do not store in frost-free freezers. Rehydrated primers and probes may be stored frozen for up to 12 months. Thawed aliquots of probes and primers may be stored in the dark up to 6 months at 2-8°C. Do not use any product (refrigerated or frozen) past the expiration date.

PROCEDURE/INTERPRETATION/LIMITATIONS/EXPECTED VALUES:
Refer to MCV Human Influenza Virus Real-time RT-PCR Detection Panel (IVD) instructions for use provided by CDC Influenza Division. The procedure may be requested by sending email to FluSupport@cdc.gov

REAGENT COMPLAINTS/QUESTIONS:
Please send comments by email to FluSupport@cdc.gov

DISTRIBUTED BY:
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