

January 26, 2006

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: K060159 Request for Evaluation of Automatic Class III Designation Under 513(f)(2)

Dear Sir or Madam:

510(k) Number for NSE Finding

The Centers for Disease Control and Prevention respectfully requests that premarket notification K060159 be considered for a risk-based classification of the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set. A "not substantially equivalent" decision was rendered for K060159 on January 26, 2006.

Statement of Cross Reference to 510(k)

The Centers for Disease Control and Prevention hereby cross-references information contained in 510(k) K060159.

Classification Being Recommended

The Centers for Disease Control and Prevention believes the documentation presented in premarket notification K060159 is sufficient to substantiate an order classifying the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set as Class II (general and special controls) pursuant to section 513 of the Federal Food, Drug and Cosmetic Act.

Potential Benefits

The HHS Pandemic Influenza Plan states that it is the responsibility of the U.S. Department of Health and Human Services to work with public health laboratories to make sure detection methods are in place to identify a pandemic threat.¹ The plan specifically states that RT-PCR assays should be incorporated into the influenza testing activities of public health laboratories, and that positive results obtained for RT-PCR assays specific for novel influenza strains should be treated as a presumptive positive for the virus.² As threat strains are identified, developing, producing and disseminating RT-PCR reagents is the responsibility of the CDC Influenza Laboratory.³ CDC and the LRN are then responsible for implementation of the RT-PCR protocols.⁴

The Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set provides a significant benefit to public health as a surveillance tool for early detection of Influenza A/H5 (Asian lineage) virus. During influenza season, this assay can allay the concerns of patients and healthcare providers by ruling out the presence of Influenza A/H5 (Asian lineage) virus

¹ U.S. Department of Health and Human Services, "Laboratory Diagnostics", Supplement 2 to *HHS Pandemic Influenza Plan* (Washington D.C.: U.S. Department of Health and Human Services, November 2005). [cited 12 January 2006] p S2-2. Available from www.hhs.gov/pandemicflu/plan/; INTERNET.

² U.S. Department of Health and Human Services, "Laboratory Diagnostics", p S2-6.

³ U.S. Department of Health and Human Services, "Laboratory Diagnostics", p S2-7.

⁴ U.S. Department of Health and Human Services, "Laboratory Diagnostics", p S2-7.

in patients with acute respiratory illness. In the event of introduction of this virus into the United States population, this assay can help determine geographic distribution of an Influenza A/H5 (Asian lineage) virus and allow public health professionals to make appropriate decisions based on a specific and sensitive assay.

Mitigation of Risk

Distribution of this product will be limited to Laboratory Response Network designated laboratories which have:

- facilities meeting the requirements for safe handling of specimens potentially containing Influenza A/H5 (Asian lineage) virus
- equipment appropriate for the preparation of specimens and proper conduct of testing
- personnel trained and experienced in the proper handling of specimens and use of molecular methods including real-time RT-PCR

Results obtained from assays in which the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set is used will be combined with other laboratory data, clinical information, and epidemiological data for the purposes of public health preparedness and response. Positive and equivocal results will be further evaluated by the CDC experts in the fields of influenza research, public health preparedness and response, and epidemiology. Any risk posed by use of the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set is mitigated by

- limited distribution to qualified laboratories
- involvement of national influenza surveillance experts in interpretation and confirmation of the results
- involvement of public health experts in response activities
- use of the Influenza A/H5 (Asian lineage) virus RT- PCR Primer and Probe Set in conjunction with other laboratory, epidemiological and clinical evaluation tools

Proposed General and Special Controls

The Centers for Disease Control and Prevention believes that general controls and special controls in accordance with FDA's draft Class II Special Control Guidance Document: Novel Influenza A Virus Reagents constitute adequate information to ensure reasonable assurance of the safety and effectiveness of the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set (K060159) via the premarket notification process 21 CFR 807. These controls parallel the safety and effectiveness information provided in K060159 for its intended use:

The Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set is intended for the in vitro qualitative detection of Influenza A/H5 (Asian lineage) virus RNA either directly in patient specimens or in viral cultures for the presumptive laboratory identification of Influenza A/H5 (Asian lineage) virus.

Testing with the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set should be used in conjunction with other laboratory testing and clinical observations for the following indications:

1. providing epidemiological information for the surveillance of human infection with Influenza A/H5 (Asian lineage) virus
2. identifying patients who may be infected with Influenza A/H5 (Asian lineage) virus based on clinical and epidemiological risk factors
 - Use of this assay is limited to Laboratory Response Network (LRN) designated laboratories.

- The definitive identification of influenza A/H5 (Asian lineage) either directly from patient specimens or from viral 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.

The CDC appreciates the consultation and guidance you have provided throughout this 510(k) submission preparation and review process. If there are any questions regarding this submission, you may contact me at (404) 639-4643, or Judy Sheldon at (404) 639-0752. You may also contact us via email or fax.

Respectfully,

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