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MAY 29 2008

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: k063765
Evaluation of Automatic Class III Designation
xTAG™ RVP (Respiratory Viral Panel)
Regulation Number: 21 CFR 866.3980
Classification: Class II
Product Code: OCC, OEM, OEP

Dear Dr. Lee:

This letter corrects our classification letter of January 3, 2008.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the xTAG™ Respiratory Viral Panel (RVP) that is intended to simultaneously detect and identify multiple respiratory virus nucleic acids in nasopharyngeal swabs from individuals suspected of respiratory tract infections. The following virus types and subtypes are identified using RVP: Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza B, Respiratory Syncytial Virus subtype A, Respiratory Syncytial Virus subtype B, Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3 virus, Human Metapneumovirus, Rhinovirus, and Adenovirus. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection if used in conjunction with other clinical and laboratory findings. It is recommended that specimens found to be negative after examination using RVP be confirmed by cell culture. Negative results do not preclude respiratory virus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions. 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. The use of additional laboratory testing (e.g., bacterial culture, immunofluorescence, radiography) and clinical presentation must be taken into consideration in order to obtain the final diagnosis of respiratory viral infection.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the xTAG™ Respiratory Viral Panel (RVP) into class II under the generic name, Respiratory viral panel multiplex nucleic acid assay. This order also identifies the special controls applicable to this device and substantially equivalent devices of this generic type.

FDA identifies this generic type of device as:

21 CFR §866.3980 Respiratory viral panel multiplex nucleic acid assay. A respiratory viral panel multiplex nucleic acid assay is a qualitative in vitro diagnostic device intended to simultaneously detect and identify multiple viral nucleic acids extracted from human respiratory specimens or viral culture. The detection and identification of a specific viral nucleic acid from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection when used in conjunction with other clinical and laboratory findings. The device is intended for detection and identification of a combination of the following viruses:

- (1) Influenza A and Influenza B
- (2) Influenza A subtype H1 and Influenza A subtype H3
- (3) Respiratory Syncytial Virus subtype A and Respiratory Syncytial Virus subtype B
- (4) Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3 virus
- (5) Human Metapneumovirus
- (6) Rhinovirus
- (7) Adenovirus.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On December 4, 2007 FDA filed your petition requesting classification of the xTAG™ Respiratory Viral Panel (RVP) into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA had issued an order on November 30, 2007 affirming that the the xTAG™ Respiratory Viral Panel (RVP) was classified in class III according to statute, because it was not substantially equivalent to a class I or class II device.

In order to classify the xTAG™ Respiratory Viral Panel (RVP) into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, FDA has determined that the xTAG™ Respiratory Viral Panel (RVP) can be classified in class II with the establishment of special controls.

FDA has identified a number of issues impacting the safety and effectiveness of a Respiratory viral panel multiplex nucleic acid assay. Failure of the Respiratory viral panel multiplex nucleic acid assay to perform as indicated may lead to erroneous or inaccurate test results and incorrect patient management decisions. A false positive result could lead to unnecessary, inappropriate, or delayed treatment of potentially more serious infection caused by bacterial or other pathogens. A false negative result could lead to failure to provide a definitive diagnosis and the correct treatment, and may contribute to unnecessary treatment. A lack of result could lead to delayed diagnosis and inadequate treatment. Additionally, failure of the device to perform as indicated when influenza subtypes are included in the respiratory viral panel may lead to inappropriate public health responses. When Human Metapneumovirus is included in the respiratory viral panel, failure of the device to perform as indicated may lead to incorrect patient management decisions.

Failure to interpret assay results in the context of the other laboratory results and the clinical presentation could lead to inappropriate or delayed treatment. The virus or viruses detected may not necessarily be the cause of the clinical symptoms, therefore positive assay results do not rule out bacterial co-infection, or co-infection with other viruses.

The special controls that are established to mitigate these risks are three guidance documents, (1) "Class II Special Controls Guidance Document: Respiratory viral panel multiplex nucleic acid assay," (2) as applicable, "Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) using nucleic acid assays," and (3), as applicable, "Class II Special Controls Guidance Document: Testing for detection and differentiation of Influenza A virus subtypes using multiplex nucleic acid assays." These three guidance documents include recommendations for performance evaluation, labeling, and measures to address the effects of ancillary reagents (reagents referenced in instructions for use of the respiratory viral panel device but not provided) on the safety and effectiveness of the RVP. FDA believes that these special controls, along with the general controls of the act, will be sufficient to provide reasonable assurance of the safety and effectiveness of respiratory viral panel multiplex nucleic acid assay.

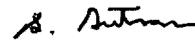
Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the respiratory viral panel multiplex nucleic acid assay they intend to market prior to marketing the device.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Zivana Tezak at (240) 276-0772.

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

INDICATIONS FOR USE

510(k) Number (if known): K063765

Device Name: xTAG™ Respiratory Viral Panel (RVP)

The xTAG™ Respiratory Viral Panel (RVP) is a qualitative nucleic acid multiplex test intended for the simultaneous detection and identification of multiple respiratory virus nucleic acids in nasopharyngeal swabs from individuals suspected of respiratory tract infections. The following virus types and subtypes are identified using RVP: Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza B, Respiratory Syncytial Virus subtype A, Respiratory Syncytial Virus subtype B, Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3 virus, Human Metapneumovirus, Rhinovirus, and Adenovirus. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection if used in conjunction with other clinical and laboratory findings. It is recommended that specimens found to be negative after examination using RVP be confirmed by cell culture. Negative results do not preclude respiratory virus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

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. The use of additional laboratory testing (e.g. bacterial culture, immunofluorescence, radiography) and clinical presentation must be taken into consideration in order to obtain the final diagnosis of respiratory viral infection.

Due to seasonal prevalence, performance characteristics for Influenza A/H1 were established primarily with retrospective specimens.

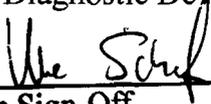
The RVP assay cannot adequately detect Adenovirus species C, or serotypes 7a and 41. The RVP primers for detection of rhinovirus cross-react with enterovirus. A rhinovirus reactive result should be confirmed by an alternate method (e.g. cell culture).

Performance characteristics for Influenza A Virus 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. If infections 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 a state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Prescription Use X and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K063765