

510(k) Summary

K091667

1.0 Submitted By:

JUN 25 2009

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2.0 Date Submitted

June 3, 2009

3.0 Device Name(s):

Proprietary Name: xTAG[®] RVP
Classification Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay [866.3980]

4.0 Legally Marketed Device

xTAG[®] RVP claims substantial equivalence to the xTAG[®] RVP originally cleared under FDA 510(k) k063765 and cleared under Special 510(k) k081483.

5.0 Device Description

The xTAG Respiratory Viral Panel includes the following components:

- Multiplex PCR primer mix (without dNTPs)
- Multiplex target specific primer extension (TSPE) primers (includes dNTPs)
- Coupled bead mix
- 10x buffer
- xTAG[®] Data Analysis Software (TDAS RVP-I)

6.0 Intended Use

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 for Influenza B, Respiratory Syncytial Virus subtype A and B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3 and

Adenovirus, 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.

7.0 Comparison to the Predicate (Description of the Modification to the Legally Marketed Device)

The xTAG Respiratory Viral Panel performance parameters remain unchanged.

8.0 Summary of Performance Data

The xTAG RVP can detect the matrix gene of 2009 Influenza A/H1N1 but can not identify the hemagglutinin gene of the 2009 Influenza A/H1N1 in clinical specimens. The studies summarized below demonstrate that xTAG RVP is an effective aid in the detection of 2009 influenza A/H1N1 strains (Ginocchio & George, 2009; Ginocchio et al. 2009):

In a study carried out during the 2009 Influenza A H1N1 (swine flu) outbreak in New York (Ginocchio & George, 2009), a total of 1,382 patient nasopharyngeal swab samples were initially tested with a variety of method including rapid antigen tests (n=1095), direct immunofluorescence (n=1164), and rapid virus culture (n=1140). Samples that tested positive for Influenza A with any of these methods, or derived from patients with a high potential to be infected with the 2009 Influenza A H1N1 strain, were further tested with xTAG RVP (n=375). A total of 201 of these samples were identified as Flu A positive by the RVP assay, two samples contained Influenza B, and other respiratory viruses in 58 samples (adenovirus, metapneumovirus, Parainfluenza 1, 2, 3, RSV, and rhinovirus). Sixty of the 201 Flu A positive samples were identified by xTAG RVP as seasonal strains (2 as H1 and 58 as H3). The remaining 141 Flu A positive samples were negative for both H1 and H3 by xTAG RVP (unsubtypable). Frozen residual portions of 101 of the 141 unsubtypable samples were forwarded to the Laboratory of Viral Diseases (Albany, NY) for further testing with the CDC rRT-PCR assay for 2009 Influenza A H1N1 (swine flu). A total of 99 of the 101 specimens tested with the CDC assay were identified as positive for 2009 Influenza A/H1N1 (CT<37). The two remaining specimens produced weak positive signals (CT>37) on one or more of the influenza targets and could not be classified as positive for the 2009 Influenza A/H1N1 strain. These two samples also produced weak positive signals in the RVP assay.

A study by Ginocchio et al. (2009) evaluated the performance of a variety of diagnostic assays, including the xTAG RVP, for the 2009 Influenza A/H1N1 surveillance. In this study, a total of 2,715 patient nasopharyngeal swab samples were tested by xTAG RVP and 1265 of these were positive for influenza A. Of the 1265, 1108 were "flu A unsubtypeable", 151 were seasonal H3N2 and 6 were seasonal H1N1. Of the 1108 flu A unsubtypeable with the xTAG RVP, all were confirmed to be Influenza A/H1N1 with the CDC rRT-PCR assay.



JUN 25 2009

Food and Drug Administration
2098 Gaither Road
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Re: K091667
Trade/Device Name: xTAG[®] Respiratory Viral Panel
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: Class II
Product Code: OCC,OEM,OEP
Dated: June 3, 2009
Received: June 9, 2009

Dear Dr. Lee:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

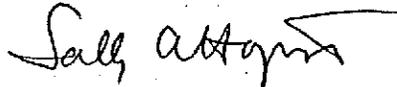
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 --

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.

Director

Division of Microbiology Devices

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Section 7.0 Indication for Use Statement

510(k) Number (if known): K091667

Device Name: xTAG[®] Respiratory Viral Panel

Indication For Use:

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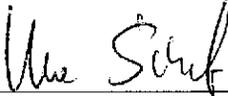
Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K091667