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U.S. Army Medical Materiel Development Activity
Robert Miller, PhD, RAC
Director, Division of Regulated Activities and Compliance
1430 Veterans Drive
Fort Detrick, MD 21702-9232

October 1, 2015

Re: K152523

Trade/Device Name: JBAIDS Influenza A & B Detection Kit
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: II
Product Code: OCC
Dated: September 2, 2015
Received: September 3, 2015

Dear Dr. Miller:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tamara V. Feldblyum -S for

Uwe Scherf, M.Sc., Ph.D.
Director
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Enclosure

Indications for Use

510(k) Number (if known)
K152523

Device Name
JBAIDS Influenza A & B Detection Kit

Indications for Use (Describe)

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Influenza A & B Detection Kit is intended for use on the JBAIDS instruments, for the in vitro qualitative detection of influenza A and influenza B viral nucleic acids isolated and purified NPS and NPW specimens from human patients with signs and symptoms of respiratory infection.

The JBAIDS Influenza A & B Detection Kit contains reverse transcriptase real-time polymerase chain reaction (rRT-PCR) assays that target the Matrix protein gene of influenza A viruses, and the Non-structural protein gene of influenza B viruses. This kit is not intended to detect influenza C viruses.

Test results are to be used in conjunction with other clinical and epidemiological information. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for detection of influenza A were established when 2009 H1N1 Influenza, Influenza A H1N1, and Influenza A H3N2 were the predominant influenza A viruses in circulation. Due to low seasonal prevalence, performance characteristics for detection of seasonal Influenza A/H1 were established primarily with retrospective and surrogate clinical specimens. When other influenza A viruses are present, performance characteristics may vary. 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 JBAIDS instructors or designees prior to use. Use of this device is limited to designated Department of Defense (DoD) laboratories equipped with the JBAIDS instruments.

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 departments for testing. Viral culture should not be attempted in these cases unless a biosafety laboratory (BSL) 3+ facility is available to receive and culture specimens.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FORT DETRICK, MARYLAND 21702-5009

510(k) Summary

1. Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

2. Administrative Information

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3. Device

Device Name/ Trade Name: JBAIDS Influenza A & B Detection Kit

Common Name: Real-time PCR assay for detection of Influenza A and Influenza B

Classification Name: Respiratory viral panel multiplex nucleic acid assay (21 CFR 866.3980)



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4. Intended Use

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Influenza A & B Detection Kit is intended for use on the JBAIDS instruments, for the in vitro qualitative detection of influenza A and influenza B viral nucleic acids isolated and purified nasopharyngeal swab (NPS) and nasopharyngeal wash (NPW) specimens from human patients with signs and symptoms of respiratory infection.

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5. Device Description

The JBAIDS Influenza A & B Detection Kit is a rRT-PCR test kit, which, when used with the JBAIDS instrument and software, allows the qualitative in vitro detection of influenza A and B viral RNA. These two assays have been optimized as freeze-dried assays with primer and fluorescent-probe sets for the detection of influenza A and B viral RNA. In particular, the influenza A assay targets a region of the matrix gene specific to the influenza A virus genera, and the influenza B assay targets a region of the nonstructural gene specific to the influenza B virus genera. The tests are performed using the previously FDA-cleared JBAIDS instrument and software. A human gene target assay (RNase P target) will be used as an inhibition and extraction control.



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6. Assay Principle

Before testing, NPS or NPW specimens are purified using Idaho Technology's 1-2-3™ Platinum Path Sample Purification Kit or the Roche MagNA Pure Compact Nucleic Acid Isolation Kit I. The resulting purified sample is added to unknown reagent vials and a sample control reagent vial, along with reconstitution buffer. When viral RNA is present, a fragment of influenza A or B viral RNA is transcribed and amplified. The amplicon is detected by fluorescence using a specific hydrolysis probe. Each probe is labeled on one end with a fluorescent reporter moiety (6-carboxyfluorescein (6-FAM)) and elsewhere with a quencher moiety (carboxy tetramethylrhodamine (TAMRA)). When the probe is intact, the quencher absorbs the light emitted by the reporter moiety. During PCR, the probe hybridizes to the target sequence before the exonuclease activity of Taq polymerase hydrolyzes the probe, separating the fluorophore from the quencher and permitting detection of the fluorescent signal generated by the reporter. The fluorescent signal increases as additional templates are amplified and more probes are hydrolyzed. JBAIDS Software analyzes the fluorescence amplification curves and reports results as positive, negative, or uncertain. A failure of the positive or negative control will result in the entire run being called invalid. Failure of the sample control yields a result of "sample control failure" when the associated sample has a negative result for the target assay. Retesting is required to resolve uncertain, invalid, or sample control failure results.

7. Substantial Equivalence

The modified JBAIDS Influenza A & B Detection System is substantially equivalent to the current legally marketed device, JBAIDS Influenza A & B Detection Kit. Additions made to the labeling to add additional strain testing did not change the intended use of the device or the fundamental scientific technology.

The JBAIDS Influenza A & B Detection Kit with additional labeling for detection of Influenza A H3N2v and H7N9 strains described is substantially equivalent to the JBAIDS Influenza A & B Detection Kit, which was cleared on September 13, 2011 under 510(k) K111775.



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Table 1: Similarities Between the JBAIDS Influenza A & B Detection Kit (this submission) and the JBAIDS Influenza A & B Detection Kit (K111775)

Element	JBAIDS Influenza A and B Detection kit (this submission)	JBAIDS Influenza A and B Detection kit (K111775)
Technology	Real time PCR using hydrolysis probes	Same
Viruses Detected	Qualitative <i>in vitro</i> detection of Influenza A and Influenza B virus nucleic acids	Same (see Table 2)
Specimen Types	Nasopharyngeal swabs and Nasopharyngeal washes	Same (see Table 2)
Extraction Methods	IT 1-2-3™ Platinum Path Sample Purification Kit and Roche MagNA Pure Compact Nucleic Acid Isolation Kit I	Same (see Table 2)
Required Instrumentation	JBAIDS Instrument	Same
Interpretation of Test Results	Automated analysis of test results and controls	Same
Reagent Storage	Reagents are stored at room temperature	Same

Table 2: Differences Between the JBAIDS Influenza A & B Detection Kit (this submission) and the JBAIDS Influenza A & B Detection Kit (K111775)

Element	JBAIDS Influenza A and B Detection kit (this submission)	JBAIDS Influenza A and B Detection kit (K111775)
Organisms Detected	Demonstrated inclusive detection of Influenza A H3N2v and A H7N9 as positive for Influenza A	Not labeled for detection of Influenza A H3N2v and H7N9.
Specimen Types	Demonstrated detection of A H3N2v and A H7N9 from simulated nasopharyngeal swabs. No testing of these strains has been performed on nasopharyngeal washes.	Nasopharyngeal swabs and washes
Extraction methods	Demonstrated detection of Influenza A H3N2v and A H7N9 from simulated nasopharyngeal swab samples extracted using the IT 1-2-3™ Platinum Path Sample Purification Kit. No testing of these strains was performed on samples extracted using the Roche MagNA Pure Compact Nucleic Acid Isolation Kit.	IT 1-2-3™ Platinum Path Sample Purification Kit and Roche MagNA Pure Compact Nucleic Acid Isolation Kit I

8. Selected Analytical Studies

The estimated analytical sensitivity or Limit of Detection (LoD) was determined for four strains of A H3N2 (two seasonal A H3N2 strains, and two swine variant, or A H3N2v, strains) and one strain of H7N9 using the Flu A assay. Simulated nasopharyngeal swab samples were extracted using the IT 1-2-3™ Platinum Path Sample Purification Kit prior to testing with the JBAIDS



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Influenza A & B Detection kit. Serial dilutions were run in triplicate, with all three replicates required to read positive in order for that dilution to be called positive. Results are shown in [Table 3](#) and [Table 4](#). This data was added to the analytical inclusivity section of the package insert.

Estimation studies suggested that the LOD for H7N9 was 4×10^4 EID₅₀ /mL. Upon refinement and running further replicates, the confirmed LOD for H7N9 was determined to be 4×10^5 EID₅₀ /mL. LOD estimation studies suggested that the LOD for H3N2v was between 2 and 32 TCID₅₀ /mL.

Table 3: Estimated LoD of H7N9 (A/Anhui/1/2013)

Strain	Concentration	No. Positive Replicates
A/Anhui/1/2013	8.0×10^5 EID ₅₀ /ml	3/3
	4.0×10^5 EID ₅₀ /ml	3/3
	8.0×10^4 EID ₅₀ /ml	3/3
	4.0×10^4 EID ₅₀ /ml	3/3
	8.0×10^3 EID ₅₀ /ml	2/3
	4.0×10^3 EID ₅₀ /ml	2/3
	8.0×10^2 EID ₅₀ /ml	1/3
	4.0×10^2 EID ₅₀ /ml	0/3
	8.0×10^1 EID ₅₀ /ml	2/3
	4.0×10^1 EID ₅₀ /ml	0/3

Table 4: Estimated LoD of H3N2 and H3N2v Strains

Strain	Isolate	LoD (TCID ₅₀ /mL)
Influenza A H3N2 (seasonal)	A/Victoria/361/2011	63.0
Influenza A H3N2 (seasonal)	A/Perth/16/2009	6.3
Influenza A swine variant H3N2v	A/West/Virginia/06/2011	31.6
Influenza A swine variant H3N2v	A/Minnesota/11/2010	2.0



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9. References

Centers for Disease Control and Prevention. Influenza A (H3N2) Variant Virus. Accessed: 26 Aug 2015: Available from: <http://www.cdc.gov/flu/swineflu/h3n2v-cases.htm>.

Clinical and Laboratory Standards Institute. Protocols for Determination of Limits of Detection and Limits of Quantitation. CLSI Approved Guidance EP17-A (2004).

Clinical and Laboratory Standards Institute. Evaluation of Precision Performance of Quantitative Measurements Methods; Approved Guidance-Second Edition, CLSI Approved Guidance EP5-A2 (August 2004).

United States Food and Drug Administration. In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path, Guidance for Industry and FDA Staff (May 1, 2007).