K100287

JUL - 6 2010

510(k) Summary

Idaho Technology Inc. JBAIDS Influenza A/H5 (Asian lineage) Detection Kit

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.

Submitted by:

U.S. Army Medical Material Development Activity
Division of Regulated Activities and Compliance
1430 Veterans Drive
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Contact Person: Robert E. Miller, Ph.D.
Date Prepared: June 15, 2010

Device name:

Trade name:
JBAIDS Influenza A/H5 (Asian lineage) Detection Kit

Common name:
Reverse-transcriptase real-time PCR assay for targeted Influenza A/H5 (Asian lineage) RNA sequences

Classification name: CFR 21.866.3332
Reagent Kit: Reagents for Detection of Specific Novel Influenza A Viruses (Class II)

Device Description: The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Influenza A/H5 (Asian lineage) Detection Kit is a real-time reverse transcriptase polymerase chain reaction (rRT-PCR) test kit, which, when used with the JBAIDS instrument and software, allows the qualitative *in vitro* detection of Influenza A/H5 (Asian lineage) viral RNA. The kit contains two freeze-dried assays with primer and fluorescent-probe sets for the detection of Influenza A/H5 (Asian lineage) viral RNA. In particular, the two assays specifically target distinct regions of the influenza A hemagglutinin gene of the highly pathogenic H5N1 viruses from the Asian lineage, without detection of other influenza A virus subtypes, including the North American lineage influenza A/H5 viruses. The tests are performed using the previously FDA-cleared JBAIDS instrument and software. A human gene target assay will be used as an inhibition and extraction control.

Assay Principle: Before testing, specimens are purified using Idaho Technology's 1-2-3™ Sample Purification Kits. The resulting purified sample is added to Unknown reagent vials and a Sample Control reagent vial, along with reconstitution buffer. When the viral RNA is present, a fragment of Influenza A/H5 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.

Intended Use:
The JBAIDS Influenza A/H5 (Asian lineage) Detection Kit is intended for use in real-time reverse-transcriptase polymerase chain reaction (rRT-PCR) assays on the Joint Biological Agent Identification and Diagnostic System (JBAIDS) instruments for the *in vitro* qualitative detection of Influenza A/H5 (Asian lineage) viral RNA in patient nasopharyngeal swab (NPS) or throat swab (TS) specimens for the presumptive laboratory identification of Influenza A/H5 (Asian lineage) virus.

Testing with the JBAIDS Influenza A/H5 (Asian lineage) Detection Kit should be 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.

Testing with the JBAIDS Influenza A/H5 (Asian lineage) Detection Kit 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 suspected 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.

Use is limited to laboratories with appropriate biosafety equipment and containment procedures. It is intended for use by experienced laboratory personnel who have training in standardized molecular testing procedures and expertise in viral diagnosis, and have received training on the JBAIDS Instrument.

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.

Indications for Use
Same as Intended Use

Same as Intended Use

Special conditions for use statement(s)

- For prescription use only
- Although this test has been shown to detect cultured human-derived Influenza A subtype H5N1 virus (Asian lineage), the performance characteristics of this test with specimens from humans infected with influenza H5N1 (Asian lineage) or other avian influenza viruses are unknown.
- Clinical specificity was established when influenza A/H3 and A/H1 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, clinical specificity may vary.
- Optimum specimen types and timing for peak viral levels during infections caused by a novel influenza A virus have not been determined. Collection of multiple specimens from the same patient may be necessary to detect the virus.
- This product can be used only with the JBAIDS instrument.
- Results from this test are intended for use with other laboratory tests and in consultation with national influenza experts.
- A negative result does not exclude the possibility of Influenza A/H5 (Asian lineage) infection. Negative test results may occur from improper specimen collection, presence of inhibitors, technical error, or sample mix-up. Test results may be affected by concurrent antiviral therapy or levels of organism in the specimen that are below the limit of detection for the test.
- The performance of the assay has not been established in individuals who received an H5N1 vaccine.
- This test has not been validated for testing specimens other than those specified or for samples that have been purified using other than the recommended IT 1-2-3™ Sample Purification Kits.
- As for any PCR assay, improper technique can lead to cross-contamination and false positive results. Good laboratory technique is essential to the proper performance of this assay. The JBAIDS Influenza A/H5 (Asian lineage) Detection Kit is intended for use by laboratory personnel who have received training on the JBAIDS instrument to perform and interpret the results from this procedure.
- The JBAIDS Influenza A/H5 (Asian lineage) Detection Kit may not generate reproducibly positive results when testing samples that have influenza A/H5 (Asian

lineage) viral RNA concentrations lower than the LoD concentration, but higher than the assay cutoff concentration.

Substantial Equivalence: The JBAIDS Influenza A/H5 (Asian lineage) Detection Kit is substantially equivalent to the Centers for Disease Control and Prevention (CDC) Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel (rRT-PCR Flu Panel) (K080570).

The CDC rRT-PCR Flu Panel is a panel of oligonucleotide primers and dual-labeled hydrolysis probes for the qualitative detection and differentiation of influenza viruses. The panel can be used to test nasopharyngeal specimens, respiratory specimens or virus culture.

Prior to testing, the samples are purified with one of four commercial available sample purification methods (see chart below). A master mix is prepared by combining the appropriate quantities of primers and probes from the rRT-PCR Flu Panel with a commercially available reverse transcription master mix. The master mix is aliquoted into a 96 well plate followed by addition of the purified samples and controls. The prepared plates are place on an ABI 7500 Fast Dx Real-Time PCR instrument and thermocycled according to the cycling conditions described in the rRT-PCR Flu Panel product insert.

Each run on the ABI includes a no-template control (nuclease-free water), a H5 virus control (noninfectious reassortant influenza A/H5 virus containing cultured human cells) and a human specimen control (cultured human cells). The human specimen control is extracted with the test samples and is intended to ensure that the extraction process was properly performed. The no-template and H5 virus control templates are added to the PCR plate prior to thermocycling.

At the conclusion of the run, the operator is required to set a baseline for all assays included in the run. The operator is then required to interpret the test results for each sample based on the results of the controls and the Ct values for each sample.

Table 1 Similarities of the JBAIDS Influenza A/H5 (Asian lineage) Detection Kit and CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel

Item	**Device**	**Predicate**
Name	**JBAIDS Influenza A/H5 (Asian lineage) Detection Kit**	**CDC rRT-PCR Flu Panel (K080570)**
Technology	Real-time PCR using hydrolysis probes	Real-time PCR using hydrolysis probes
Intended Use	Qualitative *in vitro* detection of influenza A/H5 (Asian lineage) RNA	Qualitative *in vitro* detection of influenza A/H1, A/H3, A/H5 (Asian lineage) RNA
Specimen Types	Nasopharyngeal swabs and throat swabs	Nasopharyngeal swabs, respiratory specimens or virus culture

Table 2 Differences of the JBAIDS Influenza A/H5 (Asian lineage) Detection Kit and CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel

Item	**Device**	**Predicate**
Name	**JBAIDS Influenza A/H5 (Asian lineage) Detection Kit**	**CDC rRT-PCR Flu Panel (K080570)**
Required Instrumentation	JBAIDS instrument	Applied Biosystems 7500 Fast Dx Real-time PCR instrument with SDS software v 1.4
Interpretation of Test Results	Automated analysis of test results and controls	User required to interpret test and control results
Enzyme Master Mix	Assays come in freeze-dried single use vials that include all components of master mix	Invitrogen SuperScript™ III Platinum ® One-Step Quantitative RT-PCR Kits
Extraction Methods	IT 1-2-3™ Platinum Path IT 1-2-3™ VIBE	QIAamp® Viral RNA Mini Kit, QIAGEN RNeasy® Mini Kit, Roche MagNA Pure Total Nucleic Acid Kit Roche MagNA Pure LC RNA Isolation Kit II

Performance Characteristics:

1. **Analytical Specificity – Limit of Detection:** The limit of detection (LoD) for the JBAIDS Influenza A/H5 (Asian lineage) Detection Kit was determined using TS and NPS specimens spiked with two different live virus strains (see Table 3). The LoD was first estimated by testing NPS and TS specimens spiked with 10-fold dilutions of virus. The specimens were purified with the IT 1-2-3™ VIBE Sample Purification Kit and the IT 1-2-3™ Platinum Path Purification Kit and tested. Once estimated, the LoD was confirmed by testing 20 individual specimens (from independent donors) spiked at the estimated LoD of 50 EID_{50}/mL. This level of virus was successfully detected for all 20 NPS and TS specimens purified with either the IT 1-2-3™ VIBE or the IT 1-2-3™ Platinum Path Kit Purification Kits.

Table 3 Limit of Detection by Influenza A/H5 Virus Strain

Influenza A/H5 (Asian lineage) Strain Tested	**Limit of Detection**
A/Vietnam/1203/2004 x A/Puerto Rico/8/34 reassortant	50 EID_{50}/mL
A/Anhui/01/2005/ x A/Puerto Rico/8/34 reassortant	50 EID_{50}/mL

2. **Analytical Specificity – Inclusivity & Reactivity:** Eight Influenza A/H5 (Asian lineage) strains were spiked into TS specimens at multiple concentrations and tested using the JBAIDS Influenza A/H5 (Asian lineage) Detection Kit. The lowest level of virus that was detected is shown in Table 4. For all eight strains, a spike level of 500-1000 $TCID_{50}$/mL was determined to have similar performance (with regard to detection and Cp values) as specimens spiked with 50 EID_{50}/mL of the egg grown viruses used in the LoD study.

Table 4 Influenza A/H5 (Asian lineage) Viruses Used to Evaluate Inclusivity

Panel Members	Clade	Lowest Level of Detection $TCID_{50}$/mL
Avian precursor Yunnan(A/Chicken/Yunnan/1251/03)	1.0	100
A/Vietnam/1203/2004(H5N1)-PR8/CDC-RG	1.0	100
Avian precursor Hunan (A/Duck/Hunan/795/02)	2.1	100
A/Chicken/Korea/IS/06	2.2	100
A/Scaly Breasted Munia/Hong Kong/45/2006	2.3	100
A/Japanese white-eye/Hong Kong/1038/2006	2.3	10
A/Common Magpie/Hong Kong/645/2006	2.3	100
A/Anhui/01/2005(H5N1)-PR8-IBCDC-RG	2.3	10

3. **Analytical Specificity – Exclusivity:** To ensure that the JBAIDS Influenza A/H5 (Asian lineage) Detection Kit does not cross react with other organisms, TS specimens spiked with high concentrations of the non-target organisms listed in Table 5 were prepared and tested. Specimens spiked with all 45 (100%) organisms were negative with both the Target 1 and Target 2 assays.

Table 5 Exclusivity Panel

Influenza Viruses	Non-Influenza Viruses	Bacteria/Fungi
Influenza A/H1N1 A/Brisbane/59/07	Enterovirus 71	***Bacteria***
Influenza A/H1N1 A/Denver/1/57	Adenovirus type 1 Ad. 71	*Bordetella pertussis* A639
Influenza A/H1N1 A/PR/8/34	Adenovirus type 7a S-1058	*Mycoplasma pneumoniae* M129
Influenza A/H1N1 A/FM/1/47	Coronavirus OC43	*Moraxella catarrhalis* Ne 11
Influenza A/H1N1 A/NWS/33	Coronavirus 299E	*Pseudomonas aeruginosa*
Influenza A/H3N2 A/Wisconsin/67/2005	Rhinovirus 1A	*Staphylococcus aureus* COL
Influenza A/H3N2 A/Victoria/3/75	Parainfluenza virus, type 2	*Streptococcus pneumoniae* Type 59
Influenza A/H3N2 A/Port Chalmers/1/73	Parainfluenza virus, type 3	*Legionella micdadei* Tatlock
Influenza A/H3N8 A/MAL/ALB/16/87	RSV A	*Mycobacterium tuberculosis* H37Ra-1
Influenza A/H5N1 A/TY/MA/40550/87-BEL/42	hMPV-8 Peru6-2003	*Escherichia coli O157:H7*
Influenza A/H5N1 A/DK/PA/4560069-9/06		*Neisseria elongata*
Influenza A/H5N1 A/MUTESWAN/MI/451072-2/06		*Staphylococcus epidermidis*
Influenza A/H5N2 A/DK/SC/318328-3/04		*Streptococcus pyogenes*
Influenza A/H6N2 A/Chicken/CA/32213-1/2000		
Influenza A/H7N3 A/TY/UT/24721-10/95		***Fungi***
Influenza A/H7N7 A/Mallard/Netherlands/12/2000 IB-CDC-1		*Candida albicans*
Influenza A/H9N2 A/Turkey/Wisconsin/1966		
Influenza B B/FL/04/06		
Influenza B B/Lee/40		
Influenza B B/Taiwan/2/62		
Influenza B B/GL/1739/54		
Influenza B B/Maryland/1/59		

4. **Clinical Performance:** Due to the rarity of infection with the influenza A/H5 (Asian lineage) virus, it was not possible to evaluate the clinical sensitivity of the test system using true clinical samples. As a result, a surrogate clinical sensitivity assessment was performed and a clinical specificity assessment was conducted using influenza-negative clinical specimens spiked with influenza A/H5 (Asian lineage) virus.

5. **Surrogate Clinical Sensitivity:** A panel of surrogate samples consisting of eight strains of Influenza A/H5 (Asian lineage) and six strains of seasonal influenza (Table 6) were spiked into TS or NPS specimens collected in viral transport medium (VTM). The complete panel, for both TS and NPS specimens, consisted of the following: Influenza A/H5 viruses at limit of detection (LoD), 5× LoD, 10× LoD, and 100× LoD (LoD was estimated to be 500 $TCID_{50}$/mL); seasonal influenza viruses at LoD and 100× LoD; and six specimens that were not spiked with any virus. Each specimen was purified with the IT 1-2-3™ VIBE and IT 1-2-3™ Platinum Path Sample Purification Kits. As expected, all seasonal influenza (48 total results) and influenza-negative specimens (24 total results) produced negative results. Of the 128 Influenza A/H5 virus-containing specimens, 126 produced positive results (98% success).

Table 6 Clinical Sensitivity Panel

Panel Members
Influenza A/H5 Strains
Avian precursor Yunnan(A/Chicken/Yunnan/1251/03)
A/Vietnam/1203/2004(H5N1)-PR8/CDC-RG
Avian precursor Hunan (A/Duck/Hunan/795/02)
A/Chicken/Korea/IS/06
A/Scaly Breasted Munia/Hong Kong/45/2006
A/Japanese white-eye/Hong Kong/1038/2006
Seasonal Influenza Strains
A/New Caledonia/20/1999 (H1N1)
A/Hawaii/15/2001 (H1N1)
A/New York/55/2004 (H3N2)
A/Wisconsin/67/2005 (H3N2)
B/Ohio/01/2005 (Victoria/2/87-like)
B/Florida/07/2004 (Yamagata/16/88-Like)
A/Common Magpie/Hong Kong/645/2006
A/Anhui/01/2005(H5N1)-PR8-IBCDC-RG
Unspiked samples
unspiked #1
unspiked #2
unspiked #3
unspiked #4
unspiked #5
unspiked #6

6. **Clinical Specificity:** A multicenter clinical study was conducted over a 4-month period using frozen, banked NPS and TS specimens that had been previously tested for respiratory pathogens. The specimens were obtained and tested at 3 different test sites.

   Three hundred fourteen (314) NPS specimens purified using the IT 1-2-3™ VIBE Sample Purification Kit and 299 NPS specimens purified using the IT 1-2-3™ Platinum Path Purification kit had valid negative results for both the JBAIDS Influenza A/H5 (Asian lineage) Detection Kit and the CDC rRT Flu Panel. Similarly, 298 VIBE purified and 283 Platinum Path purified TS specimens had valid negative results with both kits. These results demonstrate that the clinical specificity for NPS and TS specimens purified with the IT 1-2-3™ VIBE or Platinum Path Purification Kits and tested with the JBAIDS Influenza A/H5 (Asian lineage) Detection Kit is at least 99% with 95% confidence. Results are summarized in Table 7.

Table 7 Influenza A/H5 Comparison Results

Sample Type	Purification Kit	Site	Specimens		JBAIDS Results					Clinical Specificity Claim
			Total Tested	Removed From Study[a]	Positive	Not Detected	Inconclusive	SC Failure	Invalid	
Nasopharyngeal Swabs	IT 1-2-3™ VIBE	Site 1	160	32	0	127	0	1	0	99-100% Specificity, 95% CI
		Site 3	201	0	0	187	0	2	12[b]	
		Total	361	32 (8.9%)	0	314	0	3	12	
	IT 1-2-3™ Platinum Path	Site 1	153	21	0	132	0	0	0	99-100% Specificity, 95% CI
		Site 3	174	0	0	167	0	1	6[b]	
		Total	327	21 (6.4%)	0	299	0	1	6	
Throat Swabs	IT 1-2-3™ VIBE	Site 2	171	3	0	166	0	1	1[b,c]	99-100% Specificity, 95% CI
		Site 3	132	0	0	132	0	0	0	
		Total	303	3 (1.0%)	0	298	0	1	1	
	IT 1-2-3™ Platinum Path	Site 2	193	14	0	170	0	0	9[b]	99-100% Specificity, 95% CI
		Site 3	140	0	0	113	0	5	22[b]	
		Total	333	14 (4.2%)	0	283	0	5	31	

[a] Specimens were removed from the study if they did not have a valid result for the CDC comparator assay.

[b] Failure of external extraction control used only for clinical study.

[c] The positive control for the Target 2 assay failed and was not retested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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Director
Division of Regulated Activities and Compliance
U.S. Army Medical Materiel Development Activity
Office of the Surgeon General, US Army
1430 Veterans Drive, Fort Detrick, Maryland, 21702-9232

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Re: K100287

Trade/Device Name:	JBAIDS Influenza A/H5 (Asian lineage) Detection Kit
Regulation Number:	21 CFR §866.3332
Regulation Name:	Reagents for detection of specific novel influenza A viruses
Regulatory Class:	Class II
Product Code:	NXD
Dated:	June 21, 2010
Received:	June 28, 2010

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.

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 Part 801); 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.

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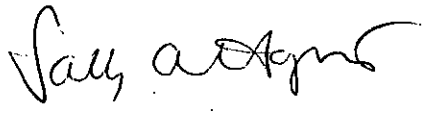
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



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

Indications for Use

510(k) Number: k100287

Device Name: JBAIDS Influenza A/H5 (Asian lineage) Detection Kit

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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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 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

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