K111778

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510(k) Summary
JBAIDS Influenza A Subtyping 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.

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Device Name: Trade Name:

JBAIDS Influenza A Subtyping Kit

Common Name:

Real-time PCR assay for differentiation of influenza A subtypes

Classification Name:

Reagents for Detection of Specific Novel Influenza A Viruses (CFR 866.3332)

Intended Use

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Influenza A Subtyping Kit is intended for the *in vitro* qualitative detection and differentiation of seasonal Influenza A/H1, seasonal Influenza A/H3, and 2009 H1N1Influenza viral nucleic acids isolated and purified from nasopharyngeal swab (NPS) and nasopharyngeal wash (NPW) specimens from human patients with signs and symptoms of respiratory infection, in conjunction with clinical and epidemiological risk factors. The JBAIDS Influenza A Subtyping Kit contains reverse transcriptase real-time polymerase chain reaction (rRT-PCR) assays for use on the JBAIDS instruments. The Flu A H1, Flu A H3, and Flu A H1 2009 assays of the JBAIDS Influenza A Subtyping Kit target a region of the hemagglutinin (HA) gene of the respective Influenza A virus. The Flu A Sw assay of the JBAIDS Influenza A Subtyping Kit targets a region of the nucleocapsid protein (NP) gene of the 2009 H1N1 Influenza virus, as well as some other Influenza A viruses of swine lineage. This kit is not intended to detect Influenza B or Influenza C viruses.

A negative result for all assays in the JBAIDS Influenza A Subtyping Kit is a presumptive negative result for Influenza A. These results should be confirmed using the JBAIDS Influenza A & B Detection Kit.

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.

Due to low seasonal prevalence, performance characteristics for detection of seasonal Influenza A/H1 were established primarily with retrospective and contrived clinical specimens.

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.

Device Description

The JBAIDS Influenza A Subtyping Kit is a real time RT-PCR test kit, which, when used with the JBAIDS instrument and software, allows the qualitative *in vitro* detection and identification of influenza A subtypes H1, H3, and H1 2009 (swine lineage) viral RNA. The assays have been optimized as freeze-dried assays with primer and fluorescent-probe sets for the detection of

influenza A/H1, A/H3, and A/2009 H1 viral RNA. In particular, the Flu A H1, Flu A H3, and Flu A H1 2009 assays target distinct regions of the hemagglutinin gene specific to those subtypes, and the Flu A Sw assay targets a region of the nucleocapsid protein gene as a secondary target for the influenza A/2009 H1(swine lineage) virus. The tests are performed using the JBAIDS instrument and software.

Assay Principle

Before testing, NPS or NPW specimens are purified using 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 along with reconstitution buffer. When viral RNA is present, a fragment of influenza A 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. Retesting is required to resolve uncertain or invalid results.

Substantial Equivalence

The JBAIDS Influenza A Subtyping System is substantially equivalent to other products in commercial distribution intended for similar use. The JBAIDS instrument has been previously cleared under K051713.

The JBAIDS Influenza A Subtyping System is substantially equivalent to the CDC Human Influenza Virus real-time RT-PCR Detection and Characterization Panel, which was cleared on September 30, 2008 under 510(k) # K080570, and the CDC Influenza 2009 A(H1N1)pdm Real-Time RT-PCR Panel, which was cleared on June 22, 2010 under 510(k) #101564.

Table 1. Similarities Between the JBAIDS Influenza A Subtyping Kit and its Predicate Devices

Element	JBAIDS Influenza A Subtyping Kit	CDC rRT-PCR Flu Panel (K080570)	CDC rRT-PCR 2009 A(H1N1)pdm Flu Panel (K101564)
Intended Use	Qualitative *in vitro* detection and differentiation of seasonal Influenza A/H1, seasonal Influenza A/H3 and Influenza A/2009 H1N1 viral nucleic acids from nasopharyngeal swab (NPS) and nasopharyngeal wash (NPW) specimens on the JBAIDS instrument after obtaining an influenza A positive test from the JBAIDS Influenza A & B Detection Kit.	Qualitative *in vitro* detection of influenza virus type A or B and for determination of the subtype of seasonal human influenza A virus, as seasonal A/HI or A/H3, if present, from viral RNA in nasopharyngeal and/or nasal swab specimens, for presumptive identification of virus in patients who may be infected with influenza A subtype A/H5 (Asian lineage) from viral RNA in human respiratory specimens and viral culture on an ABI 7500 Fast Dx Real-time PCR instrument	Qualitative *in vitro* detection of influenza virus type A and 2009(H1N1 influenza viral RNA from nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), dual nasopharyngeal / throat swabs (NPS/TS) and lower respiratory tract specimens (LRTS) from human patients with signs and symptoms of respiratory infection and/or from viral culture, on the Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR instrument.
Technology	Real-time PCR using hydrolysis probes	Real-time PCR using hydrolysis probes	Real-time PCR using hydrolysis probes
Assay Results	Qualitative	Qualitative	Qualitative
Nucleic Acid Extraction	Yes	Yes	Yes

Table 2. Differences Between the JBAIDS Influenza A Subtyping Kit and its Predicate Devices

Element	JBAIDS Influenza A Subtyping Kit	CDC rRT-PCR Flu Panel (K080570)	CDC rRT-PCR 2009 A(H1N1)pdm Flu Panel (K101564)
Viruses Detected	Influenza A/H1, Influenza A/H3 and Influenza A/2009 H1N1	Influenza A, Influenza B, Influenza A/H1, Influenza A/H3 and Influenza A/H5	Influenza A and Influenza A 2009 H1N1
Specimen types	Nasopharyngeal swabs, nasopharyngeal washes	Nasopharyngeal swabs, nasal swabs, and virus culture	Nasopharyngeal swabs, nasal swabs, nasal aspirates, nasal washes, dual nasopharyngeal / throat swabs, broncheoalveolar lavage, tracheal aspirate, bronchial wash and viral culture
Required Instrumentation	JBAIDS instrument	Applied Biosystems 7500 Fast Dx Real-time PCR instrument with SDS software v 1.4	Applied Biosystems 7500 Fast Dx Real-time PCR instrument
Interpretation of Test Results	Automated analysis of test results and controls	User required to interpret test and control results	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	Invitrogen SuperScript™ III Platinum® One-Step Quantitative RT-PCR Kits
Reagent Storage	Reagents are stored at room temperature	Reagents are stored at ≤ -20°C	Reagents are stored at ≤ -20°C
Extraction Methods	• IT *1-2-3*™ Platinum Path Sample Purification Kit • Roche MagNA Pure Compact Nucleic Acid Isolation Kit I	• Qiagen QIAamp® Viral RNA Mini Kit • Qiagen RNeasy® Mini Kit • Roche MagNA Pure TNA Kit • Roche MagNA Pure LC RNA Isolation Kit II	• Qiagen QIAamp® Viral RNA Mini Kit • Roche MagNA Pure Compact Nucleic Acid Isolation Kit I Roche MagNA Pure TNA Kit • Roche MagNA Pure LC RNA isolation Kit II • Qiagen QIAcube with QIAamp viral RNA mini kit • bioMerieux NucliSENS easyMAG

Summary of Performance Data

Clinical Performance

The clinical performance of the JBAIDS Influenza A Subtyping Kit was evaluated during a prospective study at 5 geographically separated military clinical sites over the 2010-2011 influenza season (December 2010 to April 2011). Subjects with signs and/or symptoms of influenza-like illness were enrolled. Upon obtaining informed consent,

NPS and NPW specimens were collected for JBAIDS and comparator testing. A total of 795 valid specimens were analyzed at the five study sites; 312 NPS and 483 NPW specimens. Table 3 provides a summary of demographic information for the 795 subjects for which valid specimen results were obtained in the prospective study.

Table 3. Demographic Summary for the JBAIDS Influenza A Subtyping Kit Prospective Study.

		Overall	Site 1	Site 2	Site 3	Site 4	Site 5
NPS		**312**	50	206	56	0	0
NPW		**483**	320	0	0	118	45
Total		**795**	370	206	56	118	45
Sex	Female	**405 (50.9%)**	188 (50.8%)	122 (59.2%)	23 (41.1%)	56 (47.5%)	16 (35.6%)
	Male	**390 (49.1%)**	182 (49.2%)	84 (40.8%)	33 (58.9%)	62 (52.5%)	29 (64.4%)
Age[a]	Mean	**26.4**	23.3	24.5	30.3	23.1	30.8
	Median	**24.0**	24.0	18.0	27.5	17.0	26.0
	Min	**0.5**	0.5	0.5	2.0	0.5	18.0
	Max	**92.0**	92.0	69.0	81.0	68.0	62.0
Age Range[b]	≤5	**149 (18.7%)**	88 (23.8%)	40 (19.4%)	4 (7.1%)	17 (14.4%)	0 (0%)
	6-21[c]	**229 (28.8%)**	79 (21.4%)	74 (35.9%)	10 (17.9%)	54 (45.8%)	12[c] (26.7%)
	22-49	**331 (41.6%)**	178 (48.1%)	54 (26.2%)	35 (62.5%)	34 (28.8%)	30 (66.7%)
	≥50	**86 (10.8%)**	25 (6.8%)	38 (18.4%)	7 (12.5%)	13 (11%)	3 (6.7%)

[a] 0.5 was used for all ages under 1 year for these calculations.
[b] The age groups ≤ 5 years and ≥ 50 years correspond to high risk groups for which the CDC strongly recommends seasonal influenza vaccination (http://www.cdc.gov/flu//flu/protect/keyfacts.htm).
[c] Site 5 enrolled adults only; this category reflects participants 18 to 21 years of age

Of the 795 prospective specimens, successful results were obtained for 94% (751/795) of these specimens on the first attempt (Site 1: 359/370 =97%; Site 2: 191/206 =93%; Site 3: 54/56 =96%; Site 4: 110/118 =93%; Site 5: 37/45 =98%). The remaining 6% (44/795) required retesting: "Invalid" (32/44), "Inconclusive" (11/44), and "Unsubtypeable" (1/44) (11 samples from Site 1; 15 samples from Site 2; 2 samples from Site 3; 8 sample from Site 4; and 8 sample from Site 5). Forty (40) out of 44 samples resolved upon a 1st retest and the remaining 4 samples required a re-extraction and retest and resolved.

Nucleic acid from each specimen was isolated using either the IT *1-2-3* Platinum Path Sample Purification Kit (manual sample processing) or the Roche MagNA Pure Compact Nucleic Acid Isolation Kit I (automated sample processing) and tested with the JBAIDS Influenza A Subtyping Kit. The performance of the JBAIDS Influenza A Subtyping Kit was evaluated by comparing the JBAIDS test results with a comparator/reference method. The reference method was the CDC rRT-PCT Flu Panel influenza A and influenza B assays, followed by subtype-specific PCR and bi-directional sequencing of amplicons. Clinical sensitivity was calculated as Positive Percent Agreement (PPA) and specificity was calculated as Negative Percent Agreement (NPA). The exact binomial

two-sided 95% confidence interval was calculated. The results are summarized in Table 4.

Table 4. JBAIDS Influenza A Subtyping Kit Prospective Clinical Performance Summary

Influenza A Strain	Sample Matrix	Purification Kit	PPA			NPA		
			TP/(TP+FN)	Percent	95% CI	TN/(TN+FP)	Percent	95% CI
Seasonal H1	NPW	Platinum Path	0/0	-	-	277/278	99.6%	98.0-100%
		MagNA Pure	0/0	-	-	205/205	100.0%	98.2-100%
		Combined	**0/0**	-	-	**482/483**	**99.8%**	**98.9-100%**
	NPS	Platinum Path	0/0	-	-	132/132	100.0%	97.2-100%
		MagNA Pure	0/0	-	-	180/180	100.0%	98.0-100%
		Combined	**0/0**	-	-	**312/312**	**100.0%**	**98.8-100%**
2009 H1N1	NPW	Platinum Path	50/50	100.0%	92.9-100%	227/228	99.6%	97.6-100%
		MagNA Pure	16/16	100.0%	79.4-100%	187/189	98.9%	96.2-99.9%
		Combined	**66/66**	**100.0%**	**94.6-100%**	**414/417**	**99.3%**	**97.9-99.9%**
	NPS	Platinum Path	24/24	100.0%	85.8-100%	108/108	100.0%	96.6-100%
		MagNA Pure	10/10	100.0%	69.2-100%	169/170	99.4%	96.8-100%
		Combined	**34/34**	**100.0%**	**89.7-100%**	**277/278**	**99.6%**	**98.0-100%**
Seasonal H3	NPW	Platinum Path	14/14	100.0%	76.8-100%	264/264	100.0%	98.6-100%
		MagNA Pure	19/19	100.0%	82.4-100%	186/186	100.0%	98.0-100%
		Combined	**33/33**	**100.0%**	**89.4-100%**	**450/450**	**100.0%**	**99.2-100%**
	NPS	Platinum Path	18/18	100.0%	81.5-100%	115/115	100.0%	96.8-100%
		MagNA Pure	8/8	100.0%	63.1-100%	171/171	100.0%	97.9-100%
		Combined	**26/26**	**100.0%**	**86.8-100%**	**286/286**	**100.0%**	**98.7-100%**

Seasonal influenza A/H1 virus was not circulating during the 2010-2011 influenza season (http://www.cdc.gov/flu/) and was not detected during the prospective clinical study of the JBAIDS Influenza A Subtyping Kit. To supplement the results of the clinical study, an evaluation of preselected archived samples was performed. Due to the limited availability of archived specimens, the clinical study was further supplemented with surrogate clinical contrived specimens.

Testing of Preselected Archived Specimens

Additional testing of pre-selected archived clinical NPS specimens was performed at two different clinical study sites to supplement the prospective clinical testing data. Because it is possible that the archived samples had been misidentified or had degraded during storage or previous handling, the presence or absence of Influenza A/H1 viral RNA was confirmed using "validation" PCR assays. The validation PCR assays were identical to the comparator assays that were used for the prospective clinical evaluation study. A total of 51 NPS specimens were obtained and confirmed for testing: 30 known to be positive seasonal Influenza A/H1 specimens and 21 influenza-negative specimens. Validated samples were purified using either the IT 1-2-3 Platinum Path Sample Purification Kit or

the Roche MagNA Pure Compact Nucleic Acid Isolation Kit I and then tested with the Flu A and human sample control (Flu SC) assay from the JBAIDS Influenza A & B Detection Kit and the Flu A H1 assay from the JBAIDS Influenza A Subtyping Kit. The specimens were split evenly for purification with the Platinum Path or MagNA Pure purification kits and then randomized such that the users performing the JBAIDS testing were blinded as to the expected test result.

Table 5 presents the PPA and NPA for the archived clinical specimens. Data from both extraction kits are combined due to identical performance.

Table 5. Performance Summary of Seasonal Influenza A/H1 Archived Clinical Specimens

Influenza Assay	Sample Type	PPA	Percent	95% CI	NPA	Percent	95% CI
Flu A H1	NPS	29/29	100%	88.1-100%	21/21	100%	83.4-100%

Due to the absence of seasonal Influenza A/H1 virus in circulation during the 2010-2011 influenza seasonal (http://www.cdc.gov/flu/) and lack of availability of archived NPW specimens for seasonal Influenza A/H1, contrived clinical samples (residual influenza negative NPS and NPW samples spiked with a known concentration of seasonal Influenza A/H1 virus) were used as a surrogate to further evaluate the performance of the JBAIDS Influenza A Subtyping Kit.

Testing of Surrogate Clinical Specimens

A total of 136 individual influenza-negative clinical specimens (68 NPS samples and 68 NPW samples) were spiked at a range of concentrations, including near the system limit of detection (LoD), as well as un-spiked, then randomized, and sent to two different clinical trial sites for testing. Of the 136 surrogate samples included in this study, a valid JBAIDS test result was obtained for 128 samples (62 NPW and 66 NPS). The remaining 8 samples with invalid results could not be retested due to insufficient sample volume, and were not included in the analysis.

Table 6 presents the PPA and NPA for the surrogate clinical specimens. Half of the samples were extracted using the Platinum Path purification kit and half using the MagNA pure kit. Performance from both extraction kits was identical, so results are combined.

Table 6. Performance Summary of Seasonal Influenza A/H1 Surrogate Clinical Specimens

Assay	Sample Type	PPA			NPA		
		TP/(TP+FN)	Percent	95% CI	TN/(TN+FP)	Percent	95% CI
Flu A H1	NPW	54/54	100%	93.4-100%	8/8	100.0%	63.1-100%
	NPS	59/59	100%	93.9-100%	7/7	100.0%	59.0-100%
Flu A H1 2009/ Flu A Sw	NPW	0/0	-	-	62/62	100.0%	94.2-100%
	NPS	0/0	-	-	66/66	100.0%	94.6-100%
Flu A H3	NPW	0/0	-	-	62/62	100.0%	94.2-100%
	NPS	0/0	-	-	66/66	100.0%	94.6-100%

Analyses of the clinical data set, preselected archived specimens, and surrogate clinical specimens demonstrate that the JBAIDS Influenza A Subtyping Kit is a sensitive and specific test system for the differentiation of influenza A/H1, influenza A/H3, and influenza A/2009 H1 virus subtypes.

Selected Analytic Studies

Limit of Detection

The analytical sensitivity or Limit of Detection (LoD) for each target assay (Flu A H1, Flu A H3, Flu A H1 2009, and Flu A Sw) was determined using both NPS and NPW samples spiked with quantified virus strains. The LoD was the lowest concentration where $\geq$ 95% of samples yielded positive results. Twenty (20) independent specimens from 20 unique donors were spiked with each virus strain for each sample type/purification kit combination and tested at the LoD concentration. The LoD values for representative virus strains detected by the JBAIDS Influenza A Subtyping Kit are listed in Table 7.

Table 7. LoD Concentrations for Representative Virus Strains Detected by the JBAIDS Influenza A Subtyping Kit

Assay(s)	Influenza Type	Strain	LoD (EID_{50}/mL)
Flu A H1	Influenza A H1N1	A/New Caledonia/20/1999	50[a]
		A/Hawaii/15/2001	5,000
Flu A H3	Influenza A H3N2	A/New York/55/2004	5
		A/Wisconsin/67/2005	10
Flu A H1 2009 and Flu A Sw	2009 H1N1 Influenza	A/New York/18/2009	1,500
		A/California/7/2009	5,000

[a] The aliquot of A/New Caledonia/20/1999 tested contains 17-45 times more PCR target copies per EID_{50} than the aliquot of A/Hawaii/15/2001 tested.

Inclusivity

The analytical reactivity of the JBAIDS Influenza A Subtyping Kit assays was evaluated with inclusivity panels consisting of eight seasonal influenza A H1N1 strains (Table 8), 10 seasonal influenza A H3N2 strains (Table 9), and 11 2009 H1N1 influenza strains (Table 10) that represent the genetic, temporal, and geographic diversity of the influenza analytes. Each organism was tested in a simulated NPS sample matrix at or near the system LoD (5, 50, and 500 EID_{50}/mL or $TCID_{50}$/mL for H1N1 strains; 0.5, 5 and 50 EID_{50}/mL or $TCID_{50}$/mL for H3N2 strains; and 150, 1,500 and 15,000 EID_{50}/mL or $TCID_{50}$/mL for H1N1 2009 strains). Higher concentrations were tested if the analyte was not detected at the initial test concentrations. Four (4) of the 29 influenza strains tested in this study were not detected with the appropriate JBAIDS influenza A subtyping assays.

There was considerable variability in the ability of the Flu A H1 assay to detect strains (lowest detected concentrations ranged from 5-500,000 $TCID_{50}$/mL). Sequence alignments of tested strains indicate variability potentially due to mismatches under the primers and probe. The influenza A/1/Denver/1/57 strain was not detected at a final concentration of 5,000 $TCID_{50}$/mL.

For the Flu A H3 assay, the following strains were not detected at the following concentration: A/Aichi/2/68 at 114,000 $TCID_{50}$/mL, A/Hong Kong/8/68 at 137,000 $TCID_{50}$/mL, and A/MRC-2 recomb at 7,350 $TCID_{50}$/mL. Sequence alignments indicate that the A/Aichi/2/68 and A/Hong Kong/8/68 isolates have mismatches in the probe sequence. The sequence for A/MRC-2 recomb was not available.

For the Flu A H1 and Flu A H3 assays, *in silico* evaluation of contemporary strains (2006-2011) indicate that there are few mismatches, and strains should be detected.

Table 8. Results of Influenza A H1N1 Inclusivity

Strain	Lowest Concentration Detected
A/PR/8/34	500,000 $TCID_{50}$/mL
A/NWS/33	50 $TCID_{50}$/mL
A/Weiss/43	500 $TCID_{50}$/mL
A1/FM/1/47	5 $TCID_{50}$/mL
A/Mal/302/54	5,000 $TCID_{50}$/mL
A1/Denver/1/57	ND[a]
A/Solomon Islands/3/2006	5 $TCID_{50}$/mL
A/Brisbane/59/07	50 $TCID_{50}$/mL

[a] ND stands for 'not detected'

Table 9. Results of Influenza A H3N2 Inclusivity

Strain	Lowest Concentration Detected
A/Aichi/2/68	ND[a]
A/Hong Kong/8/68	ND[a]
A/Port Chalmers/1/73	5 $TCID_{50}$/mL
A/Victoria/3/75	50 $TCID_{50}$/mL
A/Brisbane/10/07	5 $TCID_{50}$/mL
A/Taiwan/760/2007	0.5 $TCID_{50}$/mL
A/Uruguay/716/2007	0.5 EID_{50}/mL
A/Perth/16/09	5 $TCID_{50}$/mL
A/Alice	0.5 $TCID_{50}$/mL
A/MRC-2 recomb	ND[a]

[a] ND stands for 'not detected'

Table 10. Results of 2009 H1N1 Influenza Inclusivity

Strain	Lowest Concentration Detected
A/California/4/2009	1,500 $TCID_{50}$/mL
A/California/8/2009	150 EID_{50}/mL
A/England/195/2009	150 $TCID_{50}$/mL
A/Mexico/4108/2009	150 EID_{50}/mL
A/North Carolina/18/2009	1,500 $TCID_{50}$/mL
A/South Carolina/18/2009	150 $TCID_{50}$/mL
A/SwineNY/01/2009	150 $TCID_{50}$/mL
A/SwineNY/02/2009	150 $TCID_{50}$/mL
A/SwineNY/03/2009	150 $TCID_{50}$/mL
A/Texas/48/2009	1,500 $TCID_{50}$/mL
A/Washington/29/2009	150 $TCID_{50}$/mL

Exclusivity

The potential for cross-reactivity between JBAIDS influenza assays was evaluated by testing simulated NPS samples containing high concentrations of influenza viruses (tens to thousands-fold higher than LoD). Table 11 lists all of the non-target influenza strains tested at high concentrations with the Flu A H1, Flu A H3, Flu A Sw and Flu A H1 2009 assays. In all cases, the assays gave the expected negative results with the non-target influenza assays.

Three (3) Influenza A H1N1 strains, A/Maryland/12/1991, A/Iowa/1/2006, and A/swine/Wisconsin/125/1997, were detected by the Flu A Sw assay: These results were not unexpected since the first two of these strains were isolated from humans but have an origin of swine lineage and the third was isolated from swine. In addition, the Influenza A H3N2 virus strain A/SW/IA/1/99 (swine origin) was detected by both the Flu A H3 and Flu A Sw assays. Detection of swine Influenza A/H3 viruses by the Flu A H3 assay is not unexpected as the hemagglutinin sequences for swine and human isolates are very similar.

Table 11. Results of Testing for Cross-Reactivity with Influenza A Subtyping Assays

Type/Subtype		Strain	Concentration Tested	Assays Tested
Influenza A	H2N2 (Avian)	A/chicken/Pennsylvania/298101-4/2004	3.16E+07 $TCID_{50}$/mL	Flu A H1 Flu A H3 Flu A Sw Flu A H1 2009
	H3N8 (Avian)	A/MAL/ALB/16/87	1.72E+03 $TCID_{50}$/mL	
	H4N8 (Avian)	A/chicken/Alabama/1975	1.00E+08 EID_{50}/mL	
	H5N1 (Avian-Human Recombinant)	A/Vietnam/1203/2004(H5N1)-PR8	3.16E+07 EID_{50}/mL	
	H5N1 (Avian)	A/DK/PA/4560069-9/06	1.00E+05 $TCID_{50}$/mL	
	H7N3 (Avian)	A/TY/UT/24721-10/95	3.06E+04 $TCID_{50}$/mL	

Type/Subtype	Strain	Concentration Tested	Assays Tested
H6N2 (Avian)	A/Chicken/CA/32213-1/2000	1.26E+07 EID_{50}/mL	
H9N2 (Avian)	A/Turkey/Wisconsin/1966	5.60E+07 EID_{50}/mL	
H3N8 (Canine)	A/canine/Florida/43/2004	1.00E+05 $TCID_{50}$/mL	
H3N8 (Equine)	A/Equine/Ohio/01/2009	1.00E+05 $TCID_{50}$/mL	
H1N1 (Swine)	A/swine/Wisconsin/125/1997	1.00E+05 $TCID_{50}$/mL	
H1N1 (Swine)	A/SW/GB/19582/92	5.64E+03 $TCID_{50}$/mL	
H3N2 (Swine)	A/SW/IA/1/99	1.41E+03 $TCID_{50}$/mL	
H1N1 (Human of swine lineage)	A/Maryland/12/1991	1.00E+05 $TCID_{50}$/mL	
H1N1 (Human of swine lineage)	A/Iowa/1/2006	1.00E+05 $TCID_{50}$/mL	
H7N2 (Human)	A/New York/107/2003	30 µl of an unknown concentration into 1mL	
Influenza B	B/Lee/40	7.36E+03 $TCID_{50}$/mL	Flu A H1 Flu A H3 Flu A Sw Flu A H1 2009
	B/Allen/45	1.00E+05 $TCID_{50}$/mL	
	B/GL/1739/54	7.36E+03 $TCID_{50}$/mL	
	B/Maryland/1/59	7.36E+03 $TCID_{50}$/mL	
	B/Taiwan/2/62	4.54E+04 $TCID_{50}$/mL	
	B/Hong Kong/5/72	7.36E+03 $TCID_{50}$/mL	
	B/Malaysia/2506/04	5.09E+03 $TCID_{50}$/mL	
	B/FL/04/06	1.50E+04 $TCID_{50}$/mL	
	B/Brigit	3.14E+04 $TCID_{50}$/mL	
Influenza A H1N1	A/Brisbane/59/07	1.00E+05 $TCID_{50}$/mL	Flu A H3 Flu A Sw Flu A H1 2009
	A1/FM/1/47	4.24E+03 $TCID_{50}$/mL	
	A/PR/8/34	1.00E+05 $TCID_{50}$/mL	
	A/NWS/33	4.24E+03 $TCID_{50}$/mL	
	A1/Denver/1/57	4.24E+03 $TCID_{50}$/mL	
	A/Solomon Islands/3/2006	1.25E+04 $TCID_{50}$/mL	
	A/Weiss/43	4.24E+03 $TCID_{50}$/mL	
	A/Mal/302/54	1.25E+04 $TCID_{50}$/mL	
Influenza A H3N2	A/Port Chalmers/1/73	5.10E+03 $TCID_{50}$/mL	Flu A H1 Flu A Sw Flu A H1 2009
	A/Victoria/3/75	4.24E+03 $TCID_{50}$/mL	
	A/Aichi/2/68	1.00E+05 $TCID_{50}$/mL	
	A/Hong Kong/8/68	1.00E+05 $TCID_{50}$/mL	
	A/Alice (VR-776)	4.24E+03 $TCID_{50}$/mL	
	A/MRC-2 recomb (VR-777)	7.36E+03 $TCID_{50}$/mL	
	A/Brisbane/10/07	7.36E+03 $TCID_{50}$/mL	
Influenza A (swine lineage) H1N1 2009	Swine NY/02/2009	1.25E+04 $TCID_{50}$/mL	Flu A H1 Flu A H3
	Swine NY/03/2009	7.36E+03 $TCID_{50}$/mL	
	Swine NY/01/2009	3.78E+04 $TCID_{50}$/mL	
	A/Mexico/4108/2009	1.00E+05 EID_{50}/mL	
	A/California/8/2009	1.00E+05 $TCID_{50}$/mL	
	A/California/04/2009	1.00E+05 $TCID_{50}$/mL	
	A/Texas/48/2009	1.00E+05 $TCID_{50}$/mL	

Type/Subtype	Strain	Concentration Tested	Assays Tested
	A/Washington/29/2009	1.00E+05 $TCID_{50}$/mL	
	A/South Carolina/18/2009	1.00E+05 $TCID_{50}$/mL	
	A/England/195/2009	4.74E+04 $TCID_{50}$/mL	
	A/North Carolina/39/2009	1.00E+05 $TCID_{50}$/mL	

The non-influenza exclusivity panel consisted of 17 bacteria, 18 viruses, and one fungus, which were selected based on the relatedness to JBAIDS influenza analytes, clinical relevance (cause respiratory symptoms or represent nasopharyngeal flora), or high prevalence within the population (e.g. Herpes Simplex Virus). Simulated NPS samples were spiked with bacteria or fungi at a concentration of 10^6 CFU/mL or $TCID_{50}$/mL and viruses at a concentration between $10^3 - 10^5$ copies/mL or $TCID_{50}$/mL. The JBAIDS Influenza A subtyping assays did not cross-react with the exclusivity panel organisms at the test concentrations listed in Table 12.

Table 12. Non-Influenza Exclusivity Panel

Virus	Concentration Tested	Bacteria/Fungi	Concentration Tested
Adenovirus	1.00E+05 $TCID_{50}$/mL	*Bordetella pertussis*	1.00E+06 CFU/mL
Bocavirus	4.20E+07 copies/mL	*Candida albicans*	1.00E+06 CFU/mL
Coronavirus 229E	7.35E+03 $TCID_{50}$/mL	*Corynebacterium diptheriae*	1.00E+06 CFU/mL
Coronavirus OC43	6.57E+04 $TCID_{50}$/mL	*Escherichia coli*	1.00E+06 CFU/mL
Coronavirus NL63	5.10E+03 $TCID_{50}$/mL	*Haemophilus influenza*	7.80E+04 CFU/mL
Coronavirus HKU1	1.00E+05 copies/mL	*Lactobacillus plantarum*	1.00E+06 CFU/mL
Cytomegalovirus (CMV)	1.50E+04 $TCID_{50}$/mL	*Legionella pneumophila*	1.00E+06 $TCID_{50}$/mL
Enterovirus	1.00E+05 $TCID_{50}$/mL	*Moraxella catarrhalis*	1.00E+06 CFU/mL
Epstein-Barr Virus (EBV)	1.00E+05 copies/mL	*Mycobacterium tuberculosis*	1.00E+06 CFU/mL
Human Metapneumovirus	7.35E+03 $TCID_{50}$/mL	*Mycoplasma pneumonia*	1.69E+05 $TCID_{50}$/mL
Human Rhinovirus	5.10E+03 $TCID_{50}$/mL	*Neisseria elongata*	1.00E+06 CFU/mL
Measles Virus (Rubeola)	1.00E+05 $TCID_{50}$/mL	*Neisseria meningitidis*	1.00E+06 CFU/mL
Mumps	4.53E+04 $TCID_{50}$/mL	*Pseudomonas aeruginosa*	1.00E+06 CFU/mL
Parainfluenza virus 1	1.25E+04 $TCID_{50}$/mL	*Staphylococcus aureus*	1.00E+06 CFU/mL
Parainfluenza virus 2	1.50E+04 $TCID_{50}$/mL	*Staphylococcus epidermidis*	1.00E+06 CFU/mL
Parainfluenza virus 3	1.00E+05 $TCID_{50}$/mL	*Streptococcus pneumonia*	1.00E+06 CFU/mL
Parainfluenza virus 4	1.00E+05 $TCID_{50}$/mL	*Streptococcus pyogenes*	1.00E+06 CFU/mL
Respiratory Syncytial Virus	1.25E+04 $TCID_{50}$/mL	*Streptococcus salivarius*	7.59E+05 CFU/mL

Reproducibility

A multicenter study was performed to determine overall system reproducibility. Reproducibility testing occurred at three test sites utilizing six total panels. Panels of NPS and NPW samples, each, were spiked with a representative seasonal influenza A H1N1 virus (A/New Caledonia/20/1999). Panels of simulated NPS and simulated NPW samples, each, were spiked with a representative seasonal influenza A H3N2 virus (A/New York/55/2004). Finally, panels of simulated NPS and simulated NPW samples,

each, were spiked with a representative 2009 H1N1 influenza virus (A/New York/18/2009). Samples in each panel consisted of three samples spiked below LoD (high negative, LoD/20), three samples spiked with a low concentration of virus (low positive, LoD), and three samples spiked at a medium concentration of virus (medium positive, 3×LoD) for a total of nine samples per panel. Each panel was tested twice daily at each site for a total of 30 results per sample and 90 results per spike level. The detection rate was ≥ 98% for samples containing influenza virus ≥ LoD. As expected, samples spiked below LoD have variable results. Results are shown in Table 13, Table 14 and Table 15.

Table 13. Summary of Reproducibility Testing for the Flu A H1 Assay (Agreement with Expected Positive Results)

Sample Type	Virus Spike Level	IT 1-2-3 Platinum Path Sample Purification Kit Number Positive Samples/ Total Samples (% Positive Detection)				Roche MagNA Pure Compact Nucleic Acid Isolation Kit I Number Positive Samples/ Total Samples (% Positive Detection)				Both Kits, All Sites (% Pos.)	95% CI
		Site 1	Site 2	Site 3	Overall for All Sites	Site 1	Site 2	Site 3	Overall for All Sites		
NPS	3×LoD	15/15 (100%)	14/15 (93%)	15/15 (100%)	44/45 (98%)	15/15 (100%)	14/15 (93%)	15/15 (100%)	44/45 (98%)	88/90 (98%)	92.2-99.7
	LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	90/90 (100%)	96.7-99.9
	Detection ≥ LoD	**30/30 (100%)**	**29/30 (97%)**	**30/30 (100%)**	**89/90 (99%)**	**30/30 (100%)**	**29/30 (97%)**	**30/30 (100%)**	**89/90 (99%)**	**178/180 (99%)**	**96.0-99.9**
	LoD/20	15/15 (100%)	13/15 (87%)	8/15 (53%)	36/45 (80%)	13/15 (87%)	11/15 (73%)	14/15 (93%)	38/45 (84%)	74/90 (82%)	72.7-89.4
	Detection all Levels	**45/45 (100%)**	**42/45 (93%)**	**38/45 (84%)**	**125/135 (93%)**	**43/45 (96%)**	**40/45 (89%)**	**44/45 (98%)**	**127/135 (94%)**	**252/270 (93%)**	**90.0-96.0**
NPW	3×LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	90/90 (100%)	96.7-99.9
	LoD	14/15 (93%)	15/15 (100%)	15/15 (100%)	44/45 (98%)	15/15 (100%)	14/15 (93%)	15/15 (100%)	44/45 (98%)	88/90 (98%)	92.2-99.7
	Detection ≥ LoD	**29/30 (97%)**	**30/30 (100%)**	**30/30 (100%)**	**89/90 (99%)**	**30/30 (100%)**	**29/30 (97%)**	**30/30 (100%)**	**89/90 (99%)**	**178/180 (99%)**	**96.0-99.9**
	LoD/20	13/15 (87%)	15/15 (100%)	9/15 (60%)	37/45 (82%)	14/15 (93%)	14/15 (93%)	15/15 (100%)	43/45 (96%)	80/90 (89%)	80.5-94.5
	Detection all Levels	**42/45 (93%)**	**45/45 (100%)**	**39/45 (87%)**	**126/135 (93%)**	**44/45 (98%)**	**43/45 (96%)**	**45/45 (100%)**	**132/135 (98%)**	**258/270 (96%)**	**92.4-97.7**

Table 14. Summary of Reproducibility Testing for the Flu A H3 Assay (Agreement with Expected Positive Results)

Sample Type	Virus Spike Level	IT 1-2-3 Platinum Path Sample Purification Kit Number Positive Samples/ Total Samples (% Positive Detection)				Roche MagNA Pure Compact Nucleic Acid Isolation Kit I Number Positive Samples/ Total Samples (% Positive Detection)				Both Kits, All Sites (% Pos.)	95% CI
		Site 1	Site 2	Site 3	Overall For All Sites	Site 1	Site 2	Site 3	Overall For All Sites		
sNPS	3×LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	13/15 (87%)	43/45 (96%)	88/90 (98%)	92.2-99.7
	LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	90/90 (100%)	96.7-99.9
	Detection ≥ LoD	**30/30 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**90/90 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**28/30 (93%)**	**88/90 (98%)**	**178/180 (99%)**	**96.0-99.9**
	LoD/20	12/15 (80%)	10/15 (67%)	9/15 (60%)	31/45 (69%)	14/15 (93%)	13/15 (87%)	14/15 (93%)	41/45 (91%)	72/90 (80%)	70.2-87.7
	Detection all Levels	**42/45 (93%)**	**40/45 (89%)**	**39/45 (87%)**	**121/135 (90%)**	**44/45 (98%)**	**43/45 (96%)**	**42/45 (93%)**	**129/135 (96%)**	**250/270 (93%)**	**88.8-95.4**
sNPW	3×LoD	15/15 (100%)	15/15 (100%)	14/15 (93%)	44/45 (98%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	89/90 (99%)	94.0-99.9
	LoD	14/15 (93%)	15/15 (100%)	15/15 (100%)	44/45 (98%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	89/90 (99%)	94.0-99.9
	Detection ≥ LoD	**29/30 (97%)**	**30/30 (100%)**	**29/30 (97%)**	**88/90 (98%)**	**30/30 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**90/90 (100%)**	**178/180 (99%)**	**96.0-99.9**
	LoD/20	11/15 (73%)	10/15 (67%)	9/15 (60%)	30/45 (67%)	15/15 (100%)	14/15 (93%)	15/15 (100%)	44/45 (98%)	74/90 (82%)	72.7-89.5
	Detection all Levels	**40/45 (89%)**	**40/45 (89%)**	**38/45 (84%)**	**118/135 (87%)**	**45/45 (100%)**	**44/45 (98%)**	**45/45 (100%)**	**134/135 (99%)**	**252/270 (93%)**	**89.7-96.0**

Table 15. Summary of Reproducibility Testing for the Combined Results of the Flu A H1 2009 and Flu A Sw Assays (Agreement with Expected Positive Results)

Sample Type	Virus Spike Level	IT 1-2-3 Platinum Path Sample Purification Kit Number Positive Samples/ Total Samples (% Positive Detection)				Roche MagNA Pure Compact Nucleic Acid Isolation Kit I Number Positive Samples/ Total Samples (% Positive Detection)				Both Kits, All Sites	95% CI
		Site 1	Site 2	Site 3	Overall for All Sites	Site 1	Site 2	Site 3	Overall for All Sites		
sNPS	3×LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	**90/90 (100%)**	96.7-99.9
	LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	**90/90 (100%)**	96.7-99.9
	Detection ≥ LoD	**30/30 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**90/90 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**90/90 (100%)**	**180/180 (100%)**	**98.3-99.9**
	LoD/20	15/15 (100%)	15/15 (100%)	15/15[a] (100%)	45/45 (100%)	15/15[a] (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	**90/90 (100%)**	96.7-99.9
	Detection all Levels	**45/45 (100%)**	**45/45 (100%)**	**45/45 (100%)**	**135/135 (100%)**	**45/45 (100%)**	**45/45 (100%)**	**45/45 (100%)**	**135/135 (100%)**	**270/270 (100%)**	**98.9-99.9**
sNPW	3×LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15[a] (100%)	15/15 (100%)	45/45 (100%)	**90/90 (100%)**	96.7-99.9
	LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	**90/90 (100%)**	96.7-99.9
	Detection ≥ LoD	**30/30 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**90/90 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**90/90 (100%)**	**180/180 (100%)**	**98.3-99.9**
	LoD/20	15/15 (100%)	15/15 (100%)	15/15[a] (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15[a] (100%)	45/45 (100%)	**90/90 (100%)**	96.7-99.9
	Detection all Levels	**45/45 (100%)**	**45/45 (100%)**	**45/45 (100%)**	**135/135 (100%)**	**45/45 (100%)**	**45/45 (100%)**	**45/45 (100%)**	**135/135 (100%)**	**270/270 (100%)**	**98.9-99.9**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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

SEP 13 2011

Re: k111778

Trade/Device Name:	JBAIDS Influenza A Subtyping Kit
Regulation Number:	21 CFR §866.3332
Regulation Name:	Reagents for Detection of Specific Novel Influenza A Viruses
Regulatory Class:	Class II
Product Codes:	OQW, OEP, OOI
Dated:	June 20, 2011
Received:	June 23, 2011

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.

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: k111778
Device Name: JBAIDS Influenza A Subtyping Kit

Indications for Use:

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Influenza A Subtyping Kit is intended for the *in vitro* qualitative detection and differentiation of seasonal Influenza A/H1, seasonal Influenza A/H3, and 2009 H1N1Influenza viral nucleic acids isolated and purified from nasopharyngeal swab (NPS) and nasopharyngeal wash (NPW) specimens from human patients with signs and symptoms of respiratory infection, in conjunction with clinical and epidemiological risk factors. The JBAIDS Influenza A Subtyping Kit contains reverse transcriptase real-time polymerase chain reaction (rRT-PCR) assays for use on the JBAIDS instruments. The Flu A H1, Flu A H3, and Flu A H1 2009 assays of the JBAIDS Influenza A Subtyping Kit target a region of the hemagglutinin (HA) gene of the respective Influenza A virus. The Flu A Sw assay of the JBAIDS Influenza A Subtyping Kit targets a region of the nucleocapsid protein (NP) gene of the 2009 H1N1 Influenza virus, as well as some other Influenza A viruses of swine lineage. This kit is not intended to detect Influenza B or Influenza C viruses.

A negative result for all assays in the JBAIDS Influenza A Subtyping Kit is a presumptive negative result for Influenza A. These results should be confirmed using the JBAIDS Influenza A & B Detection Kit.

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.

Due to low seasonal prevalence, performance characteristics for detection of seasonal Influenza A/H1 were established primarily with retrospective and contrived clinical specimens.

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.

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 OF NEEDED)

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 111778