

SPECIAL 510(k): Device Modification  
OIR Decision Memorandum

To: The Surgeon General, Department of the Army

RE: K152523

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

Trade Name: JBAIDS Influenza A & B Detection Kit  
510(k) number: K111775

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling.

3. A description of the device **MODIFICATION(S)**.

The modification presented in this special 510k submission is the inclusion of 5 influenza A strain isolates to the analytical inclusivity table in the package insert. The five strain isolates are A/Anhui/1/2013 (H7N9), A/Victoria/361/2011 (H3N2), A/Perth/16/2009 (H3N2), A/West/Virginia/06/2011 (H3N2v), and A/Minnesota/11/2010 (H3N2v). The submitter tested the ability of the JBAIDS Influenza A & B Detection Kit to detect these 5 additional viral strains. Viral stocks were spiked into negative nasopharyngeal swab matrix and tested in triplicate at a single concentration. All strains were appropriately detected by the JBAIDS Influenza A & B Detection Kit.

4. The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

5. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics:

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

	Proposed Device	Predicate Device
Element	JBAIDS Influenza A and B Detection kit (K152523)	JBAIDS Influenza A and B Detection kit (K11775)
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.  The JBAIDS Influenza A & B Detection Kit contains reverse	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 from nasopharyngeal swab (NPS) and nasopharyngeal wash (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

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.

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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.	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.
Technology	Real time PCR using hydrolysis probes	Same
Virus Detected	Qualitative in vitro detection of Influenza A and Influenza B virus nucleic acids	Same
Specimen Types	Nasopharyngeal swabs and Nasopharyngeal washes	Same
Extraction Methods	IT 1-2-3™ Platinum Path Sample Purification Kit and Roche MagNA Pure Compact Nucleic Acid Isolation Kit I	Same
Required Information	JBAIDS Instrument	Same
Interpretation of Test	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	Proposed Device JBAIDS Influenza A and B Detection kit (K152523)	Predicate Device JBAIDS Influenza A and B Detection kit (K11775)
Organisms Detected	Demonstrated inclusive detection of one strain of Influenza A H7N9, two strains of Influenza H3N2 and 2 strains of Influenza H3N2v as positive for Influenza A	Not labeled for detection of Influenza A for these strains
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 washes and Nasopharyngeal swabs
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

Other Differences:

The package insert has been updated to include detection of 5 influenza strains to the Analytical Inclusivity section.

The following statement was added to the Analytical Inclusivity section of the package insert: “Although this test has been shown to detect novel avian influenza A (H7N9) and H3N2v cultured viruses the performance characteristics of this device with clinical specimens that are positive for novel avian influenza A (H7N9) and H3N2v influenza viruses has not been established. The JBAIDS Influenza A & B Detection Kit can distinguish between influenza A and B viruses, but it cannot differentiate influenza A subtypes.”

The following text was added to the front page of the package insert: “For Prescription Use only”

**6. Design Control Activities Summary** which includes:

- a) A potential hazard of false negative results due to emerging viruses was identified during the risk analysis. The submitter performed post-market surveillance of emerging influenza strains that could pose a risk for false negative tests. The submitter identified five strain isolates. To mitigate the risk of false negatives for these isolates, the submitter conducted analytical inclusivity study and confirmed that their device detected these isolates. The inclusivity results were included in the package insert.
- b) The sponsor updated the risk analysis for this product, as well as creating additional design history documents (tracing to verification/validation of acceptance criteria) in conformance with the design control procedure requirements as specified in 21 CFR 820.30.

c) Declaration of Conformity with Design Controls

A “Declaration of Conformity” statement was submitted for the device manufacturing facility. It was signed by the Director of Regulated Products and the Director of Quality Assurance.

d) Included in the submission were the following statements to indicate conformity:

“As required by the risk analysis, all verification and validation activities were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met as described more fully in Section 6 of the Special 510(k) Submissions for the JBAIDS Influenza A & B Detection and A Subtyping Kits.”

“The BioFire Defense, LLC manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. No recent Quality System inspections have resulted in the issuance of a violative inspection report.”

**Conclusion:**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter’s description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. On this basis, I recommend the device be determined substantially equivalent to the previously cleared device.