

**SPECIAL 510(k): Device Modification  
Decision Summary**

**To:** Sekisui Diagnostics, LLC

**RE:** K123182

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II or Class I device 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: OSOM® Influenza A&B Test

510(k) number: K092633

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 510(k) is the inclusion of the H3N2v influenza A virus strains below, to the analytical reactivity information. The submitter tested the ability of the OSOM® Influenza A&B Test to detect H3N2v influenza A viruses. The viruses used were diluted viral stocks obtained from the Centers for Disease Control and Prevention. Analytical reactivity testing was performed in duplicate on each virus and reported as the lowest dilution/concentration of the H3N2v virus that the OSOM® Influenza A&B Test was able to detect. The following H3N2v viruses were tested:

A/WEST VIRGINIA/06/2011  
A/PENNSYLVANIA/14/2010  
A/MINNESOTA/11/2010  
A/KANSAS/13/2009  
A/INDIANA/08/2011  
A/INDIANA/10/2011

The OSOM® Influenza A&B Test package insert has been updated to include the additional analytical reactivity information

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, and physical characteristics:

Similarities

Device Characteristics	New Device: OSOM® Influenza A&B Test	Predicate Device: OSOM® Influenza A&B Test (K092633)
<b>Intended Use</b>	The OSOM® Influenza A&B Test is an in- vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. This test is	The OSOM® Influenza A&B Test is an in- vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. This test is

	not intended for the detection of influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.	not intended for the detection of influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.
<b>Sample type</b>	Nasal Swab	Nasal Swab
<b>Analytical principle</b>	Lateral flow immunochromatographic assay	Lateral flow immunochromatographic assay
<b>Antibody</b>	Mouse monoclonals	Mouse monoclonals
<b>Extraction buffer volume</b>	300uL	300uL
<b>Read time for results</b>	10 minutes	10 minutes
<b>Objective Test Line</b>	Colloidal gold	Colloidal gold
<b>Internal Control</b>	Pink to purple line	Pink to purple line
<b>Control samples supplied (as prepared swabs)</b>	Positive Influenza A Positive Influenza B (Positive A acts as negative B; Positive B acts as negative A)	Positive Influenza A Positive Influenza B (Positive A acts as negative B; Positive B acts as negative A)

### Differences

The package insert has been updated to include detection of the following H3N2v viruses in the analytical reactivity information section:

A/WEST VIRGINIA/06/2011\*\*  
A/PENNSYLVANIA/14/2010\*\*  
A/MINNESOTA/11/2010\*\*  
A/KANSAS/13/2009\*\*  
A/INDIANA/08/2011\*\*  
A/INDIANA/10/2011\*\*

\*\*Although this test has been shown to detect these 2009 H1N1 and H3N2v viruses cultured from positive human respiratory specimens the performance characteristics of this device with clinical specimens that are positive for these H3N2v influenza viruses have not been established. The OSOM® Influenza A&B Test can distinguish between influenza A and B viruses, but it cannot differentiate influenza subtypes.

## 6. Design Control Activities Summary:

### a) Risk Analysis:

A Failure Mode and Effect Analysis (FMEA) method was used evaluate risk for the proposed changes to the labeling. The methods of risk analysis were consistent with 21 CFR 860, ISO: 14971. The following table is a summary of the risk analysis:

Modification	Hazard	Resolution of Risk	Test Performed	Summary of Test Method	Acceptance Criteria	Acceptance Criteria Met
Addition of 6 H3N2v Influenza A strains:  A/WEST VIRGINIA/06/2011 A/PENNSYLVANIA/14/2010 A/MINNESOTA/11/2010 A/KANSAS/13/2009 A/INDIANA/08/2011 A/INDIANA/10/2011	Non-detection of any of the 6 listed H3N2v Influenza A strains.	Confirm Analytical Sensitivity for all six H3N2v Influenza A strains.	Analytical Sensitivity Testing conducted for each of the 6 H3N2v Influenza A strains	Tested in duplicate for each dilution for each of the 6 listed H3N2v Influenza A strains.	10 minute read; positive visual result for each dilution level (line intensity $\geq 0.5$ ; per Sekisui Diagnostic QC red color chart)	Yes
	Misinterpretation of test use - test used for detection of specific novel H3N2v strain from human specimen	Labeling-limitation of test provided in Limitations and Analytical Reactivity sections.	N/A	N/A	N/A	N/A

b) Analytical Reactivity Testing was conducted as described in section 3, Device Modifications.

c) Declaration of Conformity

A "Declaration of Conformity" statement was submitted for the manufacturing facility and validation activities and signed by the Director of Quality Assurance and the Senior Director of Technical Operations respectively. The statements indicate that;

1. The manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
2. The validation activities, as required by the risk analysis, for the modification were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.

In conclusion, based on both the results of the analytical reactivity testing and the risk management report, the modified labeling is truthful and accurate. The changes do not affect the performance of the test and it is therefore substantially equivalent to the previously cleared device.

## 7. A Truthful and Accurate Statement, a 510(k) Summary, and the Indications for Use Enclosure.

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 and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and, on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.