510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K041626

B. Purpose for Submission:

New device

C. Measurand:

Flu A & Flu B antigens

D. Type of Test:

Immunochromatographic test

E. Applicant:

Meridian Bioscience, Inc.

F. Proprietary and Established Names:

ImmunoCard STAT!® Flu A&B

G. Regulatory Information:

1. <u>Regulation section:</u> 866.3330; Influenza virus serological reagents

2. <u>Classification:</u> Class: I

3. <u>Product code:</u> GNX; Antigens, CF, Influenza Virus A, B, C

4. <u>Panel:</u> 83 Microbiology

H. Intended Use:

1. <u>Intended use(s):</u>
   Immuno*Card* STAT!® Flu A&B is a rapid, qualitative, lateral-flow immunoassay for detecting both influenza A and influenza B viral nucleoprotein antigens in human nasal wash, nasopharyngeal aspirate and nasal and nasopharyngeal swab

samples. It is designed to test samples from symptomatic patients. It is recommended that all negative test results be confirmed by cell culture.

2. Indication(s) for use:
   Immuno*Card* STAT!® Flu A&B is a rapid, qualitative, lateral-flow immunoassay for detecting both influenza A and influenza B viral nucleoprotein antigens in human nasal wash, nasopharyngeal aspirate and nasal and nasopharyngeal swab samples. It is designed to test samples from symptomatic patients. It is recommended that all negative test results be confirmed by cell culture.

3. Special conditions for use statement(s):

   For prescription use

4. Special instrument requirements:

   None

I. Device Description:

The Flu A assay uses monoclonal antibodies specific for influenza A nucleoprotein as both the capture and detection antibodies. The Flu B assay uses monoclonal antibodies specific for influenza B nucleoprotein as both the capture and detection antibodies. Nasal wash or nasopharyngeal aspirate is added to Sample Diluent buffer using the transfer pipette provided with the kit. The diluted sample (approximately 1 in 2 dilution) is added to the sample port of the device. Influenza A or influenza B antigen in the diluted sample binds to the corresponding monoclonal antibody-colloidal gold conjugate as the sample moves through the device. The influenza A capture monoclonal antibody bound to the assay membrane at the test-FLU A position of the device central window binds antigen-influenza A antibody-colloidal gold complex and yields a visible pink-red line. The influenza B capture monoclonal antibody bound to the assay membrane at the test-FLU B position of the device central window binds antigen-influenza B antibody-colloidal gold complex and yields a visible pink-red line. When no antigen is present, no complex is formed and no pink-red line will appear at either the test FLU A or the test FLU B position of the device central window.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Binax NOW® Flu A& Binax NOW® Flu B

2. Predicate 510(k) number(s):

   k021649 & k021646

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Method and type	Immunochromatography Rapid test Qualitative	Immunochromatography Rapid test Qualitative
Differences		
Item	**Device**	**Predicate**
Specimen Type	Nasal Wash, Nasopharyngeal Aspirate and Nasal Swab and Nasopharyngeal Swab	Nasal wash Nasopharyngeal Swab

K. Standard/Guidance Document Referenced (if applicable):

Not applicable

L. Test Principle:

Immunochromatography

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*
   The reproducibility of Immuno*Card* STAT! Flu A&B was determined using a panel of known negative (n = 2), positive (n = 5 Flu A, 5 Flu B) and LOD (n = 2) samples that were coded and randomly sorted to mask their identities. Four of the 10 positive samples were weakly reactive. Each reproducibility panel was tested on three consecutive days by three independent test sites. All of the samples produced the expected results 100% of the time.

   b. *Linearity/assay reportable range:*

   Not applicable

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Not applicable

d. *Detection limit:*

The analytical sensitivity of this assay was established in tests with dilutions of 6 examples of influenza A (VR-95, VR-97, VR-544, VR547, VR-822 and VR-897) and 5 examples of influenza B (VR-101, VR-102, VR-295, VR-790 and VR-823) strains. The lower limit of detection with influenza A strains ranged from 890 to 74,000 virions/mL while the lower limit of detection for influenza B strains ranged from 187 to 630,000 virions/mL.

e. *Analytical specificity:*
The specificity of Immuno*Card* STAT! Flu A&B was tested utilizing bacterial, viral and yeast strains. Positive and negative respiratory specimens were spiked with $\geq 7.5 \times 10^7$/mL bacteria or yeast. Virus inoculations were performed at $\geq 1500\,\mathrm{TCID}_{50}$ or CEID_{50}/mL. None of the microorganisms tested yielded a positive result with the influenza-negative samples or interfered with detection of the influenza A and/or B positive samples. Both the negative and positive respiratory samples were positive when spiked with influenza A strain VR-100 or influenza B strain VR-295.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*
The performance of Immuno*Card* STAT! Flu A&B PLUS was evaluated by four independent laboratories (3 located in the US and one outside of the US) using either fresh or frozen samples that were characterized using cell culture.   Thirty seven of the samples were obtained from pediatric patients.

Results by sample type:

Fresh : Wash/Aspirate

	IC STAT! Flu A			IC STAT! Flu B		
	Pos	Neg	Total	Pos	Neg	Total
Tissue Culture Pos	12	3	15	2	3	5
Tissue Culture Neg	8	110	118	0	128	128
Total	120	113	133	2	131	133

Correlation – Flu A   122/133 (92%)
Sensitivity   12/15 (80%)
Specificity   110/118 (93%)

Correlation – Flu B   130/133 (98%)
Sensitivity   2/5 (40%)
Specificity   128/128 (100%)

Fresh: Swab samples

	IC STAT! Flu A			IC STAT! Flu B		
	Pos	Neg	Total	Pos	Neg	Total
Tissue Culture Pos	29	11	40	19	6	25
Tissue Culture Neg	2	229	231	0	246	246
Total	31	240	271	19	252	271

Correlation – Flu A   258/271 (95%)
Sensitivity   29/40 (73%)
Specificity   229/231 (91%)

Correlation – Flu B   265/271 (98%)
Sensitivity   19/25 (76%)
Specificity   246/246 (100%)

Frozen: Wash/Aspirate

	IC STAT! Flu A			IC STAT! Flu B		
	Pos	Neg	Total	Pos	Neg	Total
Tissue Culture Pos	23	1	24	2	0	2
Tissue Culture Neg	6	52	58	0	80	80
Total	29	53	82	2	80	82

Correlation – Flu A   75/82 (92%)
Sensitivity   23/24 (96%)
Specificity   52/58 (90%)

Correlation – Flu B   82/82 (100%)
Sensitivity   2/2 (100%)
Specificity   80/80 (100%)

Frozen: Swab samples

	IC STAT! Flu A			IC STAT! Flu B		
	Pos	Neg	Total	Pos	Neg	Total

Tissue Culture Pos	37	13	50	6	6	12
Tissue Culture Neg	7	100	107	0	145	145
Total	44	113	157	6	151	157

Correlation – Flu A   137/157 (87%)
Sensitivity   37/50 (74%)
Specificity   100/107 (94%)

Correlation – Flu B   151/157 (96%)
Sensitivity   6/12 (50%)
Specificity   145/145 (100%)

    b. *Matrix comparison:*

      Not applicable

3. Clinical studies:

    a. *Clinical Sensitivity:*

      Not applicable

    b. *Clinical specificity:*

      Not applicable

    c. Other clinical supportive data (when a. and b. are not applicable):

      Not applicable

4. Clinical cut-off**:**

    Not applicable

5. Expected values/Reference range:

    Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.