K041626

Meridian Bioscience, Inc.
Cincinnati, OH

MAR 16 2005

## SUMMARY OF SAFETY AND EFFECTIVENESS

## IDENTIFICATION INFORMATION

## SUBMITTER'S INFORMATION

**This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.20.**

**SUBMITTER'S NAME AND ADDRESS:** Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, OH 45244

**PHONE NUMBER:** (513) 271-3700

**FAX NUMBER:** (513) 272-5213

**CONTACT PERSON:** Susan Rolih
Official Correspondent

**DATE SUMMARY PREPARED:** March 11, 2005

**TRADE NAME:** Immuno*Card* STAT! Flu A & B

**COMMON NAME:** Rapid, qualitative lateral-flow immunoassay for the detection of Influenza A and B antigen

**CLASSIFICATION NAME:** Antigen, CF (including CF control), influenza virus A, B, C

**REGULATION:** 866.3330

**INTENDED USES:**

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 pediatric and adult patients. It is recommended that all negative test results be confirmed by cell culture.

**PREDICATE DEVICES:**

Immuno*Card* STAT! Flu A & B is intended to detect the same analytes as other cleared devices including:

- **Binax NOW® Flu A + B** [a rapid lateral-flow immunoassay cleared to market under 510(k)s K021649 and K021646] (Binax, Inc. South Portland, ME)
- **BD Directigen® Flu A+B** [a rapid enzyme immunoassay cleared to market under 510(k) K001364] (Becton Dickinson & Co., Sparks, MD)
- **FLU OIA** [an optical immunoassay cleared to market under 510(k) K023556] (Thermo-Biostar Inc., Louisville, CO)
- **Quickvue®** Influenza A+ B Test [a rapid lateral-flow immunoassay cleared to market under 510(k) K031899] (Quidel, Inc., San Diego, CA)
- **Xpext®** Flu A/B [a rapid immunochromatographic assay cleared to market under 510(k) K031565] (Remel, Inc., Lenexa, KS)

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- **Zstatflu®** Test for Influenza types A & B Virus [an endogenous viral-encoded enzyme assay cleared to market under 510(k) K982429] (ZymeTx, Inc., Oklahoma City, OK)

**BACKGROUND:**

Influenza is a highly contagious, epidemic to pandemic acute viral respiratory disease caused by several genera for the Orthomyxoviridae family. Influenzavirus A and Influenzavirus B are the two genera most commonly associated with disease in humans. (1,2) Influenza infection rates tend to be highest in pediatric populations, while serious complications from influenza disease are more common in the elderly. (2) Clinical signs and symptoms begin after a 1-4 day incubation period and include cough, fever, myalgia and malaise. The clinical presentation of influenza can range from asymptomatic infection to fatal pneumonia. (1) Influenza co-circulates with other respiratory pathogens, hence it is important to differentiate influenza from other respiratory diseases. (2) Antiviral drugs in general have shown more significant clinical benefit when administered within 48 hours of the appearance of symptoms, which obviates the need for the rapid detection of influenza. Not all antiviral drugs are effective against both influenza A and influenza B, therefore it is important to distinguish between the two. (2,4)

Influenza A and B can be detected in human respiratory samples by a variety of methods including cell culture, immunofluorescent assay and enzyme immunoassay. Cell culture isolation remains the gold standard for the detection of influenza, yet the procedure can take 7 days to complete. (1) Immunofluorescent antibody-based tests are moderately sensitive, yet highly dependent on specimen quality and preparation. The rapid detection of influenza using enzyme and microparticle-based immunoassays has become an important aspect of patient management in patients of all ages with acute respiratory disease due to influenza. (1,3,4) The results from this test are used to support data available from the patient's clinical evaluation and assist the physician in determining the course of action.

***Type of test***

Immuno*Card* STAT! Flu A & B is a rapid, qualitative lateral-flow immunoassay screening test.

***Specimen type***

The following specimens have been found compatible with Immuno*Card* STAT! Flu A & B

1. Nasal wash
2. Nasopharyngeal aspirate
3. Nasopharyngeal swab
4. Nasal swab

***Conditions for use***

Immuno*Card* STAT! Flu A & B is designed for use by laboratory professionals under the normal environmental conditions. The assay, which is stored at 2-8 C when not in use, is brought to room temperature prior to use. Normal laboratory lighting, humidity and temperature do not affect the performance of the assay.

***Contraindications***

There are no contraindications associated with the use of this product.

***Special instrument requirements***

No instruments are used with this product.

### *Combination with other medical devices*

No other medical devices are used in combination with this device.

## DEVICE DESCRIPTION AND TECHNOLOGICAL PRINCIPLES

### *Reagents*

Immuno*Card* STAT! Flu A & B is distributed as a test kit that includes the following reagents:

**Immuno*Card* STAT! Flu A & B Test Device:** A chromatography strip housed in a plastic frame and enclosed in a foil pouch with a desiccant. The membrane carries immobilized monoclonal anti-influenza A and anti-influenza B capture antibodies at the TEST line and goat anti-mouse antibody at the CONTROL line. The strip also contains colloidal gold conjugated to monoclonal anti-influenza A and anti-influenza B as the detection antibodies.

**Sample Diluent:** A buffered protein solution containing sodium azide (0.095%) as a preservative.

**Positive Control:** Inactivated influenza A and influenza B virus in a buffered solution containing sodium azide (0.095%) as a preservative.

### *Equipment needed to use the device*

There is no equipment needed to use this device.

### *Interfering substances*

Whole blood, at concentrations greater than 0.5% may interfere with the interpretation of test results.

### *Calibrators*

There are no calibrators used with this device.

### *Controls*

The assay includes an internal CONTROL line that is used to demonstrate that sample has been applied, that it has flowed correctly and that the conjugated detector antibody is active at the time of testing. A colorless to light pink background around the Flu A and Flu B TEST and CONTROL lines serves as a negative control and indicates that reagents were performing correctly at the time of use.

Positive Control Reagent and Sample Diluent (used for a negative control reagent) are supplied as external controls. These reagents also serve as indicators that the test was performed correctly, that the capture and detector antibodies were active at the time of use, and that the membrane supports proper sample flow.

Failure of the internal and external control to produce the expected results suggests the test was not performed correctly (ie, incorrect volume of reagents added; incorrect incubation temperature or times used or that reagents were not brought to room temperature prior to testing).

### *Technological principles*

ImmunoCard STAT! Flu A & B uses specific monoclonal antibodies directed at the nucleoproteins of influenza A or influenza B as the capture and detector antibodies. Monoclonal influenza A and monoclonal influenza B are immobilized on the membrane of the test device at the reaction site marked FLU A and FLU B, respectively. Monoclonal influenza A and influenza B conjugated to colloidal gold are suspended within the membrane. To perform the test, sample (nasal wash, nasopharyngeal aspirate, nasopharyngeal swab, nasal swab) is first diluted with Sample Diluent, then added to the sample port of the Test Device. Influenza A or influenza B antigens in the sample bind the conjugate detector antibodies as the sample migrates through the device. The influenza A-gold conjugate complex will bind at the window site marked FLU A producing a visible pink-red line. Similarly, a pink-red line will appear when the influenza B-gold conjugate complex binds at the window site marked FLU B. In the absence of antigen, no pink-red line appears at either the FLU A or FLU B sites.

Goat anti-mouse antibody is bound at the membrane site marked "Control". A visible pink-red line should appear at this position each time a sample or control reagent is tested. Failure to obtain a visible pink-red control line invalidates the test and is an indication of assay failure.

## DEMONSTRATION OF EQUIVALENCE TO PREDICATE DEVICES

### The Limit of Detection (LOD)

To determine the LOD, the assay was evaluated with influenza A and influenza B antigen preparations (ATCC) diluted in pH 7.2 phosphate buffered saline containing sodium azide (PBSA). Table 6-1 shows the LOD for the strains of influenza tested. For the purposes of this evaluation, virions/mL is the same as $TCID_{50}$/mL.

***Table 6-1. LOD determination for* ImmunoCard STAT! Flu A & B.**

| Strain ID | Strain Type | Limit of Detection (LOD) |
|---|---|---|
| VR-102 | Flu B | 533 v/mL |
| VR823 | Flu B | 630,000 v/mL |
| VR101 | Flu B | 530,000 v/mL |
| VR295 | Flu B | 187 v/mL |
| VR790 | Flu B | 15,000 v/mL |
| VR-822 | Flu A | 74,000 v/mL |
| VR97 | Flu A | 5,300 v/mL |
| VR95 | Flu A | 35,000 v/mL |
| VR547 | Flu A | 8,800 v/mL |
| VR544 | Flu A | 890 v/mL |
| VR897 | Flu A | 5,600 v/mL |

Legend: v/mL = virions per milliliter

### Clinical trials

Three independent laboratories and Meridian's Development Laboratory performed testing on archival frozen (retrospective) or fresh (prospective) samples collected from symptomatic patients. Each laboratory tested the samples by Binax NOW Flu A and NOW Flu B and ImmunoCard STAT! Flu A & B (substantially equivalent devices), ImmunoCard STAT! Flu A & B and culture.

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The data in Table 6-2 shows the overall sensitivity and specificity of ImmunoCard STAT! Flu A&B in comparison to culture with wash/aspirate and swab samples. In Table 6-3, the data is further divided to show the performance of prospective (freshly collected) versus retrospective (frozen) samples.

**Table 6-2 Performance of Wash/Aspirate Vs Swab samples**

| Wash/Aspirate Specimens | ICS Flu A | | | Binax Flu A | | | ICS Flu B | | | Binax Flu B* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pos | Neg | Total | Pos | Neg | Total | Pos | Neg | Total | Pos | Neg | Total |
| Tissue Culture Pos (Std) | 35 | 4 | 39 | 34 | 5 | 39 | 4 | 3 | 7 | 4 | 3 | 7 |
| Tissue Culture Neg (Std) | 14 | 162 | 176 | 10 | 166 | 176 | 0 | 208 | 208 | 2 | 205 | 207 |
| Total | 49 | 166 | 215 | 44 | 171 | 215 | 4 | 211 | 215 | 6 | 208 | 214 |

*1 Binax Flu B Invalid

| Swab Specimens | ICS Flu A | | | Binax Flu A* | | | ICS Flu B | | | Binax Flu B* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pos | Neg | Total | Pos | Neg | Total | Pos | Neg | Total | Pos | Neg | Total |
| Tissue Culture Pos (Std) | 66 | 24 | 90 | 53 | 37 | 90 | 25 | 12 | 37 | 13 | 24 | 37 |
| Tissue Culture Neg (Std) | 9 | 329 | 338 | 4 | 333 | 337 | 0 | 391 | 391 | 31 | 359 | 390 |
| Total | 75 | 353 | 428 | 57 | 370 | 427 | 25 | 403 | 428 | 44 | 383 | 427 |

*1 Binax Flu A Invalid, 1 Binax Flu B Invalid

**Table 6-3 Performance of prospective and retrospective samples**

| Fresh samples – Wash/Aspirate | ICS Flu A | | | Binax Flu A | | | ICS Flu B | | | Binax Flu B* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pos | Neg | Total | Pos | Neg | Total | Pos | Neg | Total | Pos | Neg | Total |
| Tissue Culture Pos (Std) | 12 | 3 | 15 | 11 | 4 | 15 | 2 | 3 | 5 | 2 | 3 | 5 |
| Tissue Culture Neg (Std) | 8 | 110 | 118 | 5 | 113 | 118 | 0 | 128 | 128 | 1 | 126 | 127 |
| Total | 20 | 113 | 133 | 16 | 117 | 133 | 2 | 131 | 133 | 3 | 129 | 132 |

*1 Binax Flu B Invalid

| Fresh samples – Swab | ICS Flu A | | | Binax Flu A* | | | ICS Flu B | | | Binax Flu B* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pos | Neg | Total | Pos | Neg | Total | Pos | Neg | Total | Pos | Neg | Total |
| Tissue Culture Pos (Std) | 29 | 11 | 40 | 19 | 21 | 40 | 19 | 6 | 25 | 9 | 16 | 25 |
| Tissue Culture Neg (Std) | 2 | 229 | 231 | 2 | 228 | 230 | 0 | 246 | 246 | 0 | 245 | 245 |
| Total | 31 | 240 | 271 | 21 | 249 | 270 | 19 | 252 | 271 | 9 | 261 | 270 |

*1 Binax Flu A Invalid, 1 Binax Flu B Invalid

| Frozen samples – Wash/Aspirate | ICS Flu A | | | Binax Flu A | | | ICS Flu B | | | Binax Flu B | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pos | Neg | Total | Pos | Neg | Total | Pos | Neg | Total | Pos | Neg | Total |
| Tissue Culture Pos (Std) | 23 | 1 | 24 | 23 | 1 | 24 | 2 | 0 | 2 | 2 | 0 | 2 |
| Tissue Culture Neg (Std) | 6 | 52 | 58 | 5 | 53 | 58 | 0 | 80 | 80 | 1 | 79 | 80 |
| Total | 29 | 53 | 82 | 28 | 54 | 82 | 2 | 80 | 82 | 3 | 79 | 82 |

| Frozen samples – Swab | ICS Flu A | | | Binax Flu A | | | ICS Flu B | | | Binax Flu B | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pos | Neg | Total | Pos | Neg | Total | Pos | Neg | Total | Pos | Neg | Total |
| Tissue Culture Pos (Std) | 37 | 13 | 50 | 34 | 16 | 50 | 6 | 6 | 12 | 4 | 8 | 12 |
| Tissue Culture Neg (Std) | 7 | 100 | 107 | 2 | 105 | 107 | 0 | 145 | 145 | 31 | 114 | 145 |
| Total | 44 | 113 | 157 | 36 | 121 | 157 | 6 | 151 | 157 | 35 | 122 | 157 |

### Characterization of samples producing discordant results

The data collected during clinical trials is shown in the spreadsheets provided at the end of these sections. The results can be summarized as follows:

Table 6-4. Samples producing discrepant results.

| Sample Number | ICSFAB Results | Culture Results | | Comments PCR Results |
|---|---|---|---|---|
| 1-100 | Neg | A Pos | FN | Pos (Flu A) |
| 1-178 | Neg | A Pos | FN | Pos (Flu A) |
| 1-180 | Neg | B Pos | FN | Pos (Flu A) |
| 1-193 | Neg | B Pos | FN | Neg |
| 1-198 | Neg | A Pos | FN | Pos (Flu A) |
| 1-20 | A Pos | Neg | FP | Pos (Flu A) |
| 1-205 | Neg | B Pos | FN | No PCR |
| 1-206 | Neg | A Pos | FN | No PCR |
| 1-21 | Neg | A Pos | FN | No PCR |
| 1-216 | Neg | A Pos | FN | No PCR |
| 1-220 | Neg | A Pos | FN | No PCR |
| 1-224 | Neg | B Pos | FN | No PCR |
| 1-233 | Neg | A Pos | FN | No PCR |
| 1-24 | A Pos | Neg | FP | No PCR |
| 1-251 | Neg | B Pos | FN | Pos (Flu A) |
| 1-259 | Neg | A Pos | FN | Pos (Flu A) |
| 1-26 | Neg | A Pos | FN | Pos (Flu A) |
| 1-263 | Neg | A Pos | FN | No PCR |
| 1-269 | Neg | B Pos | FN | No PCR |
| 1-27 | Neg | A Pos | FN | No PCR |
| 1-270 | Neg | A Pos | FN | Pos (Flu A) |
| 1-271 | A Pos | Neg | FP | Pos (Flu A) |
| 1-278 | Neg | B Pos | FN | Pos (Flu A) |
| 1-288 | Neg | A Pos | FN | No PCR |
| 1-289 | Neg | B Pos | FN | No PCR |
| 1-29 | Neg | A Pos | FN | No PCR |
| 2-08 | A Pos | Neg | FP | Pos (Flu A) |
| 2-101 | A Pos | Neg | FP | No PCR |
| 2-106 | A Pos | Neg | FP | Pos (Flu A) |
| 2-15 | A Pos | Neg | FP | Pos (Flu A) |
| 2-52 | A Pos | Neg | FP | Pos (Flu A) |
| 2-54 | A Pos | Neg | FP | Pos (Flu A) |
| 2-61 | Neg | A Pos | FN | Pos (Flu A) |
| 2-62 | A Pos | Neg | FP | Pos (Flu A) |
| 3-120 | Neg | B Pos | FN | Pos (Flu A) |
| 3-121 | Neg | B Pos | FN | Pos (Flu A) |
| 3-123 | Neg | B Pos | FN | No PCR |
| 3-14 | Neg | A Pos | FN | Pos (Flu B) |
| 3-20 | Neg | A Pos | FN | No PCR |
| 3-22 | A Pos | Neg | FP | Pos (Flu B) |
| 3-31 | A Pos | Neg | FP | Pos (Flu B) |
| 3-4 | Neg | A Pos | FN | Pos (Flu B) |
| 3-48 | A Pos | Neg | FP | No PCR |
| 3-5 | Neg | A Pos | FN | Pos (Flu B) |
| 3-52 | A Pos | Neg | FP | Pos (Flu B) |
| 3-8 | Neg | A Pos | FN | No PCR |
| 3-82 | A Pos | Neg | FP | Pos (Flu B) |
| 4-137 | Neg | A Pos | FN | Pos (Flu B) |
| 4-142 | A Pos | Neg | FP | Pos (Flu A) |
| 4-152 | Neg | B Pos | FN | Pos (Flu A) |
| 4-171 | Neg | A Pos | FN | Pos (Flu A) |
| 4-180 | Neg | B Pos | FN | Pos (Flu A) |
| 4-182 | Neg | B Pos | FN | Pos (Flu A) |
| 4-183 | A Pos | Neg | FP | No PCR |
| 4-191 | A Pos | Neg | FP | No PCR |

Table 6-4 Continued.

| Sample Number | ICSFAB Results | Culture Results | | Comments PCR Results |
|---|---|---|---|---|
| 4-216 | A Pos | Neg | FP | No PCR |
| 4-39 | A Pos | Neg | FP | No PCR |
| 4-52 | A Pos | Neg | FP | Pos (Flu A) |
| 4-58 | A Pos | Neg | FP | Neg |
| 4-64 | Neg | A Pos | FN | Pos (Flu A) |
| 4-68 | Neg | A Pos | FN | No PCR |
| 4-69 | Neg | A Pos | FN | No PCR |
| 4-70 | Neg | A Pos | FN | No PCR |
| 4-71 | Neg | B Pos | FN | Neg |
| 4-82 | A Pos | Neg | FN | Neg |
| 4-89 | Neg | A Pos | FN | Neg |
| 2-25 | A Pos | Overgrown | Overgrown | Pos (Flu A) |
| 2-31 | A Pos | Overgrown | Overgrown | Pos (Flu A) |
| 2-50 | Neg | Overgrown | Overgrown | Neg |
| 2-57 | Neg | Overgrown | Overgrown | Neg |
| 2-60 | A Pos | Overgrown | Overgrown | Pos (Flu A) |

Legend: FN = false negative, FP = false positive

### Reproducibility

A reproducibility panel, consisting of 14 coded specimens, were sent to the three clinical sites. Ten of these samples were classified by the predicate devices Binax NOW Flu A and NOW Flu B as positive. Two additional samples were at the limit of detect of Immuno*Card* STAT! Flu A & B and two samples were negative. The samples were expected to produce a positive or negative result. Even though the trial sites were instructed to grade reactions, there were no criteria regarding the strength of a positive reaction that was expected. Table 6-6 shows that all samples demonstrated intra- and inter-assay reproducibility of 100%.

### High dose hook effect

There was no high dose hook effect observed in verification or clinical testing performed with this assay.

## CONCLUSIONS

Immuno*Card* STAT! Flu A & B:

1. Can be used reliably for the rapid detection of influenza A and influenza B antigens in human respiratory specimens
2. Performs similarly to the predicate devices Binax NOW Flu A and NOW Flu B.

Table 6.6. Results with reproducibility test panel #1

| | Clinical Site 1 | | | Clinical Site 2 | | | Clinical Site 3 | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample ID | Day 1 | Day 2 | Day 3 | Day 1 | Day 2 | Day 3 | Day 1 | Day 2 | Day 3 |
| 1 LP Flu A | 3 | 8 | 7 | 2 | 1 | 5 | 4 | Pos | 5 |
| 2 LP Flu A | 3 | 3 | 3 | 2 | 0.5 | 1 | 3.5 | Pos | 4 |
| 3 LP Flu B | 0.5 | 1 | 1 | 0.5 | 0.5 | 0.5 | 3 | 1 | 2 |
| 4 LP Flu B | 3 | 4 | 4 | 1 | 2 | 3 | 6 | Pos | 5 |
| 5 MP Flu A | 4 | 5 | 4 | 4 | 3 | 5 | 5 | Pos | 6 |
| 6 MP Flu A | 4 | 3 | 4 | 2 | 3 | 3 | 6.5 | 2 | 1 |
| 7 MP Flu B | 3 | 4 | 3 | 3 | 3 | 4 | 4.5 | Pos | 5 |
| 8 MP Flu B | 5 | 5 | 6 | 3 | 5 | 4 | 5 | 6 | 6.5 |
| 9 HP Flu A | 7 | 6 | 6 | 7 | 5 | 5 | 6.5 | 2 | 6.5 |
| 10 HP Flu B | 9 | 9 | 8 | 7 | 8 | 8 | 9 | 10 | 10 |
| 11 N | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 12 N | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 13 Limit of detect A | 1 | 2 | 2 | 1 | 0.5 | 1 | 2.5 | 2 | 1.5 |
| 14 Limit of detect B | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| Total positive score | 42.5 | 50.0 | 48.0 | 32.5 | 31.5 | 39.5 | 55.5 | 24 | 53.5 |
| Average positive score | 3.5 | 4.2 | 4.0 | 2.7 | 2.6 | 3.3 | 4.6 | 3.4 | 4.5 |
| Percent correlation | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |

Legend: LP = low positive, MP = moderate positive, HP = high positive, N = negative,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 16 2005

Ms. Susan Rolih
Vice President, Regulatory Affairs and Quality Assurance
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, OH 45244

Re: k041626
Trade/Device Name: Immuno*Card* STAT! Flu A&B PLUS
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: Class I
Product Code: GNX
Dated: February 28, 2005
Received: March 1, 2005

Dear Ms. Rolih:

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 such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

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
# ImmunoCard STAT! Flu A&B PLUS

510(k) Number (if known): K041626

Device Name: ImmunoCard STAT! Flu A&B PLUS

Indications For Use:

ImmunoCard STAT! Flu A&B PLUS is a rapid, qualitative, lateral-flow immunoassay for detecting both influenza A and influenza B viral nucleoprotein antigens in human nasal aspirate, 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.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off



Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K041626