

**510(k) Summary**

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**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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**1) Submitter name, address, contact** Roche Diagnostics Corporation  
9115 Hague Rd.  
Indianapolis, IN 46250  
(317) 845-2000

Contact Person: Luann Ochs

Date Prepared: September 8, 1999.

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**2) Device name** Proprietary name: Roche Diagnostics Influenza A/B Rapid Test  
  
Common name: Influenza virus detection reagents  
  
Classification name: Antigens, CF (including CF control), influenza virus A, B, C

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**3) Predicate device** We claim substantial equivalence to the Biostar Flu OIA, optical immunoassay for the rapid detection of influenza A and B.

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## 510(k) Summary, Continued

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**4) Device Description**

The Influenza A/B Rapid Test consists of swabs, reaction cups, test strips, and reagent solutions.

The test detects the viral nucleoprotein associated with the viral nucleic acid. The nucleoprotein is released by lysing the virus envelop with the lysis/elution solution. Since the nucleoprotein is type specific only (not subtype specific), the test uses two pairs of monoclonal antibodies – one pair is specific for Influenza A, the other is specific for Influenza B. The antibody pairs are conjugated to either biotin or digoxigenin.

In the presence of the viral antigen, a sandwich complex is formed, consisting of the biotin-conjugated antibody, the nucleoprotein, and the digoxigenin-conjugated antibody. When the test strip is placed in the reaction cup, the complex migrates chromatographically, solubilizing colloidal gold particles incorporated in the red pad of the strip. The colloidal gold particles bind to the digoxigenin of the complex, which is then bound by the biotin to the immobilized streptavidin on the strip (positive result line). Any excess gold particles continue to migrate to the second line (control line), which then becomes visible. This indicates the correct chromatographic migration.

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**5) Intended use**

The Influenza A/B Rapid Test is a qualitative immunoassay for the rapid detection of Influenza A/B viral antigens from throat swab specimens. This test is intended for professional *in vitro* diagnostic use to aid in the diagnosis of Influenza infections, and to gather epidemiological information for detection of Influenza outbreaks. When used for diagnosis, negative assay results should be confirmed by cell culture. This assay does not detect the presence of Influenza C viral antigens.

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## 510(k) Summary, Continued

### 6) Comparison to predicate device

The Roche Diagnostics Influenza A/B Rapid Test is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Biostar Flu AB OIA.

Feature	RDC Influenza A/B Rapid Test	Biostar Flu OIA
Intended use	Detection of Influenza A and B viral antigen	Detection of Influenza A and B viral antigen
Indication for use	Aid in the diagnosis of influenza A or B viral infections.	Aid in the diagnosis of influenza A or B viral infections.
Sample type	Throat swab	Throat swab, nasal aspirate, nasopharyngeal swab, or sputum.
Test Principle	Direct visualization of antigen-antibody complex binding to a surface.	Direct visualization of antigen-antibody complex binding to a surface.
Results	Positive or negative qualitative results	Positive or negative qualitative results
Quality control	Internal procedural quality control, external quality control solutions	Internal procedural quality control, external quality control solutions
Performance	Sensitivity 68.4% Specificity 80.7%	Sensitivity 62% Specificity 80%

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## 510(k) Summary, Continued

### 6) Comparison to predicate device, continued

#### Differences

<b>Feature</b>	<b>RDC Influenza A/B Rapid Test</b>	<b>Biostar Flu OIA</b>
Procedure	Rapid, simple procedure: 1. Extract sample in solution for 1 minute. 2. Add antibody reagents and mix. 3. Place test strip in solution. 4. Read results after 10 minutes.	Complicated, long procedure: 1. Extract sample in solution for 3 minutes. Add reagent. 2. Pipet one drop of sample onto test surface. Wait 6 minutes. 3. Wash the test surface. 4. Blot the test surface. 5. Add substrate reagent. Wait 6 minutes. 6. Wash the test surface. 7. Blot test surface. 8. Read results.
Total Assay Time	12 minutes	20 minutes
Incubation Time	10 minutes	15 minutes

#### Benefits:

The RDC Influenza A/B Rapid Test is easier to perform than the Biostar Flu OIA. The Influenza A/B Rapid Test has fewer procedural steps, and can be completed in about 12 minutes, versus about 20 minutes for the Biostar Flu OIA. Both tests utilize throat swab specimens, and contain antibodies to viral nucleoprotein for the detection of Influenza A or B.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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DEC 20 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Luann Ochs  
Regulatory Program Manager  
Roche Diagnostics Corporation  
9115 Hague Road  
Indianapolis, Indiana 46250-0457

Re: K993048  
Trade Name: Roche Diagnostics Influenza A/B Rapid Test  
Regulatory Class: I  
Product Code: GNX  
Dated: November 9, 1999  
Received: November 10, 1999

Dear Mr. Ochs:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

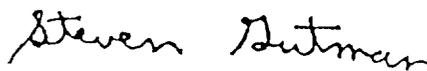
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,

A handwritten signature in cursive script that reads "Steven Gutman".

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):  
Device Name: Roche Diagnostics Influenza A/B Rapid Test  
Indications for Use:

The Influenza A/B Rapid Test is a qualitative immunoassay for the rapid detection of Influenza A/B viral antigens from throat swab specimens. This test is intended for professional *in vitro* diagnostic use to aid in the diagnosis of Influenza infections, and to gather epidemiological information for detection of Influenza outbreaks. When used for diagnosis, negative assay results should be confirmed by cell culture. This assay does not detect the presence of Influenza C viral antigens.

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IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Woody Dubois*

(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number   K993048  

Prescription Use   X    
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)