K022133

DEC 1 0 2002

510(k) SUMMARY

SUBMITTED BY:

BECTON, DICKINSON AND COMPANY
7 LOVETON CIRCLE
SPARKS, MD 21152
Phone: 410-316-4988
Fax: 410-316-4499

CONTACT NAME: Colleen A. Kistler, Regulatory Affairs Specialist

DATE PREPARED: June 28, 2002

DEVICE TRADE NAME: BD Directigen™ EZ RSV

DEVICE COMMON NAME: Antigen, CF, respiratory syncytial virus

DEVICE CLASSIFICATION: 21 CFR§866.3480

PREDICATE DEVICES:
Cell Culture
Direct Fluorescent Antibody (DFA)
Directigen™ RSV (K882629)

INTENDED USE:

The BD Directigen™ EZ RSV test is a rapid chromatographic immunoassay for the direct and qualitative detection of Respiratory Syncytial Virus (RSV) antigen in nasopharyngeal washes, nasopharyngeal aspirates, nasopharyngeal swabs, nasopharyngeal swab/washes, lower respiratory specimens (sputum, tracheal aspirates and bronchoalveolar lavage), and other swabs (pharyngeal, lower nasal, nose/throat) from patients suspected of having a viral respiratory infection.

DEVICE DESCRIPTION:

The BD Directigen™ EZ RSV test is a chromatographic assay to qualitatively detect RSV antigen in samples extracted from respiratory specimens. When extracted specimens are added to the test device, RSV A and/or B antigens bind to the antibody-colloidal gold conjugate in the test strip forming an antigen-antibody complex. This complex migrates across the test strip to the reaction area and is captured by the line of RSV antibody on the membrane. Excess conjugate binds to a second line of inactivated RSV antigen that serves as a functional control. A positive result is indicated by the appearance of two reddish purple lines in the read window, one line next to the Test "T" and the other next to the Control "C". The absence of a reddish purple line next to the "T" and the presence of a reddish purple line next to the "C" indicate a negative result. The test is considered uninterpretable is no visible reddish purple line is present next to the "C".

DEVICE COMPARISON:

The BD Directigen™ EZ RSV was compared to viral cell culture, direct fluorescent antibody (DFA) tests, and the Directigen™ RSV test. Although there are some differences between the BD Directigen™ EZ RSV test and the predicate devices, these differences do not present new issues of safety and effectiveness. The impact of these differences on the safety and effectiveness of the BD Directigen™ EZ RSV test was assessed using accepted scientific methods.

SUMMARY OF PERFORMANCE DATA:

Analytical Sensitivity

The limit of detection (LOD) for the BD Directigen™ EZ RSV test was established for a total of five RSV strains; two RSV A and three RSV B strains.

Viral Strain	Viral Type	LOD ($TCID_{50}$)
RSV (Long)	A	3.95×10^3
RSV (A-2)	A	5.95×10^3
RSV (9320)	B	4.05×10^2
RSV (Washington)	B	7.03×10^3
RSV (Wild)	B	5.56×10^2

Cross Reactivity

A panel of 99 microorganisms (including bacteria, yeasts and viruses) were cultured and tested at appropriate concentrations in triplicate with the BD Directigen™ EZ RSV test. None of the microorganisms tested in the panel were shown to cross react with the BD Directigen™ EZ RSV test.

Interfering Substances

A variety of substances were tested with the BD Directigen™ EZ RSV test at concentration levels comparable to or greater than levels that may be present in patient respiratory samples. Substances tested included blood, mouthwashes, throat drops, nasal sprays, cold medications and prescription medications. Each substance was tested in triplicate. None of the substances evaluated were shown to interfere with the performance of the BD Directigen™ EZ RSV test.

Reproducibility

The reproducibility of the BD Directigen EZ RSV test was evaluated at three sites. The overall reproducibility for the BD Directigen RSV EZ test was 99.1%.

Clinical Performance:
The overall sensitivity and specificity of the BD Directigen™ EZ RSV test for RSV when compared to culture were 80% and 92%, respectively. The performance characteristics of the BD Directigen™ EZ RSV as compared to cell culture for each specimen type are shown in Table 1.

Table 1: Summary of the Performance of the BD Directigen EZ RSV (EZ) Test Compared to Culture for all Specimen Types

		Culture/ EZ						Discrepant Resolution for Culture - / EZ + Specimens	
Specimen Type	n	+/+	-/+	+/-	-/-	**Sensitivity (%)** (95% CI)	Specificity (%) (95% CI)	# PCR tested	# PCR +
Nasopharyngeal Wash	358	130	30	20	178	86.7 80.2 – 91.6	85.6 80.1 – 90.1	30	22
Nasopharyngeal Aspirate	405	90	24	27	264	76.9 68.2 – 84.2	91.7 87.6 – 94.6	18[2]	12
Nasopharyngeal Swab/Wash	162	28	6	11	117	71.8 55.1 – 85.0	95.1 89.7 – 98.2	6	2
Nasopharyngeal Swab	286	20	20	10	236	66.7 47.2 – 82.7	92.2 88.2 – 95.2	20	11
Other Swabs[1]	73	3	1	1	68	75.0 19.4 – 99.4	98.6 92.2 – 99.9	0[3]	0
Lower Respiratory	51	5	1	1	44	83.3 35.9 – 99.6	97.8 88.2 – 99.9	1	0

(+) = RSV positive (-) = RSV negative (#) = number
1 Refer to Limitations of the Procedure for additional information on these specimen types
2 Two specimens not submitted for PCR testing; four specimens had insufficient quantity for PCR testing
3 One specimen not submitted for PCR testing

There were 82 specimens that were culture negative, BD Directigen™ EZ RSV test positive. PCR testing was performed on 75 of the 82 specimens; a total of 47 of the 75 specimens were positive by PCR. The uninterpretable rate for the BD Directigen™ EZ RSV test was 0.0%.

Overall performance of the BD Directigen™ EZ RSV test is substantially equivalent[1] to viral cell culture and DFA tests that were in use prior to May 28, 1976 and to the BD Directigen™ RSV test.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 3 2003

Ms. Colleen Kistler
Regulatory Affairs
BD Diagnostic Systems
Becton, Dickenson and Company
7 Loveton Circle
Sparks, MD 21152

Re: K022133
Trade/Device Name: BD Directigen™ EZ RSV Kit
Regulation Number: 21 CFR 866.3480
Regulation Name: Respiratory Syncytial Virus Serological Reagents
Regulatory Class: Class I
Product Code: GQG
Dated: September 23, 2002
Received: September 24, 2002

Dear Ms. Kistler:

This letter corrects our substantially equivalent letter of December 10, 2002, regarding the BD Directigen™ EZ RSV Kit. The revised Indications for use and 510(k) summary are enclosed.

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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): k022133

Device Name: BD Directigen™ EZ RSV Test

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Freddie M. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K02 2133

(Optional Format 3-10-98)

For Prescription Use ✓

510(k) SUMMARY

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CONTACT NAME: Colleen A. Kistler, Regulatory Affairs Specialist

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DEVICE DESCRIPTION:

The BD Directigen™ EZ RSV test is a chromatographic assay to qualitatively detect RSV antigen in samples extracted from respiratory specimens. When extracted specimens are added to the test device, RSV A and/or B antigens bind to anti-RSV conjugated to visualizing particles in the test strip. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by the line of antibody on the membrane. A positive result is indicated by the appearance of two reddish purple lines in the read window, one line next to the Test "T" and the other next to the Control "C". The absence of a reddish purple line next to the "T" and the presence of a reddish purple line next to the

"C" indicate a negative result. The test is considered uninterpretable if no visible reddish purple line is present next to the "C".

DEVICE COMPARISON:

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SUMMARY OF PERFORMANCE DATA:

Several analytical studies and a clinical study were performed to establish the performance characteristics of the assay.

Analytical Studies: The limit of detection (LOD) for the BD Directigen™ EZ RSV test was established for two RSV A and three RSV B strains. A panel of 99 microorganisms (including bacteria, yeasts and viruses) were cultured and tested at appropriate concentrations in triplicate with the BD Directigen™ EZ RSV test. A variety of substances were tested with the BD Directigen™ EZ RSV test at concentration levels comparable to or greater than levels that may be present in patient respiratory samples. Substances tested included blood, mouthwashes, throat drops, nasal sprays, cold medications and prescription medications. Each substance was tested in triplicate. The reproducibility of the BD Directigen EZ RSV test was evaluated at three sites.

Clinical Study: A total of 1176 specimens, consisting of nasopharyngeal washes, nasopharyngeal aspirates, nasopharyngeal swabs, and nasopharyngeal swab/washes from patients suspected of having RSV were evaluated with the BD Directigen EZ RSV test in a multicenter trial during the 2001-2002 RSV season.

Based on the results of the analytical and clinical studies, the performance of the BD Directigen™ EZ RSV test is substantially equivalent[1] to viral cell culture and DFA tests that were in use prior to May 28, 1976 and to the BD Directigen™ RSV test.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this

notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.