K021789

NOV 2 0 2002

510 (k) Summary

This 510(k) summary of safety and effectiveness information for the QuickLab RSV is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The following information as presented in the Premarket Notification [510(k)] for the QuickLab RSV Test constitutes data supporting a substantially equivalent determination. The assigned 510(k) number is: 021789.

Sponsor:	Integrated Biotechnology Corporation
Address:	366 Ridgepoint Drive Carmel, IN 46032
Contact Person:	Sally A. Booth, M.D. VP, Regulatory Affairs
Telephone:	(317) 848-3260 (telephone) (317) 848-3269 (fax)
Manufacturer:	Virotek, L.L.C.
Address:	900 Asbury Drive Buffalo Grove, IL 60089
Contact Person:	David Seitelman
Telephone:	(847) 634-4500 ext. 253 (telephone) (847) 634-7394
Device Trade Name:	QuickLab™ RSV
Common Name:	Direct antigen detection immunoassay for Respiratory Syncytial Virus
Classification Name:	Respiratory syncytial virus serological reagent (see 21 C.F.R. § 866.3480)
Product Code:	GOG

Substantial Equivalence:
The QuickLab RSV is substantially equivalent to the Directigen RSV Test Kit, 510(k) # K882629 and other FDA-cleared devices used for the qualitative detection of respiratory syncytial virus directly form clinical specimens.

Intended Use:
The QuickLab RSV Test is intended for the rapid, qualitative detection of respiratory syncytial virus fusion protein directly form nasopharyngeal swab, and nasal aspirate specimens in children less than 6 years and adults over the age of 60.. The test is intended for use as an aid in the rapid laboratory diagnosis of acute respiratory syncytial virus infection in patients with symptoms consistent with RSV infection. It is recommended that negative test results be confirmed by cell culture.

Principle of the Test:
The QuickLab RSV is a lateral flow immunogold assay for the direct visual detection of RVS protein F in clinical samples. The basis for protein F detection is in the use of a red - colored gold labeled mouse monoclonal anti-RSV protein F antibody that after addition of extracted sample travels laterally along the strip test device membrane. This lateral flow carries the mixture of sample and gold-labeled anti- RSV protein F through a membrane adsorbed monoclonal anti-RSV protein F Test Line (T) and then through a membrane adsorbed goat anti-mouse immunoglobulin Control Line (C). When RSV protein F is present in clinical samples, the fluid phase mouse anti-RSV protein F binds this antigen and this formation of antigen - antibody complex is then in turn bound at the Test Line (T). The unbound or excess mouse anti - RSV protein F passes through the Test Line (T) and is bound at the Control Line (C) by goat anti-mouse immunoglobulin.

Therefore, in the presence of RSV protein F antigen, 2 red lines become visible: one at the Test Line (T) and a second at the Control Line (C). But when RSV antigen is absent only one red line appears at the Control Line (C).

Physiological Basis For the Test:
Respiratory syncytial virus is a highly contagious, acute, viral infection of the respiratory tract. The causative agent is a single stranded (negative strand) RNA virus of the paramyxoviridae family. RSV is now recognized as the leading cause of hospitalization of children during the first year of life. It is also the major viral cause of nosicomial illness in children already hospitalized for other reasons. Half of all infants become infected during their first year of life. Virtually all have been infected by their second year. Infection carries an associated mortality rate of 0.5%, especially in premature infants or children with underlying lung disease.

RSV antigens may be detected in clinical specimens by immunoassay. The QuickLab RSV Test is a lateral-flow immunoassay using monoclonal antibodies directed against RSV fusion protein antigens.

Comparison of Technological Characteristics:
Both QuickLab RSV and Directigen perform qualitative tests for the RSV antigen by means of an antibody-based immunochromatographic assay which gives a visual readout of results. Both use nasopharyngeal specimens, which require minimal sample preparation, and capture the RSV antigen on a membrane coated with monoclonal antibodies to RSV proteins. Both use internal and external quality controls and take 15 minutes or less to complete. Both tests are performed at ambient temperature. Directigen is a flow through format whereas QuickLab is a lateral flow format. Quick Lab

utilizes gold as the indicator whereas Directigen uses nitro blue tetrazolium and indoxylphosphate. Directigen is an enzyme immunoassay whereas QuickLab is an immunoassay which does not employ an enzyme.

Safety and Effectiveness:

Analytical Sensitivity:

There are two subgroups of respiratory syncytial virus (RSV), A and B. Both subgroups contain the fusion protein targeted by the QuickLab RSV test. Two subgroup A and two subgroup B strains of RSV tested were positive in the QuickLab RSV test.

Analytical Specificity (Cross-Reactivity):

The immunological specificity of the QuickLab RSV test was demonstrated by testing 39 potential cross-reacting bacteria and viruses with the test. The cross-reactivity panel included viruses and bacteria that may be present in respiratory specimens. None of the organisms tested showed cross reactivity with the QuickLab RSV test.

Reproducibility:

Reproducibility testing was conducted in at IBC. Five masked samples were tested by three operators on each of three days. The data for this in-house reproducibility is shown below.

QuickLab RSV In-House Reproducibility			
RSV Long Strain (pfu/mL)	**Number Replicates**	**Frequency (%) Positives (95% C.I.)**	**Frequency (%) Negatives (95% C.I.)**
1.9×10^5	30	**83.3** (65.3 – 94.4)	**16.7** (5.64 – 34.7)
1.12×10^5	90	**67.8** (57.1 – 77.3)	**32.2** (28.8 – 42.9)
1.02×10^5	90	**58.9** (48.0 – 69.2)	**41.1** (30.8 – 51.9)
9.30×10^4	90	**50.0** (39.3 – 60.7)	**50.0** (39.3 – 60.7)
7.40×10^4	90	**23.3** (15.1 – 33.4)	**76.6** (66.6 –84.4)

Reproducibility studies were also conducted to show that doctor's office personnel with diverse educational backgrounds and work experience at three physician office laboratories (POL) can perform the test accurately and reproducibly. Testing was performed on five levels of RSV antigen at three distinct sites by two operators at each site in replicates of three on three consecutive days. The results are shown below.

QuickLab RSV POL Reproducibility			
RSV Long Strain (pfu/mL)	**Number Replicates**	**Frequency (%) Positives (95% C.I.)**	**Frequency (%) Negatives (95% C.I.)**
7.7×10^5	54	**100** (93.4 - 100)	**00.0** (0.0 – 6.6)
1.9×10^5	54	**100** (93.4 - 100)	**00.0** (0.0 – 6.6)
1.12×10^5	54	**74.1** (60.4 - 85.0)	**25.9** (14.9 – 39.65)
1.02×10^5	54	**61.1** (46.9 – 74.1)	**38.8** (25.9 – 53.12)
7.40×10^4	54	**22.2** (12.0 – 77.7)	**77.7** (64.4 – 87.96)
4.7×10^4	54	**00.0** (0.0 – 6.6)	**100** (93.4 - 100)

Clinical Performance

The performance of the QuickLab RSV Test was compared to Tissue Culture, EIA and Direct Fluorescent Antibody (DFA) in a prospective multi-center field clinical study in the Midwest and Ontario Canada during the 2002 flu season. In this trial, the Quick Lab RSV test was compared to DFA at the two United States sites or Tissue Culture and EIA at one Canadian site. The study comprised a total of 197 nasal aspirate and nasopharyngeal swab samples obtained from patients symptomatic for RSV infection. All samples were split to allow testing of the same sample by QuickLab and the reference method (Tissue Culture and EIA at the Canadian site or DFA at the U.S. sites). The age of the patients ranged from 2 days to 100 years of age. The sample type in the U.S. consisted of nasopharyngeal swabs and aspirates and the sample type in Canada was entirely nasopharyngeal swabs.

United States Data

There were a **total of 104** samples tested in the United States. There were **90** nasal aspirates, **7** nasoparyngeal swabs, and **7** samples with no designation of sample type given. All 104 of the samples tested in the United States were compared to DFA as the reference method as shown in the following table.

United States: QuickLab RSV Compared to DFA			
		DFA Result	
		Pos	Neg
Quick Lab Results	Pos	42	2
	Neg	3	57

Pos Agreement: 42/45 = 93.3% (95% C.I. = 80.7 -98.6%)
Neg Agreement: 57/59 = 96.6% (95% C.I. = 88.3 -99.6%)

A subset of the U.S data, the **90** samples designated as nasal aspirates is shown in the following table.

United States: QuickLab RSV Nasal Aspirate Samples Compared to DFA			
		DFA Result	
		Pos	Neg
Quick Lab Results	Pos	35	2
	Neg	2	51

Pos Agreement: 35/37= 94.6% (95% C.I. = 81.8- 99.3%)
Neg Agreement: 51/53= 96.2% (95% C.I. = 87.7- 99.3%)

Note: The 7 samples with no sample type designation and the 7 nasopharyngeal swab samples in the U.S. have not been broken out into separate tables but are included in Table 2. Of the 7 samples designated as nasopharyngeal swabs in the U.S., 3 were positive and 4 were negative and there was 100% positive agreement and 100% negative agreement with DFA.

Canadian Data

There were a **total of 93** samples tested in Canada. All were nasopharyngeal swab samples. The reference test for **92** of these was **both** Tissue Culture and EIA and **one** sample had **only EIA** as the reference for a total of **93**. The performance data for QuickLab against the two reference methods is shown in the following two tables.

QuickLab RSV Compared to Tissue Culture in Canada. (All Nasopharyngeal Swabs)			
		Tissue Culture Result	
		Pos	Neg
QuickLab Results	Pos	10	10
	Neg	0	72

Sensitivity: 10/10 = 100% (95% C.I. = 69.2 – 100 %)
Specificity: 72/82 = 87.8% (95% C.I. = 80.7 – 94.9%)

QuickLab RSV Compared to EIA in Canada (All Nasopharyaryngeal Swabs)			
		EIA Result	
		Pos	Neg
Quick Lab Results	Pos	20	1
	Neg	1	71

Pos Agreement: 20/21= 95.2% (95% C.I. = 76.2- 99.9%)
Neg Agreement: 71/72= 96.6% (95% C.I. = 92.5- 99.9%)

Summary of Clinical Data For All Sites

For all samples at all sites: There were a total of **197** samples, **104** in the U.S. and **93** in Canada:

Overall positive agreement = 93.9% (95% C.I. = 85.4-97.6%)
Overall negative agreement = 97.7% (95% C.I. = 93.5- 99.2%)

For Nasaopharyngeal Swabs: There were a total of **100** samples, **7** in the U.S. and **93** in Canada:

Overall positive agreement = 95.8% (95% C.I = 79.8 – 99.3%)
Overall negative agreement= 98.7% (95% C.I. = 92.9 – 99.8%)

For Nasal Aspirates There were a total of **90** samples in the U.S.

Pos Agreement: = 94.6% (95% C.I. = 81.8- 99.3%)
Neg Agreement: = 96.2% (95% C.I. = 87.7- 99.3%)

Note: 7 samples in the U.S. had no designation of sample type and are not included in the breakdown of nasopharyngeal swab performance (N = 100) and nasal aspirate performance (N = 90). These 7 samples are included in the overall performance data for all samples at all sites (N = 197)

Interfering Substances
Interfering Substance testing demonstrated no interference with the performance of the QuickLab when tested with whole blood, mucin, albuterol, and 17 other over the counter (OTC) substances.

CONCLUSION:
Based on the foregoing and other information in this application, Integrated Biotechnology Corporation has shown that the performance data provide reasonable assurance of the safety and effectiveness of the QuickLab RSV for its proposed indications for use. Further, the performance studies in this application demonstrate that QuickLab RSV is substantially equivalent to its claimed predicate device under conditions of intended use and establish its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 0 2002

Sally A. Booth, M.D.
V.P. Regulatory Affairs
Integrated Biotechnology Corporation
366 Ridgepoint Drive
Carmel, IN 46032

Re: k021789
Trade/Device Name: QuickLab™ RSV
Regulation Number: 21 CFR 866.3480
Regulation Name: Respiratory Syncytial Virus Serological Reagents
Regulatory Class: Class I
Product Code: GQG
Dated: October 3, 2002
Received: October 4, 2002

Dear Dr. Booth:

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

Indications For Use

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510(k) Number (if known): __K021789_____

Device Name: __ QuickLab RSV_____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K021789

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)