OCT 2 1 2003

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Vital Answers For Better Health...NOW™

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K032166

SUBMITTER: Binax, Inc.
217 Read Street
Portland, Maine 04103
(207) 772-3988 (Office)
(207) 871-5751 (FAX)

CONTACT PERSON: Pamela S. Angell
pangell@binax.com (email)

TRADE NAME: Binax NOW® RSV Test

COMMON NAME: RSV ICT, Binax NOW® RSV test

CLASSIFICATION NAME: Antigen, CF (including CF Controls), Respiratory Syncytial Virus (per 21 CFR 866.3480)

PREDICATE DEVICE: BD Directigen™ EZ RSV Test, 510(k) #K022133

DEVICE DESCRIPTION:
The Binax NOW® RSV Test is an immunochromatographic membrane assay used to detect RSV antigen in nasopharyngeal specimens. A test strip, containing gold-conjugated and immobilized anti-RSV antibodies, is mounted on the right side of a cardboard, book-shaped hinged test device. Swab specimens (controls and patients) require a sample preparation step, in which the sample is eluted off the swab into transport media or saline. Nasal wash samples do not require any preparation. The sample to be tested is added to a pad at the top of the test strip, and the test device is closed. RSV antigen present in the sample reacts to bind anti-RSV conjugated antibody. The resulting antigen-conjugate complexes are captured by immobilized anti-RSV antibody, forming the Sample Line. Immobilized Control Line antibody, which appears as a blue line in an untested device, captures a visualizing conjugate, forming a pink Control Line. The sample is contained, and results are available within 15 minutes.

INTENDED USE:
The Binax NOW® RSV Test is a rapid immunochromatographic assay for the qualitative detection of respiratory syncytial virus (RSV) fusion protein antigen in nasal wash and nasopharyngeal swab specimens from symptomatic patients. This test is intended for in vitro diagnostic use to aid in the diagnosis of RSV infections in neonatal and pediatric patients under the age of five. It is recommended that negative test results be confirmed by culture.

TECHNOLOGICAL CHARACTERISTICS:
Both the Binax NOW® RSV Test and the BD Directigen™ EZ RSV test are simple rapid immunochromatographic assays utilizing colloidal gold conjugate and an antibody striped membrane to capture and visualize antigen.

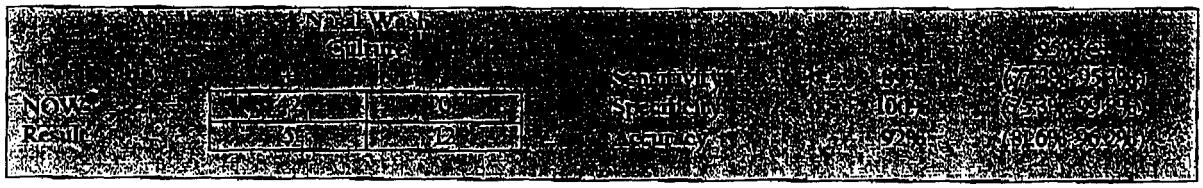
PERFORMANCE SUMMARY:
The Binax NOW® RSV Test has already been determined to be substantially equivalent (SE) to the BD RSV Test (K882629) for the detection of RSV in nasal wash specimens. Data supporting this SE determination was presented in the original 510(k) K021687 and is included in the following summary. New data presented in the Performance Section of this application, and summarized below, establishes SE of the NOW® RSV test to the BD EZ RSV test (K022133) when testing nasopharyngeal swab specimens.

Analytic Reactivity (as reported in original 510(k) K021687):
There are two known subgroups of respiratory syncytial virus (RSV) and both contain the conserved fusion protein targeted by the Binax NOW® test.[1] Six (6) subgroup A clinical isolates and five (5) subgroup B clinical isolates tested were positive in the Binax NOW® test.

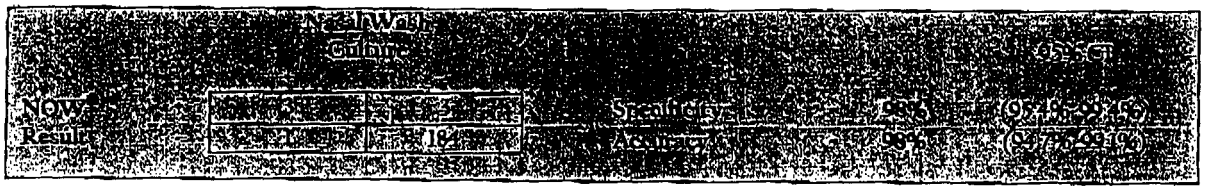
Analytic Specificity (Cross-Reactivity):
To demonstrate the immunologic specificity of the Binax NOW® test, 48 potential cross-reactants were tested in the Binax NOW® test. The cross-reactant panel included bacteria and viruses that may be present in respiratory specimens. Bacteria tested at concentrations greater than 1×10^8 organisms/ml and viruses tested at concentrations greater than 1×10^5 $TCID_{50}$/ml did not cross-react in the Binax NOW® Test. Metapneumovirus was tested at a concentration of 2×10^3 $TCID_{50}$/ml and did not cross-react.

Nasal Wash - Clinical Sensitivity and Specificity (as reported in original 510(k) K021687):
The Binax NOW® RSV Test was evaluated in both retrospective and prospective clinical studies.

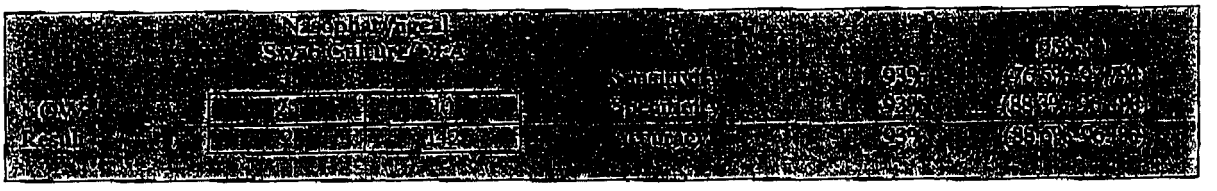
Retrospective Study:
Fifty-nine (59) viral cultured nasal wash specimens, obtained from a teaching university/medical center in the northeast, were tested in the NOW® test. NOW® test performance versus viral cell culture (including 95% confidence intervals) was calculated using standard methods.



Prospective Study:
In a multi-center prospective study, the Binax NOW® test was used to evaluate 191 nasal wash specimens collected from patients presenting with RSV-like symptoms. NOW® test performance versus viral cell culture (including 95% confidence intervals) was calculated using standard methods.



Nasopharyngeal Swab - Clinical Sensitivity and Specificity:
In a multi-center prospective study, the Binax NOW® test was used to evaluate 179 nasopharyngeal swab specimens collected from patients presenting with RSV-like symptoms. NOW® test performance versus DFA/viral cell culture (including 95% confidence intervals) was calculated using standard methods.



Interfering Substances:
The Binax NOW® test was found not to cross-react with 17 of 18 substances that may be artificially introduced into the nasal cavity or nasopharynx or that are naturally present in respiratory specimens. Each potentially interfering substance was diluted to the appropriate concentration in a saline/BSA solution and tested in the Binax NOW® Test. A portion of each of these solutions was also spiked with the limit of detection (LOD) level of a viable RSV before testing in the Binax NOW® Test. All substance generated expected results in the Binax NOW® Test, with the exception of the antiviral Palivisumab, which interefered with Binax NOW® Test detection of RSV.

Reproducibility *(as reported in original 510(k) K021687):*
A blind study of the Binax NOW® test was conducted at 3 separate sites using a panel of coded specimens containing negative, low positive (LOD), and low/moderate positive controls. Participants performed testing on 3 different days. One hundred percent (100%) of the 234 samples tested were correctly interpreted.

Product Stability:
Stability studies of the Binax NOW® RSV Test and kit controls support the assigned expiry dating.

References:
1) Lopez, Juan A., R. Bustos, C. Orvell, M. Berois, J. Arbiza, B. Garcia-Barreno, J. Melero. Antigenic Structure of Human Respiratory Syncytial Virus Fusion Glycoprotein. Jr. of Virology, vol. 72, no. 8, August 1998, pp. 6922-6928

Signed Pamela S Angell Date 10/20/03
Pamela S. Angell
Regulatory Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 21 2003

Ms. Pamela Angell
Regulatory Manager
Binax, Inc.
217 Read Street
Portland, ME 04103

Re: K032166
Trade/Device Name: BINAX NOW® RSV Test
Regulation Number: 21 CFR 866.3480
Regulation Name: Respiratory Syncytial Virus Serological Reagents
Regulatory Class: Class I
Product Code: GQG
Dated: September 15, 2003
Received: October 14, 2003

Dear Ms. Angell:

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

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 ENCLOSURE

510(k) Number (if known): K032166

Device Name: Binax NOW® RSV Test

Indications For Use:

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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 10/20/03

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032166

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)