K091489

SEP 04 2009

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510(k) Summary

SUBMITTER
Binax, Inc.
10 Southgate Rd
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(207) 730-5824 (Office)
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CONTACT PERSON
Erin E. Kenaley
Erin.Kenaley@invmed.com (email)

DATE PREPARED
August 13, 2009

TRADE NAME
Clearview Advanced™ Strep A Test

COMMON NAME
Rapid Strep A test, Strep A dipstick test

CLASSIFICATION NAME
Antigens, All Groups, Streptococcus Spp. Serological Reagents (GTY) (per 21 CFR 866.3740)

PREDICATE DEVICES
Genzyme OSOM® Ultra Strep A Test (K992658)

DEVICE DESCRIPTION:
The Clearview Advanced™ Strep A test is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen directly from a throat swab sample. To perform the test, Reagent 1 (R1) is added to the extraction tube which is coated with a mixture of conjugate antibodies and a lytic enzyme extraction reagent.

The lytic enzyme is mixed with colloidal gold conjugated to rabbit anti-Strep A and a second colloidal gold control conjugate antibody. The reagents are dried onto the bottom of an extraction tube forming a red spot. The extraction/conjugate pellet is resuspended with R1 and the throat swab is added to the extraction tube. The Strep A antigen is extracted from the sample and the swab is removed. The test strip is immediately placed in the extracted sample. If Group A Streptococcus is present in the sample, it will react with the anti-Strep A antibody conjugated to the gold particle. The complex will then be bound by the anti-Strep A capture antibody and a visible red test line will appear, indicating a positive result. To serve as an on-board procedural control, the blue line observed at the control site prior to running the assay will turn red, indicating that the test has been performed properly. If Strep A antigen is not present, or present at very low levels, only a red control line will appear. If the red control line does not appear, or remains blue, the test result is invalid.

INTENDED USE

The Clearview Advanced Strep A test is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens as an aid in the diagnosis of Group A Streptococcal infection.

TECHNOLOGICAL CHARACTERISTICS

The Clearview Advanced Strep A test and the Genzyme OSOM Ultra Test utilize similar lateral flow immunochromatographic technology. Both tests are rapid immunoassays that employ specific antibodies immobilized onto a solid phase to capture and visualize Group A Streptococcal antigens.

PERFORMANCE SUMMARY

Clinical Performance

The clinical performance of the Clearview Advanced Strep A test was established in a multi-center, prospective clinical study conducted in 2008-2009 at five geographically diverse physician office, clinics, and emergency departments within the United States.

A total of 297 throat swab specimens were evaluated by comparing the Clearview Advanced Strep A test to bacterial culture. In this study, sensitivity was 91.5% (95% CI 85.0% to 95.3%) and specificity was 95.0% (95% CI 90.7% to 97.3%).

		Bacterial Culture Results	
		Positive	Negative
Clearview Advanced Strep A Test Results	Positive	107	9
	Negative	10	170
	Total	117	179

* denotes 95% Confidence Interval
Sensitivity-91.5% (85.0% to 95.3%)*
Specificity-95.0% (90.7% to 97.3%)*

Analytical Sensitivity (Limit of Detection)

The Clearview Advanced Strep A test limit of detection (LOD), defined as the concentration of Group A Streptococcus bacteria that produces positive Clearview Advanced Strep A test results approximately 95% of the time, was identified by evaluating different concentrations of Group A Streptococcus in the Clearview Advanced Strep A test. The detection limit of the Clearview Advanced Strep A test was determined to be $1x10^4$ organisms/test.

Analytical Specificity (Cross-Reactivity)

To determine the analytical specificity of the Clearview Advanced Strep A test, 38 commensal and pathogenic microorganisms including bacteria, viruses and yeast that may be present in the mouth or throat were tested. All of the following microorganisms were negative when tested at a concentration of $1x10^8$ organisms/test.

Streptococcus Group B	*Streptococcus salivarius*	*Haemophilus parainfluenzae*	*Neisseria subflava*
Streptococcus Group C	*Arcanobacterium haemolyticum*	*Haemophilus influenzae*	*Proteus vulgaris*
Streptococcus Group F	*Bordetella pertussis*	*Klebsiella pneumoniae*	*Pseudomonas aeruginosa*

Streptococcus Group G	*Candida albicans*	*Moraxella catarrhalis*	*Serratia marcescens*
Streptococcus anginosus	*Corynebacterium diphtheriae*	*Moraxella lacunata*	*Staphylococcus aureus*
Streptococcus mitis	*Enterococcus faecalis*	*Neisseria gonorrhoeae*	*Staphylococcus epidermidis*
Streptococcus mutans	*Enterococcus faecium*	*Neisseria lactamica*	*Staphylococcus haemolyticus*
Streptococcus oralis	*Escherichia coli*	*Neisseria meningitides*	*Yersinia enterocolitica*
Streptococcus pneumoniae	*Fusobacterium necrophorum*	*Neisseria mucosa*	
Streptococcus sanguis	*Haemophilus parahaemolyticus*	*Neisseria sicca*	

Reproducibility

A blind study of the Clearview Advanced Strep A test was conducted at 3 separate sites using panels of blind coded specimens. Participants tested each sample multiple times on 5 different days, with no significant difference between runs (5 different days), between sites (3 sites), and between operators (6 operators). The results are presented below:

Sample	Site 1 Detection	Site 2 Detection	Site 3 Detection	Overall Detection
Diluent (True Negative)	0% (0/60)	0% (0/60)	0% (0/59)**	**0% (0/179)**
$1x10^5$(Moderate Positive)	100% (60/60)	98% (59/60)	100% (60/60)	**99% (179/180)**
$1x10^4$(LOD/C_{95} Concentration)	100% (60/60)	100% (60/60)	83% (50/60)	**94% (170/180)**
$3.2x10^3$ (Near the cut-off/C_{50} Concentration)	80% (48/60)	58% (34/59)*	10% (6/60)	**49% (88/179)**

* 2 invalid results excluded from the data analysis

Signed Angela Drysdale Date 8/14/09

Angela Drysdale

Sr. Manager of Clinical Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

SEP 04 2009

Erin E. Kenaley
Clinical Affairs Specialist
Binax, Inc.
10 Southgate Road
Scarborough, ME 04074

Re: K091489
Trade/Device Name: Clearview Advanced ™ Strep A Test
Regulation Number: 21 CFR 866.3740
Regulation Name: *Streptococcus* spp. exo-enzyme reagents
Regulatory Class: Class I
Product Code: GTY
Dated: August 13, 2009
Received: August 19, 2009

Dear Ms. Kenaley:

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.

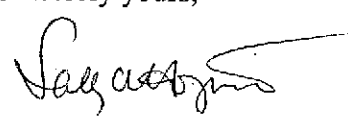
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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,



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

Indication for Use

510(k) Number (if known): K091489

Device Name: Clearview Advanced™ Strep A Test

Indication For Use:

The Clearview Advanced™ Strep A test is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens as an aid in the diagnosis of Group A Streptococcal infection.

Prescription Use ___X___ And/Or Over the Counter Use ____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091489