NOV 2 2 2005

510-K SUMMARY OF SAFETY AND EFFECTIVENESS

Assigned 510-K Number: K052092

Submitted By: Rapid Pathogen Screening, Inc.
101 Phillips Park Drive
South Williamsport, PA 17702

Submission Contact: Robert Sambursky, MD

Date Prepared: September 14, 2005

Device Trade Name: RPS Adeno Detector

Predicate Devices: SA Scientific, Inc.
SAS Adeno Test
K990630

Device Classification: Adenovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to adenovirus in serum. The identification aids in the diagnosis of disease caused by adenoviruses and provides epidemiological information on these diseases. Adenovirus infection may cause pharyngitis, acute respiratory diseases, gastroenteritis, and conjunctivitis

I. Device Category: Class I

RPS Adeno Detector differs from serologic tests by its ability to directly detect the antigen, a conserved epitope on the hexon portion of the adenovirus, which is characteristic and consistent for all serotypes.

II. Product Code: GOD

III. Regulation Number: 866.3020; Adenovirus serological reagents [Antigens, Cf (including control)].

Intended Use: The RPS Adeno Detector is a rapid immunochromatography test for visual, qualitative *in-vitro* detection of adenoviral antigens (hexon protein) directly from human eye fluid. The test is

intended for use as an aid in the rapid differential diagnosis of acute adenoviral conjunctivitis. All negative test results should be confirmed by cell culture.

1. Indication(s) for use:
   Local (in tears of the eye) adenovirus detection associated with acute infectious conjunctivitis

2. Special condition for use statement(s):
   For use by health professionals only

3. Special instrument Requirements
   None

Physiologic Basis of the Test:

Morphologically, adenoviruses are nonenveloped DNA viruses with an icosahedral structure about 80 nm in diameter [4]. Adenovirus has been implicated in diseases affecting the respiratory, ocular and gastrointestinal systems [1], [2], [3].

Adenovirus is a frequent cause of infectious conjunctivitis. Human adenoviruses are classified into 6 subgenera and 51 serotypes [6],[10]. Approximately one third of the human adenovirus serotypes have been associated with common forms of adenoviral related eye infections [11] but the most common causes of acute conjunctivitis are related to serotypes 3, 4, 8, 11, 19 and 37 [12]. The serotypes have the following associations: serotypes 8, 19 and 37 are most responsible for epidemic keratoconjunctivitis [13],[14],[15]; serotypes 3, 4, 5 and 7 tend to cause pharyngeal-conjunctival fever, which usually affects children [13]; serotypes 1–11 and 19 are the primary cause of nonspecific follicular conjunctivitis [13]. However, the other serotypes can also produce clinically indistinguishable episodes of acute follicular conjunctivitis [4], [14], [16].

Cell culture in combination with immunofluorescence remains the "gold standard" for identifying adenovirus in conjunctival specimens [5]. Virus isolation requires a laboratory infrastructure, technical expertise, and may take up

to 2 weeks to complete. In addition, the differential diagnosis of various forms of conjunctivitis (viral, bacterial, allergic) is often difficult because they manifest similar symptoms.

Device Description:

The RPS Adeno Detector utilizes technology based on lateral flow immunochromatography. Adenoviral antigen, hexon protein, when present in the patient sample is captured between two antigen specific antibodies. One antibody is immobilized in the detection zone of the device. The second antibody is labeled with colloidal gold. The detector is a disposable, rapid test requiring 10 minutes for a result.

The patient's lower eyelid is gently retracted to expose the inferior fornix. The eye fluid is collected on the sterile sample collector by gently swabbing the inferior fornix with the sampling pad on the test cover to gain a sample of tears for point of care analysis. The sample collector is reassembled to the immunoassay cassette. Sample transfer happens automatically.

Analysis of the sample starts when the absorbant pad of the strip is dipped into a provided buffering solution. After 1-10 minutes, red colored lines in the read out area will appear. One line (control line) only indicates a (Adenoviral) negative result, where as two lines (control line and test line) indicate a (Adenoviral) positive result.

It is best used within 7 days of developing a red eye consistent with infectious conjunctivitis.

Predicate device Comparison

Features	RPS Inc. RPS Adeno Detector	Cell Culture	SA Scientific, Inc. SAS Adeno Test
K Number	K052092	None	K990630
Intended Use	The RPS Adeno Detector allows for the rapid, visual, qualitative *in vitro* detection of adenovirus and its serotypes directly from eye fluid on the conjunctiva.	The gold standard for the qualitative determination Adenovirus from conjunctival swabs	A rapid test for the qualitative determination of *in vitro* Adenovirus antigen from conjunctival swabs
Specimen Types	Eye conjunctival mucosa swab	Conjunctival swab	Conjunctival swab
Matrix	Eye fluid	Eye fluid	Eye fluid
Techno-logy	Lateral flow immunoassay	Growth on hepatic cells; confirmatory immunofluorescence	Lateral flow immunoassay
Antigen Detected	Adenovirus	Living Adenovirus	Adenovirus
Predicate Devices	SA Scientific, Inc. SAS Adeno Test	None	Meridian, Inc. Adenoclone

Summary of Performance Data:

Clinical Studies

A total of 175 samples were collected and tested from patients who developed a red eye consistent with infectious conjunctivitis within the last 7 days.

Clinical performance data of the RPS Adeno Detector compared against viral cell culture are summarized in the following scheme:

	Viral Culture		
RPS Adeno Detector		±	=
	±	37	12*
	=	5	121

Sensitivity:	88% (37/42), 95% CI (confidence interval) = 74.4% - 96%
Specificity:	91% (121/133), 95% CI = 84.8% - 95.2%
Overall agreement:	90 % (158/175), 95% CI = 84.9% - 94.2%
Positive predictive value:	76 % (37/49), 95% CI = 61.1% - 86.7%
Negative predictive value:	96 % (121/126), 95% CI = 91% - 98.7%

* Out of the 12 culture negative RPS positive samples 3 were found to be PCR positive

Conclusion:

Analytical testing, including analytical sensitivity, specificity, cross-reactivity, and interference were conducted. These studies further demonstrated the suitability of the product for professional use as a point of care device. Such studies also established both the substantial equivalence of the RPS Adeno Detector to viral culture and the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 2 2005

Rapid Pathogen Screening, Inc.
c/o Robert Sambursky, M.D.
13946 Wood Duck Circle
Bradenton, FL 34202

Re: k052092
Trade/Device Name: RPS Adeno Detector
Regulation Number: 21 CFR 866.3020
Regulation Name: Adenovirus Serological Reagents
Regulatory Class: Class I
Product Code: GOD
Dated: September 23, 2005
Received: September 29, 2005

Dear Dr. Sambursky:

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.

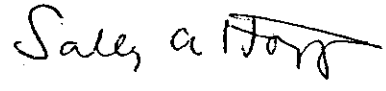
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

Indications for Use

510(k) Number (if known): K 052092

Device Name: RPS Adeno Detector

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052092