K010582

MAY - 7 2001



## 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 K010582

**Submitter:**
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121
Phone: 858-535-2030
Fax: 858-535-2035

**Date:**
23 February 2001

**Contact Person:**
Robert Hudak

**Product Name**:
ACON® Strep A Rapid Test Strip

**Common Name**:
Immunochromatographic test for the qualitative detection of Group A Streptococcal antigen from a throat swab specimen.

**Device Classification:**
The ACON Strep A Rapid Test Strip is similar to other FDA-cleared devices for the qualitative detection of Group A Streptococcus Antigen from throat swab specimens. These tests are used to aid in the diagnosis of Group A Streptococcus infection. (21 CFR 866.3740). Serological test systems for the detection of Group A Streptococcus antigen have been classified as Class I devices.

**Classification Name**:
Streptococcus spp. Serological reagents

**Intended Use:**
The ACON Strep A Rapid Test Strip is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

**Description:**
The ACON® Strep A Rapid Test Strip is a qualitative, lateral flow immunochromatographic assay for the detection of Strep A antigen from a throat swab. The test is a heterogeneous, sandwich immunoassay, based on the principle of antigen-antibody immunochemistry, that

uses a mixture of polyclonal antibodies to reliably produce a visually discernible colored line in the test region if Strep A antigen is present at a concentration of roughly 2.5 x $10^5$ organisms per swab or greater.

**Predicate Device:**
Wyntek OSOM® Strep A Test 510(k) Number K961423
Wyntek Diagnostics, Inc.
6146 Nancy Ridge Dr., Suite 101
San Diego, California 92121

**Comparison to a Predicate Device:**
A summary comparison of the features of the ACON Strep A Rapid Test Strip and the Wyntek OSOM® Strep A Test **is** shown below.

| Feature | ACON® Strep A Rapid Test Strip | OSOM® Strep A Test |
|---|---|---|
| Intended Use | A rapid chromatographic immunoassay for the qualitative detection of Strep antigens from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection. | The qualitative detection of Group A streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture. |
| Indications for Use | Professional & point of care use. | Professional & point of care use. |
| Specimen | Throat Swab | Throat Swab |
| Endpoint | Colored Lines | Colored Lines |
| Materials Provided | Test Strips<br>Disposable extraction tubes<br>Swabs (Dacron)<br>Extraction Reagents A & B<br>Positive Control (Non-viable Strep A)<br>Negative Control (Non-viable Strep C)<br>Package Insert<br>Procedure Card | Test Strips<br>Extraction test tubes<br>Sterile Swabs<br>Extraction Reagents A & B<br>Positive Control (Non-viable Strep A)<br>Negative Control (Non-viable Strep C)<br>Package Insert |
| Methodology | Membrane Particle Assay | Membrane Particle Assay |
| Extraction Reagent Color Reaction | Reagent A – Red Color<br>Reagent B – Clear Color<br>Combined Reagents – Yellow color | Reagent 1 – Pink Color<br>Reagent 2 – Clear Color<br>Combined Reagents – Yellow color |
| Extraction Time | 1 minutes | 1 minutes |
| Test Time | 5 minutes | 5 minutes |
| Format | Immunochemical, Strep A antigen /antibody, immunoassay principle | Immunochemical, Strep A antigen/antibody, immunoassay principle |
| Organism | Both viable and non-viable group A | Both viable and non-viable group A |

**Safety and Effectiveness Data:**

**Accuracy**

A multi-center clinical evaluation was conducted with specimens from 525 patients presenting with signs and symptoms of pharyngitis. This evaluation compared the result of the ACON® Strep A Rapid Test Strip and another commercially available lateral flow Strep-A test strip device, the Wyntek OSOM® Strep A test to the customary Strep A confirmed culture technique. The data from this study yielded the following results:

ACON Strep A Rapid Test Strip compared to Wyntek OSOM Strep A test

| | |
|---|---|
| Positive Agreement: | 111/113 = 98% |
| Negative Agreement: | 357/386 = 92% |
| Overall Agreement: | 468/499 = 94% |

ACON Strep A Rapid Test Strip compared to Strep A confirmed Culture

| | | |
|---|---|---|
| Sensitivity: | 120/124 = 97% | (91% to 99%)* |
| Specificity: | 355/375 = 95% | (92% to 97%)* |
| Accuracy: | 475/499 = 95% | (93% to 97%)* |
| PPV (+): | 120/140 = 86% | (79% to 91%)* |
| NPV (-): | 355/359 = 99% | (97% to 100%)* |

* Denotes 95% confidence intervals

**Sensitivity**

Eight (8) different strains of Strep A were evaluated with the ACON Strep A Rapid Test Strip. The minimum detectable level differed slightly depending upon the strain being tested. The detection level of all of the strains was roughly within one magnitude in concentration of each other. Five (5) strains showed a minimum detectable level at roughly $10^4$ organisms per swab while three (3) strains showed a minimum detectable level at roughly $10^5$ organisms per swab.

In addition, the throat swab specimens from the study that yielded beta-hemolytic colony growth were assigned a semi-quantitative value expressed as rare, 1+, 2+, 3+ or 4+. The ability of the ACON Strep A Rapid Test Strip to detect these various concentration levels is shown below.

| Culture Classification | ACON/Culture | % Correct |
|---|---|---|
| Negative (Specificity) | 355/375 = | 95% |
| Rare | 10/11 = | 91% |
| 1+ | 9/9 = | 100% |
| 2+ | 17/19 = | 89% |
| 3+ | 36/37 = | 97% |
| 4+ | 48/48 = | 100% |
| Total Positive (Sensitivity) | 120/124 = | 97% |
| Total (Overall Agreement) | 475/499 = | 95% |

**Specificity**

Specificity studies were conducted by individually spiking the various bacterial strains listed below on swabs at a final concentration of $1.0 \times 10^7$ org/swab, then evaluating the swabs in duplicate according to the package insert. None of the organism demonstrated any cross-reactivity in the test. The organisms tested were:

*Bordetella pertussis*
*Branhamella catarrhalis*
*Candida albicans*
*Corynebacterium diphtheriae*
*Enterococcus durans*
*Enterococcus faecalis*
*Hemophilus influenzae*
*Klebsiella pneumoniae*
*Neisseria gonorrhea*
*Neisseria meningitidis*
*Neisseria sicca*
*Neisseria subflava*
*Pseudomonas aeruginosa*
*Serratia marcescens*
*Staphylococcus aureus (Cowan)*
*Staphylococcus epidermidis*
*StrepC*
*Strep B*
*Strep F*
*Strep G*
*Streptococcus agalactiae*
*Streptococcus canis*
*Streptococcus equi* subsp *equi*
*Streptococcus mutans*
*Streptococcus pneumoniae*
*Streptococcus sanguis*

**Interfering Substances**

No interference to an expected negative or positive result was observed in our studies when using specimens containing the following substances at a final concentration of 1%:

Cherry Halls Cough Drops
Menthol Halls Cough Drops
Robitussin Cough Syrup
Dimetapp Cough Elixir
Vicks Chloraseptic Spray
Cepacol Chloraseptic Spray
Listerine Mouthwash
Scope Mouthwash

**Intra and inter-assay variability**

Studies to evaluate inter- and inter-assay variability demonstrated that the test yielded that expected results >99% of the time

**Lot-to-Lot Variability**

Studies to evaluate the manufacturability and consistency of the product on a lot-to-lot basis have shown this test to be highly reproducible.

**Conclusion**

These studies demonstrate the substantial equivalency of the ACON® Strep A Rapid Test Strip to the Wyntek OSOM® Strep A test, which is already marketed. They further demonstrate the suitability of this product for professional and point-of-care use, in addition to demonstrating its safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 7 2001

Mr. Robert Hudak
Vice President of Research
and Development
ACON Laboratories, Inc.
4018 Sorrento Valley Boulevard
San Diego, CA 92121

Re: 510(k) Number: K010582
Trade/Device Name: Acon® Strep A Rapid Test Strip
Regulation Number: 866.3740
Regulatory Class: I
Product Code: GTY
Dated: March 10, 2001
Received: April 11, 2001

Dear Mr. Hudak:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## 9. INDICATIONS FOR USE

510(k) Number: K010582

Device Name: The ACON® Strep A Rapid Test Strip

Indications For Use: The ACON® Strep A Rapid Test Strip is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection. This test is indicated for professional and point of care use only.

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(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010582

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(Per 21 CFR 801.109)