

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

K061496

B. Purpose for Submission:

New device

C. Measurand:

Legionella pneumophila serogroup 1 antigens

D. Type of Test:

Immunochromatographic rapid assay

E. Applicant:

SA Scientific, Ltd.

F. Proprietary and Established Names:

SAS™ Legionella Test

G. Regulatory Information:

1. Regulation section: 21CFR 866.3300, Haemophilus spp. Serological Reagents
2. Classification: Class: II
3. Product code: MJH: Legionella, spp., ELISA
4. Panel: 83 Microbiology

H. Intended Use:

The SAS™ Legionella Test is a visually read, in vitro immunochromatographic rapid assay for the presumptive qualitative detection of *Legionella pneumophila* serogroup 1 antigens in human urine. This test is intended to aid in the presumptive diagnosis of Legionnaires' disease in conjunction with culture and other methods for patients with signs and symptoms of pneumonia.

2. Indication(s) for use:

The SAS™ Legionella Test is a visually read, in vitro immunochromatographic rapid assay for the presumptive qualitative detection of *Legionella pneumophila* serogroup

1 antigens in human urine. This test is intended to aid in the presumptive diagnosis of Legionnaires' disease in conjunction with culture and other methods for patients with signs and symptoms of pneumonia.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

None

I. Device Description:

The SAS™ Legionella test utilizes a combination of polyclonal antibodies against the antigens of *Legionella pneumophila*. The SAS™ Legionella test begins with the addition of urine to the test device. The specimen is absorbed by the sample pad and then moves through the conjugate pad which contains dried gold conjugated antibodies which are specific for *Legionella pneumophila* antigens; if the Legionella antigens are present in the urine sample, a “half-sandwich” immunocomplex is formed. This immuno-complex then migrates via capillary action along a nitrocellulose membrane containing immobilized antibodies to *Legionella pneumophila* antigens. The immobilized antibodies bind the “half-sandwich” immuno-complex to form a “whole sandwich” immuno-complex. Thus, when the “whole sandwich” is formed, a visible, pink colored line develops in the specimen zone on the test device. In the absence of a Legionella antigen, a “sandwich” immuno-complex is not formed and a negative result is indicated. To serve as a procedural control, a pink colored control line will always appear in the control zone regardless of the presence or absence of Legionella antigen. The test is in a cassette format.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Binax™ Now® Legionella Urinary Antigen Test

2. Predicate 510(k) number(s):

K982238

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Specimen Type Method and type	Human urine Qualitative Immunochromatography	Human urine Qualitative Immunochromatography
Antigen detected	<i>L. pneumophila</i> serogroup 1	<i>L. pneumophila</i> serogroup 1
Differences		
Item	Device	Predicate
Sample application	Direct urine	Urine in swab

K. Standard/Guidance Document Referenced (if applicable):

Not applicable

L. Test Principle:

Immunochromatography

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The reproducibility of the SAS™ Legionella Test was evaluated at three clinical laboratory sites. The SAS™ Legionella Test was tested against a panel of six (6) specimens of which included four levels of positives and two negatives. The low and high positives were from the purified Legionella antigen. Negative were comprised of either urine or Legionella antigen below the detectable limit. Three (3) different laboratory personnel assayed each specimen at each laboratory facility over 3 days. The overall reproducibility for the SAS™ Legionella Test was 100%.

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Not applicable

d. Detection limit:

The limit of detection of the SAS™ Legionella test was determined to be 5×10^4 . *Legionella pneumophila* serogroup 1 ATCC 323152 was prepared using BCYE agar. A dilution of the working concentration was performed. The limit of detection of the SAS™ Legionella Cassette Test was determined from these concentrations.

e. Analytical specificity:

Analytical Specificity: Forty-Nine (49) fresh patient urines from healthy individuals were collected prospectively and assayed at a clinical site. One hundred percent (100%) of these were found to be negative by the SAS™ Legionella test.

Ninety-nine (99) urines from patients diagnosed for other etiological respiratory tract infections (84 culture confirmed, 15 suspected) were tested using the SAS™ Legionella Test. The results showed a lack of reactivity in 98/99 samples (99.0%).

Bacterial Cross-Reactivity: To confirm the analytical specificity of the SAS™ Legionella Test, bacterial cultures likely to be found in the respiratory tract were tested. All yielded negative results. To confirm a lack of interference by other bacterial species in the SAS™ Legionella Test, purified Legionella antigen was added to bacterial cultures likely to be found in the respiratory tract. All tests yielded positive results.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Clinical Sensitivity and Specificity: Three clinical sites (USA and Netherlands) tested three hundred twenty four (324) retrospective frozen specimens using the SAS™ Legionella Cassette test. These samples were previously tested for Legionella by cell culture.

Sensitivity: $95/105 \times 100 = 90.5\%$ (95% CI 83.2 – 95.3%)
Specificity: $208/219 \times 100 = 95.0\%$ (95% CI 91.2 – 97.3%)

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.