A Rapid Visual Assay for the Qualitative Detection of Respiratory Syncytial Virus Antigen in Nasopharyngeal Specimens

**SA Scientific**, Texas, USA

**SA Scientific, Ltd.**  
4919 Golden Quail  
San Antonio, TX 78240 USA

**FOR IN-VITRO DIAGNOSTIC USE**

**CLIA COMPLEXITY: WAIVED**

**STORE AT 15° TO 30°C**

For Technical Assistance Call 800-272-2710  
Outside the USA Call 210-699-8800

The following transport media have been tested and found to be compatible with **SAS™ RSVAlert Test**: 

1. 0.9% Saline PBS  
2. PBS 0.5% Gelatin  
3. Triplosacryl Styr Broth  
4. Todd Hewlett Broth  
5. VCA CULTURETTE™ 
6. Hydrosaline  
7. HIMEM

**PROCEDURE FOR USE WITH NASOPHARYNGEAL ASPIRATES:**

1. Place swab specimen into 0.75-3 ml of transport medium or saline.
2. Mix the swab and transport media or saline vigorously.
3. Express excess liquid from swab.
4. Dispose of swab into appropriate container.

**TEST PROCEDURE FOR SPECIMENS:**

1. Remove the test from the pouch and lay it on a flat surface.
2. Label test with the specimen type and ID.
3. Squeeze and fit the entire pipette with sample.
4. Squeeze and dispense the entire contents of the pipette into test device.

**SPECIMEN COLLECTION, STORAGE AND TRANSPORTATION:**

Acceptable specimens include nasopharyngeal washes, aspirates, and swabs. Specimens should be transported to laboratory immediately after collection. Specimens may be stored at 2-8°C for up to 48 hours or at -20°F for up to one week.

**SPECIMEN PREPARATION:**

Acceptable specimens include nasopharyngeal washes, aspirates, and swabs.

**PRECAUTIONS:**

1. For in vitro diagnostic use only.
2. In accordance with the principles of Good Laboratory Practice, it is strongly recommended that all specimens be treated as potentially infectious and handled with all necessary precautions.
3. Discard all used devices into a biohazard container.
4. Do not use kits after the stated expiration date, and do not mix kit components from different lots.

**INTENDED USE**

**SAS™ RSVAlert** antigen test kit is a rapid visual and qualitative assay for the detection of Respiratory Syncytial Virus (RSV) antigen in nasopharyngeal specimens in neonatal and pediatric patients. The test is for in-vitro diagnostic use only. It is recommended that negative test results be confirmed by cell culture.

**BACKGROUND**

Respiratory syncytial virus is a member of the Paramyxoviridae family and is the most significant respiratory pathogen for infants and children. Infection usually causes mild to moderate upper respiratory illness that may lead to life threatening pneumonia or bronchiolitis. RSV infections are seasonal and are most prominent from December to March in the northern hemisphere. The virus is spherical in shape with a lipoprotein envelope synthesized from the plasma membrane of the infected host cell. The virus is spread rapidly through droplets dispersed in the air or secretions from the respiratory tract of infected individuals. The incubation period is 3-7 days. Specimens from patients are obtained by using nasopharyngeal aspiration, washes and swabs.

**MATERIALS & REAGENTS PROVIDED**

1. Test Device.
2. SAS™ RSVAlert Extraction Buffer (Contains mucolytic agent and 0.1% sodium azide as a preservative).
3. Disposable extraction tubes with filtered caps.
4. Disposable pipettes (150µl ea).
5. Package insert.

**MATERIALS NOT PROVIDED**

1. Timer.
2. RSV positive control.
3. RSV negative control.
4. Disposable Transfer Pipettes (1ml ea).

**PROCEDURE FOR USE WITH NASOPHARYNGEAL WASHS:**

1. Nasopharyngeal wash samples may be treated with buffer solutions, such as a) 0.9% sodium chloride or saline or b) 0.1% sodium azide as a preservative.

**INTERPRETATION OF RESULTS**

Negative Result  
Any pink colored band in the control (C) area without a pink colored band in the specimen (S) area is a negative result.

Positive Result  
Any pink colored band in the control (C) area with a pink colored band in the specimen (S) area is a positive result.

Invalid Result  
No pink colored band in the control (C) area of the test is an invalid result. If the test is invalid, repeat the test or call Technical Assistance.
LIMITATIONS

1. The SARS™ RSVAlert Test is for the detection of viable and non-viable RSV particles. This test is not for confirmation of a respiratory infection caused by other microorganisms.

2. The SARS™ RSVAlert Test is dependent on antigen load and may not correlate with other tests used for the detection of RSV such as Cell culture performed on the same specimen.

3. Frozen specimens should be maintained and brought to room temperature before use.

4. False negatives may result from inadequate specimen collection, such as over dilution, improper handling or transport.

5. A negative test result does not rule out possible RSV infection. Patient diagnosis should always include laboratory test results and all other clinical information available.

QUALITY CONTROL

Internal Controls

Each test device includes an internal procedural control. The appearance of a Control Line in the C region of the test device is a positive procedural control. Correct procedural technique, specimen flow and test device performance is confirmed when a control line appears in the C (control) area of the membrane. If the control line fails to appear in the C (control) area, the test result is invalid.

External Controls

Negative and positive controls for RSV antigen should be tested and the appropriate results obtained. External quality controls should be performed on each lot.

PERFORMANCE CHARACTERISTICS

Accuracy by Comparison:

Laboratory Studies

Sixty-three (63) frozen patient samples were obtained from several laboratories. An RSV virucal culture was performed on each sample. Each sample was thawed and a SARS™ RSVAlert Test was performed.

SAS™ RSVAlert Test

* Confirmed Positive by EIA.

Percent Positive Agreement: (57/63) = 92.0% (95% CI, 84.9% to 97.3%)

Percent Negative Agreement: (5/63) = 8.1% (95% CI, 3.7% to 14.8%)

SAS™ RSVAlert Test - *

Sensitivity: (50/58) = 100% (95% CI, 95.7% to 100%)

Specificity: (5/63) = 8.1% (95% CI, 3.7% to 14.8%)

Relative Sensitivity: (86/90) = 95.6% (95% CI, 89.0% to 98.8%)

Relative Specificity: (32/34) = 94.1% (95% CI, 80.3 to 99.3%)

SAS™ RSVAlert Test - *

SAS™ RSVAlert Test - *

CLINICAL SPECIFICITY AND SENSITIVITY

Prospective Study

One hundred thirty-two (131) clinical samples collected over two (2) seasons were tested blindly and prospectively using the SARS™ RSVAlert Test and compared to Cell Culture. The results are shown in the table below.

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<thead>
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<th>Type</th>
<th>RSV Viral Strain Limit of Detection ( TCID, 50 / ml )</th>
</tr>
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<tr>
<td>A</td>
<td>RSV (typing) 99.9 x 109 TCID50/ml</td>
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<tr>
<td>B</td>
<td>RSV (A-2) 9.1 x 1010 TCID50/ml</td>
</tr>
<tr>
<td>C</td>
<td>RSV (wild-type) 9.1 x 109 TCID50/ml</td>
</tr>
<tr>
<td>D</td>
<td>RSV (Washington) 1.1 x 1010 TCID50/ml</td>
</tr>
<tr>
<td>E</td>
<td>RSV (Wild-type) 8.9 x 109 TCID50/ml</td>
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CLINICAL COMPARISON

Nasopharyngeal Swabs

Two clinical sites tested twenty-eight (28) clinical swab specimens blindly and prospectively using the SARS™ RSVAlert Test and the Other Commercial RSV Test. The results are shown below.

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CROSS REACTIVITY/INTERFERENCE STUDY

To confirm the analytical specificity of the SARS™ RSVAlert Test, classical and viral cultures were likely to be observed in the respiratory tract were tested. Bacterial cultures were tested at 1.0 x 108 cfu/ml and the viral cultures at 1.0 x 109 TCID50/mL. All yielded negative results.

To confirm noninterference of the SARS™ RSVAlert Test, RSV whole virus 9320 at titer 1.11 x 103.5 TCID50/0.2 ml was added to the bacterial cultures and viral cultures at 1.0 x 108 cfu/ml and 1.0 x 109 TCID50/mL, respectively. All yielded positive results.

Bacterial Cross Reactivity

Candida albicans
Straphococcus sp gr a
Chlamydia trachomatis
Corynebacterium diphtheriae
Haemophilus influenzae type A
Mycoplama pneumoniae
Serratia marcescens
Staphylococcus aureus
Varicella zoster
Cytomegalovirus
Echovirus 11
Echovirus 3
Echovirus 6
HSV Type-1
HSV Type-2

Viral Cross Reactivity Panel

Adenovirus 5
Influenza A
Adenovirus 7
Influenza B-Hong Kong
Adenovirus 10
Parainfluenza 1
Coxsackie A9
Parainfluenza 2
Coxsackie B5
Parainfluenza 3
Coxsackie B6
Varicella zoster
Cytomegalovirus
Rhinoivus 1A
Echovirus 11
Rhinoivus 2
Echovirus 13
Rhinoivus 15
Echovirus 6
HIV Type-1
HIV Type-2

Other Commercial RSV Test

Percent Positive Agreement: (62/63) = 97.8% (95% CI, 93.9% to 99.9%)

Percent Positive Agreement: (60/63) = 95.3% (95% CI, 91.5% to 99.9%)

SAS™ RSVAlert Test - *

* All four were confirmed positive by EIA and Cell Culture.

Percent Positive Agreement: (83/87) = 95.4% (95% CI, 88.6% to 97.8%)

Percent Negative Agreement: (17/11) = 82.1% (95% CI, 63.1% to 93.3%)

Analytical Sensitivity (Limit of Detection)

The limit of detection (LOD) of the SARS™ RSVAlert Test was determined for five (5) RSV strains. These strains included three (3) RSV B and two (2) RSV A strains.

REFERENCES


70-Pd-irrelevant

Revision 8/8/94

M4™ is a trademark of REMEL, Inc. ATCC® is a registered trademark of American Type Culture Collection CULTURETTE™ is a trademark of Becton Dickinson and Company

MegaCor GmbH Friedrich List Str. 40 D-70771 Leinfelden Echterdingen – Germany

Authorised Representative: