SAS™
RSV Control Kit

For Use with SAS™ RSV Test

For *In-Vitro* Diagnostic Use
Store at 2° to 8°C

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

SA Scientific™

4919 Golden Quail
San Antonio, Texas 78240 USA

INTENDED USE
SAS™ RSV Controls are for use with SAS™ RSV Test kits. These controls are for professional use only.

INTRODUCTION
The use of known controls in the laboratory is invaluable. It is important to verify testing procedures to confirm that the results reported are valid. Testing with SAS™ RSV Control Kit will provide assurance that SAS™ RSV test kits are performing properly.

PRINCIPLE OF THE TEST
The SAS™ RSV Control Kit set is designed to assist in verifying kit performance of the SAS™ RSV Test. The positive control contains RSV antigen and should produce a positive result in test kits. The negative control does not contain the RSV antigen and should produce a negative result. If the proper results are not achieved, then the SAS™ RSV Test kit may not be working properly and results should be considered inconclusive.

REAGENTS
1. RSV Positive Control - RSV antigen (Long Strain) containing sodium azide 0.1%
2. RSV Negative Control - contains sodium azide 0.1%

PRECAUTIONS
1. For *in-vitro* diagnostic use only.
2. Refer to the package insert of the SAS™ RSV Test for specific precautions of that test kit.
3. Do not use controls if cloudy or precipitates are observed in the vials. This may be an indication of reagent instability or deterioration.
4. These controls contain 0.1% of sodium azide, which may react with lead and copper plumbing to form explosive metal azides. Drains should be flushed thoroughly with water after disposing of controls to prevent azide buildup.
5. Do not use controls beyond expiration date.
6. Specimens and controls should be considered potentially hazardous and handled in the same manner as an infectious agent.

STORAGE
The SAS™ RSV Control Kit is to be stored refrigerated (2° to 8°C) for the duration of the shelf life. The controls must be brought to room temperature (15° to 30°C) before use.

PROCEDURE
Materials Provided
1. RSV Positive Control (contains inactivated RSV)
2. RSV Negative Control (without RSV)

Materials Required But Not Provided
SAS™ RSV Test kit

Directions For Use

Allow the controls to reach room temperature (15°C to 30°C) prior to testing. The controls are ready to use. No dilution or extraction is required.
The controls are used in place of the specimen/extraction buffer solution and should be tested according to the package insert of the SAS™ RSV Test.

INTERPRETATION OF RESULTS
Positive RSV Control Results
The test should produce a positive result as outlined in the SAS™ RSV Test kit.

Negative RSV Control Results
The test should produce a negative result as outlined in the SAS™ RSV Test kit.

Invalid Results
See the invalid results section of the package insert from the SAS™ RSV Test kit. The test should be repeated.

QUALITY CONTROL
Good laboratory practice recommends the use of positive and negative controls to assure functionality of reagents and proper performance of assay procedure. The Positive Control and Negative Control provided are intended to monitor for substantial reagent failure and will not monitor the antigen extraction procedure or will not ensure precision at the assay cut-off. It is recommended that these controls be tested once with each new lot number and thereafter as recommended by the user's laboratory and applicable guidelines. Quality control requirements must be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to NCCLS EP12-A and 42 CFR 493.1202(c) for guidance on appropriate QC practices. In addition, the user may wish to test additional controls such as a positive patient specimen to monitor for antigen extraction and stability.

LIMITATIONS PROCEDURE
These controls are formulated for use as quality control specimens in the reagent verification of SAS™ RSV Test. See the package insert for guidelines in procedure and interpretation.
Refer to the SAS™ RSV Test for further limitations.

EXPECTED VALUES
The RSV Positive Control should produce a positive result. The RSV Negative Control should produce a negative result. If the desired result is not achieved, it may be an indication of the following:

The test kit is not performing properly.
The test was not performed correctly according to the package insert.

Invalid results should be analyzed to determine probable causes and provide solutions for corrective actions.

PERFORMANCE CHARACTERISTICS
The SAS™ RSV Control Kit has been designed to produce correct results when used with the SAS™ RSV Test. These controls have been tested with SAS™ RSV Test kits and were found to produce satisfactory results.[1]

REFERENCES
1. Data on file, SA Scientific, Inc.

70-pi-rsvcontrol.doc
10-04
CE