SAS™
Legionella Controls

SAS™ Legionella Controls are for use in monitoring the *in vitro* diagnostic performance of the SAS™ Legionella Test; their performance has not been evaluated with other Legionella assays. These controls are for prescription use only.

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

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INTENDED USE

SAS™ Legionella Controls are for use in monitoring the *in vitro* diagnostic performance of the SAS™ Legionella Test presumptive qualitative detection of *Legionella pneumophila* serogroup 1 antigens in human urine; their performance has not been evaluated with other Legionella assays. These controls are for prescription use only.

INTRODUCTION

The use of known quality control material in the laboratory is invaluable. It is important to verify testing procedures to confirm that the results reported are valid. Testing with SAS™ Legionella Controls will provide assurance that SAS™ Legionella test kits are performing properly.

PRINCIPLE OF THE TEST

The SAS™ Legionella Controls set is designed to assist in verifying the kit performance of the SAS™ Legionella Test. The positive control contains formaldehyde inactivated *Legionella pneumophila* serogroup 1 from culture, and it should produce a positive result in the SAS™ Legionella Test kits. The negative control does not contain the inactivated Legionella antigen serogroup 1, and it should produce a negative result. If the proper results are not achieved, then the SAS™ Legionella Test kit may not be working properly and results should be considered inconclusive. It is recommended that the SAS™ Legionella Controls should be performed on each new SAS™ Legionella Test kit box opened.

REAGENTS

1. Legionella Positive Control, 1mL – base medium of synthetic urine, formaldehyde inactivated *Legionella pneumophila* serogroup 1 antigen containing sodium azide 0.1%
2. Legionella Negative Control, 1mL – synthetic urine with a formulation based on normal human urine, salts, pH, and specific gravity as indicated by Clinical Chemistry; contains sodium azide 0.1%

PRECAUTIONS

1. For *in-vitro* diagnostic use only.
2. Refer to the package insert of the SAS™ Legionella Test for specific precautions of that test kit.
3. Do not use controls if cloudiness 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™ Legionella Controls are 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) prior to use.

PROCEDURE

Materials Provided

Legionella Positive Control – 1mL (contains inactivated *Legionella pneumophila* serogroup 1 antigen)
Legionella Negative Control – 1mL (synthetic matrix without *Legionella pneumophila* serogroup 1 antigen)

Materials Required But Not Provided

SAS™ Legionella Test kit

Directions For Use

1. Allow the controls to reach room temperature (15°C to 30°C) prior to testing.
2. The controls are used in place of the urine specimen.
3. Invert vial for mixing prior to use; no dilution or extraction is required.
4. Place 4 drops or 150µL into the SAS™ Legionella Test well.
5. Read results at 15 minutes.

Please refer to device package insert for further details.

INTERPRETATION OF RESULTS

Positive Legionella Control Results
The test is positive if one colored line appears in the S (specimen) area and one colored line appears in the C (control) area. Any colored line in the specimen area should be considered positive. Colored lines may appear lighter or darker than one another. Specimens with Legionella antigen levels near the threshold of the test may develop color (faint lines) over time after the 15 minute reading. A line that appears after 15 minutes is not diagnostic and should be ignored.

Negative Legionella Control Results
The test is negative if a colored line appears in the C (control) area only.

Invalid Results
The test is invalid and should be repeated if a colored line does not appear in the C area even if a colored line appears in the S (specimen) area. Colored lines

that appear in the S (specimen) area after 15 minutes are not diagnostic and should be ignored.

QUALITY CONTROL

Correct procedural technique and SAS™ Legionella Test kit performance is confirmed when using this control set. The appearance of a Control line in the C region of the device is a positive procedural control. Correct procedural technique, specimen flow and device performance is confirmed when a colored line appears in the C (control) area of the membrane. If the colored line fails to appear in the C (control) area, the test result is invalid.

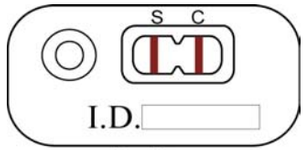
A clear background is an internal negative procedural control. The background color should be white to light pink and should not interfere with the reading of the test result. If any result is difficult to interpret, the test should be repeated with the same sample to eliminate error. Obtain a new sample and retest when the original sample repeatedly produces unreadable results. It is recommended that the internal quality controls be recorded for each sample run.

LIMITATION OF PROCEDURE

1. These controls are only formulated for use as quality control material to verify that the SAS™ Legionella Test is performing properly.

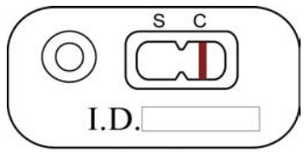
EXPECTED VALUES

The Legionella Positive Control should produce a positive result.



Positive

The Legionella Negative Control should produce a negative result.



Negative

If the desired result is not achieved, it may be an indication of the following:

1. The test kit is not performing properly.
2. 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™ Legionella Controls have been designed to produce correct results when used with the SAS™ Legionella Test kit. These controls have been tested with SAS™ Legionella Test kits and were found to produce the expected results.[1]

REFERENCES

1. Data on file, SA Scientific, Inc.
2. Source of the antigen from ATCC