

SAS™ Adenovirus Controls

FOR USE WITH
SAS™ ADENOVIRUS TESTS

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™ Adenovirus Controls are controls for use with SAS™ Adenovirus 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™ Adenovirus Controls will provide assurance that SAS™ Adenovirus test kits are performing properly.

PRINCIPLE OF THE TEST

The SAS™ Adenovirus Controls set is designed to assist in verifying kit performance of SAS™ Adenovirus tests. The positive controls contain inactivated adenovirus and should produce a positive result in test kits which are designed to detect these levels. The negative control does not contain the inactivated adenovirus and should produce a negative result. If the proper results are not achieved, then the adenovirus kit being tested may not be working properly and results should be considered inconclusive.

REAGENTS

1. Adenovirus Positive Control – inactivated adenovirus containing sodium azide 0.1%
2. Negative Control - contains sodium azide 0.1%

PRECAUTIONS

1. For *in-vitro* diagnostic use only.
2. Refer to the package insert of the SAS™ Adenovirus test being used 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™ Adenovirus 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) before use.

PROCEDURE

Materials Provided

1. Adenovirus Positive Control (contains inactivated adenovirus)
2. Negative Control (without adenovirus)

Materials Required But Not Provided

The SAS™ Adenovirus test being tested and any other materials outlined in the package insert of the test kit.

Directions For Use

1. Allow the controls to reach room temperature (15°C to 30°C) prior to testing. The controls are ready to use. No dilution is required.
2. The controls are used in place of the specimen and should be tested according to the package insert of the adenovirus kit being checked.

INTERPRETATION OF RESULTS

Positive Results

The test should produce a positive result as outlined in the adenovirus test kit being tested if the kit is designed to detect this low level.

Negative Adenovirus Control Results

The test should produce a negative result as outlined in the adenovirus test kit being tested.

Invalid Results

See the invalid results section of the package insert from the adenovirus test kit being tested. The test should be repeated.

QUALITY CONTROL

Correct procedural technique and adenovirus test performance is confirmed when using

this control set. It is recommended that these controls be used according to the package insert of the adenovirus test kit being tested.

LIMITATIONS PROCEDURE

1. These controls are formulated for use as quality control specimens in the reagent verification of SAS™ Adenovirus tests. See the package insert for guidelines in procedure and interpretation.
2. Refer to the SAS™ Adenovirus test being checked for further limitations.

EXPECTED VALUES

The Adenovirus Positive Control should produce a positive result. The Negative Adenovirus Control should produce a negative result. 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™ Adenovirus Controls have been designed to produce correct results in SAS™ Adenovirus test kits. These controls have been tested with SAS™ Adenovirus test kits and were found to produce satisfactory results.¹

REFERENCES

1. Data on file, SA Scientific, Inc.

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