

Sure-Vue®

Adenovirus Controls

For Use with Sure-Vue® Adeno Test

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

Distributed by:

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To Order:
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INTENDED USE

Sure-Vue® Adenovirus Controls are controls for use with Sure-Vue® Adeno 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 Sure-Vue® Adenovirus Controls will provide assurance that Sure-Vue® Adeno test kits are performing properly.

PRINCIPLE OF THE TEST

The Sure-Vue® Adenovirus Controls set is designed to assist in verifying kit performance of Sure-Vue® Adeno Test. The positive controls contain inactivated Adenovirus and should produce a positive result in test kits. The negative control does not contain the inactivated Adenovirus and should produce a negative result. If the proper results are not achieved, then the Sure-Vue® Adeno Test kit may not be working properly and results should be considered inconclusive.

REAGENTS

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

PRECAUTIONS

1. For *in-vitro* diagnostic use only.
2. Refer to the package insert of the Sure-Vue® Adeno 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 Sure-Vue® 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

Adenovirus Positive Control (contains inactivated Adenovirus)
Adenovirus Negative Control (without Adenovirus)

Materials Required But Not Provided

Sure-Vue® Adeno 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 or extraction is required.
2. The controls are used in place of the specimen/extraction buffer solution and should be tested according to the package insert of the Sure-Vue® Adeno Test.

INTERPRETATION OF RESULTS

Positive Results

The test should produce a positive result as outlined in the Sure-Vue® Adeno Test kit.

Negative Results

The test should produce a negative result as outlined in the Sure-Vue® Adeno Test kit.

Invalid Results

See the invalid results section of the package insert from the Sure-Vue®

Adeno Test kit. The test should be repeated.

QUALITY CONTROL

Correct procedural technique and Sure-Vue® Adeno Test kit performance is confirmed when using this control set. It is recommended that these controls be used according to the package insert of the Sure-Vue® Adeno Test kit.

LIMITATIONS PROCEDURE

1. These controls are formulated for use as quality control specimens in the reagent verification of Sure-Vue® Adeno Test. See the package insert for guidelines in procedure and interpretation.
2. Refer to the Sure-Vue® Adeno Test for further limitations.

EXPECTED VALUES

The Adenovirus Positive Control should produce a positive result. The Adenovirus Negative 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 Sure-Vue® Adenovirus Controls have been designed to produce correct results when used with Sure-Vue® Adeno Test kits. These controls have been tested with Sure-Vue® Adeno Test kits and were found to produce satisfactory results.¹

REFERENCES

1. Data on file.