

# Sure-Vue® Rotavirus Controls

For Use with Sure-Vue® Rota Test

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

Distributed by:

Fisher HealthCare  
9999 Veterans Memorial Drive  
Houston, TX. 77038-2499

For Technical Assistance: 1-888-727-3315

To Order:  
Phone: 1-800-640-0640  
Fax: 1-800-290-0290

## INTENDED USE

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

## PRINCIPLE OF THE TEST

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

## REAGENTS

1. Rotavirus Positive Control – inactivated Rotavirus containing sodium azide 0.1%
2. Rotavirus 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® Rota 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® Rotavirus 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

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

### Materials Required But Not Provided

Sure-Vue® Rota 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® Rota Test.

## INTERPRETATION OF RESULTS

### Positive Results

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

### Negative Results

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

## Invalid Results

See the invalid results section of the package insert from the Sure-Vue® Rota Test kit. The test should be repeated.

## QUALITY CONTROL

Correct procedural technique and Sure-Vue® Rota 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® Rota Test kit.

## LIMITATIONS PROCEDURE

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

## EXPECTED VALUES

The Rotavirus Positive Control should produce a positive result. The Rotavirus 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® Rotavirus Controls have been designed to produce correct results when used with Sure-Vue® Rota Test kits. These controls have been tested with Sure-Vue® Rota Test kits and were found to produce satisfactory results.<sup>1</sup>

## REFERENCES

1. Data on file.

Revised 12 -02

®Sure-Vue is a trademark of Fisher Scientific Company