



Microbix Biosystems Inc.
265 Watline Avenue
Mississauga, Ontario, Canada L4Z 1P3
Tel 905-361-8910 Fax 905-361-8911

Product Name:

Rotavirus Positive Sample

Catalogue Number: PT-35-01

Storage: Store this preparation at 2°C to 8°C.

Description: This product contains inactivated rotavirus in storage buffer.

Intended use: The product is to be used as a positive test sample in commercially-available clinical antigen test kits, and in non-commercial clinical laboratory tests for the detection of rotavirus antigens. The product is commonly used as a challenge sample in laboratory proficiency testing programs. It is recommended that product is tested according to kit Manufacturer's instructions for testing of clinical samples.

Hazards: We are aware of no specific biological hazards associated with this product. The preparation has been inactivated and should contain no infectious material. Generally accepted good laboratory practices appropriate to biological reagents should be employed in its handling. The buffer solution contains 0.02% sodium azide (CAS No. 26628-22-8) as a preservative.

Strain: Simian rotavirus SA11, ICTV 00.060.0.03.001.00.201.001

Cultured in: MA104 cells

Agent description: Taxonomy: *Rheoviridae/Rotavirus/Rotavirus A/Simian rotavirus SA11*. Virions consist of a capsid, a core, and a nucleoprotein complex. Virus capsid is not enveloped. Capsid/nucleocapsid is isometric with icosahedral symmetry and has a diameter of 80 nm. The genome is segmented and consists of eleven segments of linear double-stranded RNA. Rotavirus is the most common cause of severe diarrhea among children. The incubation period for rotavirus disease is approximately 2 days. The disease is characterized by vomiting and watery diarrhea for 3 - 8 days, and fever and abdominal pain occur frequently.

Preparation: A cellular monolayer of MA104 cells is infected with Rotavirus particles. Cell culture lysate is harvested and clarified.

Assistance: If you have any questions regarding the production, testing or use of this antigen, please send them together with any relevant data to Microbix Technical Services, at Customer.Service@Microbix.com or fax 905-361-8911. Your complete satisfaction with the performance of this product is important to us.

Quality Control Information

Product name: Rotavirus positive sample

Lot number: 160911

Test Kit	Target	Result
Immuno card STAT Rotavirus Catalogue # 750030	Rotavirus	Positive
SAS Rota Test Catalogue # 069020	Rotavirus	Positive
Combi-Strip (Rota and Adeno) Catalogue # C-1004	Rotavirus & adenovirus	Positive (Adenovirus negative)
Quick Vue Influenza A and B Catalogue # 20183	Influenza A & B	Negative
Xpect RSV Catalogue # R24601	Respiratory Syncytial Virus	Negative
Quick Vue Chlamydia Catalogue # OB006	Chlamydia	Negative

Inactivation: Rotavirus antigen is inactivated using UV irradiation. This procedure is effective primarily by damaging viral RNA. Rotavirus inactivation is assessed using a double-passage assay in tissue culture. Rotavirus antigen is inoculated onto an MA104 cell monolayer and incubated for three days. The infected culture is passaged and scored after a further 3 days of incubation for infectivity. The culture is monitored for cytopathic effect. An absence of cytopathic affect, within the limit of the assay, indicates the inactivation of the antigen.

Result: No viral replication detected.

Quality Control Summary: This lot meets specifications and is released for shipment.

Expiry Date: 09-January, 2012

Quality Assurance Signature

23-Septemeber, 2011