



**Microbix Biosystems Inc.**

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*Product Name:*

## Rotavirus antigen

*Catalogue Number:* EL-35-02

*Storage:* Store this antigen preparation frozen at - 70 °C to - 100 °C . Repeated freezing and thawing should be avoided.

*Hazards:* We are aware of no specific hazards associated with this product. The reagent has been inactivated and should contain no infectious material. Generally accepted good laboratory practices appropriate to biological reagents should be employed when handling this product.

*Strain:* SA-11

*Cultured In:* MA104, an established cell line from African Green Monkey Kidney.

*Buffer:* PBS

*Agent Description:* Rotaviruses cause enteric disease with symptoms characterized by diarrhea, vomiting, abdominal discomfort, and fever. Diarrhea ranges from mild to severe and can cause fatal dehydration. Transmission is by the fecal-oral route (and possibly the respiratory route).

*Preparation:* MA104 cellular monolayer was infected with Rotavirus particles. Crude lysate was harvested and partially clarified.

*Inactivation:* This rotavirus antigen is UV inactivated. The effectiveness of inactivation was tested by inoculation of MA104 monolayer with antigen. The culture was monitored for rotavirus specific CPE for 7 dpi in triplicate.

*Description:* The preparation is free of detergent. Residual non-viral protein comes from host tissue and culture medium.

*Recommendations for Use:* After complete thawing, vortex the antigen gently and keep it on ice prior to use.

*Assistance:* If you have any questions regarding the production, testing or use of this antigen, please send them by email to [customer.service@microbix.com](mailto:customer.service@microbix.com) or fax 905-361-8911, with any relevant data, to Microbix Technical Services. Your complete satisfaction with the performance of this product is important to us.

## Quality Control Information

*Product Name:* **Rotavirus antigen**

*Lot Number:* 35024A1

Microbix performs quality control tests to ensure each batch meets in-house specifications. Test results are provided with each lot of antigen shipped. Antigen users require this information for a number of reasons:

- to maintain a record for good manufacturing purposes,
- to correlate user results with Microbix results and
- for use as a starting point for those just starting with either a new antigen or developing a new assay.

*Test:*

*Specific Activity:* Specific activity of the product was performed using ImmunoSTAT card assay and compared to that of the reference antigen.

*Result:* Positive signal. Signal intensity is scored as "9.5" at 10x dilution.  
Reference Lot 35004A1R signal intensity is scored as "2" at 10x dilution.

*Inactivation Assay:* Inactivation assay is performed in duplicate. Test antigen is inoculated onto MA104 cell monolayers. These are incubated 3 days. On the 3rd day, the monolayers are examined for plaques. One live virus particle is capable of developing a plaque. The preparation is considered inactivated when no plaques are observed.

*Result:* No growth detected



Quality Assurance Signature:

28-February, 2011