



Microbix Biosystems Inc.

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

Product Name:

Respiratory Syncytial Virus (HRSV) Positive Sample

Catalogue Number: PT-07-01

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

Description: This product contains inactivated Human respiratory syncytial virus (HRSV) 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 RSV 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: Human respiratory syncytial virus, Long strain. ICTV 01.048.2.01.001

Cultured in: BSC-1 cells

Agent description: Taxonomy: *Paramyxoviridae/Pneumovirinae/Pneumovirus/Human respiratory syncytial virus*. Virions consist of an envelope and a nucleocapsid. Virions are spherical to pleomorphic; filamentous and other forms are common. Virions measure (60-)150-250(-300) nm in diameter; 1000-10000 nm in length. The genome is not segmented and contains a single molecule of linear negative-sense, single-stranded RNA. Virions may also contain occasionally a positive sense single-stranded copy of the genome. HRSV is a respiratory virus that infects the lungs and breathing passages. Most otherwise healthy people recover from HRSV infection in 1 to 2 weeks. However, infection can be severe in some people, such as certain infants, young children, and older adults.

Preparation: Optimally infected cells are disrupted by sonication and then subjected to low speed centrifugation. The clarified cell lysate is pooled with supernatant from the infected culture and concentrated using cross flow ultrafiltration with a 30,000 molecular weight cut off membrane.

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: Respiratory syncytial virus (HRSV) positive sample

Lot number: 010911

Test Kit	Target	Result
Binax NOW RSV Catalogue # 430-022	Respiratory Syncytial Virus	Positive
Xpect RSV Catalogue # R24601	Respiratory Syncytial Virus	Positive
Quick Vue RSV Catalogue # 20193	Respiratory Syncytial Virus	Positive
Combi-Strip (Rota and Adeno) Catalogue # C-1004	Rotavirus & adenovirus	Negative
Quick Vue Chlamydia Catalogue # OB006	Chlamydia	Negative
Quick Vue Influenza A & B Catalogue # 20183	Influenza A & B	Negative

Inactivation: HRSV antigen is inactivated using gamma radiation. This procedure is effective primarily by damaging viral RNA. The effectiveness of inactivation is tested by inoculating a suitable cell line monolayer with antigen. The culture is monitored for cytopathic effect for 5 days. If no sign of infection is observed the culture is passaged into a fresh monolayer. The second passage is monitored for a further 5 days. 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-September, 2011