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Product Name:

Influenza B Positive Sample

Catalogue Number: PT-14-01

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

Description: This product contains inactivated influenza B virus 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 influenza B 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: Influenza B/Hong Kong/5/72. ICTV 00.046.0.04.001

Cultured in: MDCK cells.

Agent description: Taxonomy: *Orthomyxoviridae/Influenzavirus B/Influenza B virus*. Virions consist of an envelope, a matrix protein, a nucleoprotein complex, a nucleocapsid, and a polymerase complex. Virions are spherical to pleomorphic; filamentous forms occur (sometimes). Virions measure 80-120 nm in diameter, 200-300(-3000) nm in length. The genome is segmented and consists of eight segments of linear negative-sense, single-stranded RNA. Influenza B virus can cause mild to severe illness, and at times can lead to death, though disease is generally less severe than influenza A. It may cause fever, cough, sore throat, runny or stuffy nose, aches, and sometimes diarrhea and vomiting.

Preparation: MDCK cells are infected in tissue culture, and supernatant culture medium is harvested 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: Influenza B positive sample

Lot number: 220811

Test Kit	Target	Result
Xpect Flu A & B Catalogue # R24600	Influenza A & B	Positive (Influenza A negative)
Binex Now Influenza A & B Catalogue # 416-000	Influenza A & B	Positive (Influenza A negative)
Quick Vue Influenza A & B Catalogue # 20183	Influenza A & B	Positive (Influenza A negative)
Quick Vue RSV Catalogue # 20193	Respiratory Syncytial Virus	Negative
Combi-Strip (Rota and Adeno) Catalogue # C-1004	Rotavirus & adenovirus	Negative
Quick Vue Chlamydia Catalogue # OB006	Chlamydia	Negative

Inactivation: Influenza B antigen is inactivated by gamma irradiation. This procedure is effective primarily by damaging viral RNA. Influenza B inactivation is assessed using a double-passage assay in tissue culture. Influenza antigen is inoculated onto an MDCK cell monolayer and incubated for three days. The infected culture is passaged and scored after a further 3 days of incubation for infectivity. The presence of viable influenza B is assessed by hemagglutination (HA) assay on a cell suspension of the final culture. An absence of HA reactivity, 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: 27-December, 2011

Quality Assurance Signature

07-September, 2011