

Human Reference Immune Globulin to Respiratory Syncytial Virus, CBER RSV Lot 1

Catalog No. NR-21973

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Product Description: Human plasma was obtained from normal healthy donors, some of whom had probably been infected with respiratory syncytial virus (RSV) in the past. Immune globulin was purified from plasma pools using a modified Cohn-Oncley cold ethanol fractionation process and cation and anion exchange chromatography. The preparation was treated with tri-n-butyl phosphate, octoxynol 9, and polysorbate 80 at 18°C to 25°C for a minimum of 60 minutes to remove or inactivate viruses, 35 nm filtered, and incubated at low pH and elevated temperature. The final immune globulin (10%) is a sterile 100 mg/mL protein preparation stabilized with 0.25 M glycine (pH 4.6 to 5.1). At least 98% of the protein is immune globulin. The osmolality is 240 to 300 mOsmol/kg.

Lot: RSV-1¹

Manufacturing Date: OCT2010

TEST	SPECIFICATIONS	RESULTS
Geometric Mean Neutralization Titers by Plaque Reduction Neutralization Assay at 1% Immune Globulin^{1,2} RSV A2 (absence of complement) RSV A2 (presence of complement) RSV B1 (absence of complement) RSV B1 (presence of complement)	Report results Report results Report results Report results	189 ± 37 873 ± 148 289 ± 59 2096 ± 490
Neutralization Titers by Microneutralization Assay at 1% Immune Globulin^{2,3} RSV A2 (presence of complement) RSV B1 (presence of complement)	Report results Report results	99 ± 49 976 ± 315
Concentration	Report results	100 mg/mL
Sterility	35 nm sterile-filtered	35 nm sterile-filtered

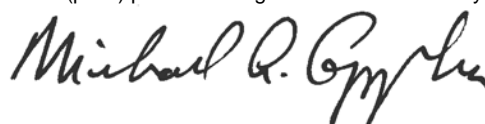
¹Each individual plasma donation was tested using licensed serological tests for hepatitis B surface antigen (HBsAg) and for antibodies to human immunodeficiency virus (HIV-1/HIV-2) and hepatitis C virus (HCV) and found to be negative. Pools of plasma were also tested using licensed nucleic acid tests for HIV-1 and HCV and found to be negative. Notwithstanding these safety measures, universal precautions should be used when handling biological materials derived from human sources, such as NR-21973.

²Results are presented as the antilog of the reciprocal of the 50% endpoint titer calculated using the Kärber method (mean ± standard deviation). All neutralization assays were performed on HEP-2 cell monolayers in 24-well plates in the absence or presence of 5% guinea pig complement, as indicated.

³NR-21973 was diluted to a final concentration of 1% immune globulin in PBS (pH 7) prior to testing in neutralization assays.

Date: 30 APR 2015

Signature:



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