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

Catalog No. NR-21973

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For research use only. Not for human use.

Contributor:

U.S. Food and Drug Administration

Manufacturer:

Baxter S.A., Lessines, Belgium

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. The immune globulin was purified from the plasma pools using a modified Cohn-Oncley cold ethanol fractionation process, as well as cation and anion exchange chromatography. The immune globulin was further treated to remove or inactivate viruses using solvent detergent treatment (with tri-n-butyl phosphate, octoxynol 9, and polysorbate 80 at 18°C to 25°C for a minimum of 60 minutes), 35 nm filtration and low pH incubation at an 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 was determined to be immune globulin. The osmolality was determined to be 240 to 300 mOsmol/kg.

Material Provided:

Each vial contains approximately 2 mL of immune globulin (10%) in 0.25 M glycine (pH 4.6 to 5.1).

Note: Dilute 1:10 to a final concentration of 1% immune globulin in sterile PBS (pH 7.4) prior to testing in virus neutralization assays.

Packaging/Storage:

NR-21973 was packaged aseptically in glass tubes. It is provided frozen and should be stored at -20°C or colder immediately upon arrival.

Citation:

Acknowledgment for publications should read "The following reagent was obtained through BEI Resources, NIAID, NIH: Human Reference Immune Globulin to Respiratory Syncytial Virus, CBER RSV Lot 1, NR-21973."

Biosafety Level: 1

Appropriate safety procedures should always be used with this material. Laboratory safety is discussed in the following publication: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: U.S. Government Printing Office, 2009; see www.cdc.gov/biosafety/publications/bmbl5/index.htm.

Each 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. As an additional safety measure, pools of plasma were tested using licensed nucleic acid tests for HIV-1 and HCV and found to be negative.

Universal Precautions should be used when handling biological materials derived from human sources, such as NR-21973.

Disclaimers:

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