

Panel of Human Antiserum and Immune Globulin to Respiratory Syncytial Virus

Catalog No. NR-32832

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Product Description: NR-32832 is a panel containing: 1) pooled human reference antiserum to respiratory syncytial virus (RSV), 2) three pooled human control antiserum preparations of varying titers to RSV, 3) human reference immune globulin to RSV, prepared from pooled human plasma, and 4) human serum depleted of immunoglobulin G (IgG) for use as a negative control.

Lot: 63492188

**NR-4020, Human Reference Antiserum to Respiratory Syncytial Virus
Lot V-327-501-572 (Wyeth Vaccines Research Lot 06594)**

TEST	SPECIFICATIONS	RESULTS
Geometric Mean Neutralization Titers by Plaque Reduction Neutralization Assay¹		
RSV A2 (absence of complement)	Report results	442 ± 126
RSV A2 (presence of complement)	Report results	1379 ± 59
RSV B1 (absence of complement)	Report results	422 ± 20
RSV B1 (presence of complement)	Report results	3335 ± 473

¹Results 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.

**NR-4021, Human Antiserum to Respiratory Syncytial Virus, High Control
Lot V-327-512-572 (Wyeth Vaccines Research Lot 06937)**

TEST	SPECIFICATIONS	RESULTS
Geometric Mean Neutralization Titers by Plaque Reduction Neutralization Assay¹		
RSV A2 (absence of complement)	Report results	1897 ± 864
RSV A2 (presence of complement)	Report results	4286 ± 542
RSV B1 (absence of complement)	Report results	1641 ± 470
RSV B1 (presence of complement)	Report results	7113 ± 371

¹Results 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.

**NR-4022, Human Antiserum to Respiratory Syncytial Virus, Medium Control
Lot V-327-513-572 (Wyeth Vaccines Research Lot 06938)**

TEST	SPECIFICATIONS	RESULTS
Geometric Mean Neutralization Titers by Plaque Reduction Neutralization Assay¹		
RSV A2 (absence of complement)	Report results	255 ± 51
RSV A2 (presence of complement)	Report results	1017 ± 117
RSV B1 (absence of complement)	Report results	161 ± 16
RSV B1 (presence of complement)	Report results	1698 ± 245

¹Results 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.

Certificate of Analysis for NR-32832

NR-4023, Human Antiserum to Respiratory Syncytial Virus, Low Control Lot V-327-514-572 (Wyeth Vaccines Research Lot 06939)

TEST	SPECIFICATIONS	RESULTS
Geometric Mean Neutralization Titers by Plaque Reduction Neutralization Assay¹		
RSV A2 (absence of complement)	Report results	310 ± 7
RSV A2 (presence of complement)	Report results	1063 ± 147
RSV B1 (absence of complement)	Report results	410 ± 93
RSV B1 (presence of complement)	Report results	1084 ± 118

¹Results 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.

NR-21973, Human Reference Immune Globulin to Respiratory Syncytial Virus Lot RSV-1

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


¹Results 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.

²NR-21973 was diluted to a final concentration of 1% immune globulin in PBS (pH 7) prior to testing in neutralization assays.

NR-49447, Human IgG-Depleted Serum Lot 63499869 (BBI Solutions SF142-2, Lot 104-207)

TEST	SPECIFICATIONS	RESULTS
Immunoglobulin (Ig) Levels		
IgA	< 0.4 g per liter	0.16 g per liter
IgG	< 5.0 g per liter	< 0.3 g per liter
IgM	< 0.2 g per liter	< 0.1 g per liter
Bioburden	< 10 CFU per mL	Pass

Date: 14 MAY 2015

Signature: 

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