

## **Certificate of Analysis for NR-31082**

## Monoclonal Anti-West Nile Virus E Protein, Clone MGAWN1 (Reference Lot 1-FIN-1027), Humanized IgG1

## Catalog No. NR-31082

This reagent is the property of the U.S. Government.

Product Description: Antibody Class: IgG1k

NR-31082 is a humanized IgG1, neutralizing monoclonal antibody that recognizes domain III of West Nile virus E protein, but not the E protein of other closely related flaviviruses.

Lot: 61277164 Manufacturing Date: 07FEB2011

TEST	SPECIFICATIONS	RESULTS
Appearance	Clear to slightly opalescent Colorless to pale yellow or pale brown May contain visible particles	Slightly opalescent Pale yellow solution No visible particles
Identity (ELISA)	Identity confirmed	Identity confirmed
Purity by SDS-PAGE (Reducing Conditions)	≥ 95.0%	99.4%
Purity by SDS-PAGE (Non-Reducing Conditions)	≥ 92.0%	99.4%
Protein Concentration by Spectrophotometry OD <sub>280</sub>	22.5 to 27.5 mg per mL	24.2 mg per mL
Relative Potency	0.65 to 1.35	0.98
Isoelectric Focusing	1 predominant band 2-4 minor bands pH range within 8.1 to 9.1 Compares to Reference Standard	1 predominant band 3 minor bands pH range within 8.5 to 8.8 Compares to Reference Standard
Size-Exclusion HPLC  Monomeric IgG  Total %HMW <sup>1</sup> Total %LMW <sup>2</sup>	≥ 95.0% ≤ 5.0% ≤ 4.0%	99.5% 0.5% 0.0%
Particulates ≥ 10 µm ≥ 25 µm	< 6000 per vial < 600 per vial	< 387 per vial < 30 per vial
Polysorbate 80 Concentration	0.025 to 0.20 mg per mL	0.10 mg per mL
Osmolality	250 to 360 mOsm per kg H <sub>2</sub> O	297 mOsm per kg H <sub>2</sub> O
Sterility	No growth (negative)	No growth (negative)
Endotoxin	< 0.17 EU per mg	0.0038 EU per mg
pH	4.9 to 5.7	5.4

<sup>&</sup>lt;sup>1</sup>HMW – High Molecular Weight species with apparent molecular weight greater than IgG monomer

<sup>2</sup>LMW – Low Molecular Weight species with apparent molecular weight less than IgG monomer

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**Date:** 20 FEB 2013

Signature:

Title:

Technical Manager, BEI Authentication or designee

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