

Certificate of Analysis for NR-19347

Mycobacterium leprae, ND-O-HSA (PGL-I based Glycoconjugate of Human Serum Albumin)

Catalog No. NR-19347

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

Product Description: NR-19347 was made using the serologically active terminal disaccharide (ND; natural disaccharide) portion of phenolic glycolipid-I (PGL-I) linked to human serum albumin (HSA) via an octyl linker arm.

Lot: 59581263 Manufacturing Date: 11JAN2011

QC testing was performed by Colorado State University under the Leprosy Research Support Contract (NIH). The Colorado State University documentation for lot ND-O-HSA 1.11.11.KL is attached.

ATCC[®], on behalf of BEI Resources, hereby represents and warrants that the material provided under this certificate has been subjected by the contractor to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and accurate to the best of ATCC[®]'s knowledge.

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NR-19347_59581263_24JAN2012



SUPPORTING INFECTIOUS DISEASE RESEARCH

Certificate of Analysis for NR-19347

QUALITY CONTROL SHEET FOR ND-O-HSA (SYNTHETIC PGL-I)

General Information

Product Lot Number: ND-O-HSA 1.11.11.KL

BEI lot number, catalogue number: 59581263 NR-19347

Purification Information

Starting material: ___disaccharide hydrazide Batch AL 20-22, 20 mg; human serum albumin, 26.0 mg

Starting Material Lot #: AL 20-22 hydrazide 84 mg total

Protocol used (SOP #'s): Delphi Chatterjee protocol with minor modifications by Dr. Kai Li (Zhang, J., D. Chatterjee, P. J. Brennan,

J. S. Spencer, and A. Liav. 2010. A modified synthesis and serological evaluation of neoglycoproteins containing the natural

disaccharide of PGL-I from Mycobacterium leprae. Bioorg. Med. Chem. Lett. 20:3250-3253)

Date started: 1/10/11 Date completed: 1/11/11

Notebook; page(s): Kai Li Notebook #1, pp 96

Additional notes (if applicable): Protein concentration of pooled fractions determined by BCA assay. Number of disaccharide

sugar residues per BSA calculated to be 41 according to MALDI data.

Quality Control Information:

Total volume: 2 ml per fraction, fractions 27-41 pooled Total amount of ND-O-HSA: 18.25 mg

Date lyophilized: 1/24/11 MALDI: 1/13/11 Notebook and page(s): Kai Li Notebook #1, pg 96

ELISA assay: ELISA assay on fractions to determine which ones contain peak activity performed on 1/11/11, J. Spencer, Book 5, ND-O-BSA and PGL-I, pg 20. Serial two-fold dilutions of ND-O-HSA coated per well (50 nanogram → 25 pg), this batch

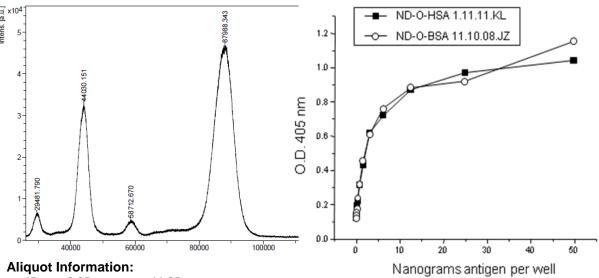
compared with reference standard batch ND-O-BSA 11.10.10.JZ. mAb CS-48 culture supernatant 1:5 dilution; ELISA assay

performed on 1/18/11, pg 22.

QC MALDI and ELISA:

MALDI





<u>45</u> x 0.25 mg = <u>11.25</u> mg <u>14</u> x 0.5 mg = <u>7.0</u> mg

(QC checked by ELISA)

1/18/11 date

(Laboratory Supervisor)

1/18/11 date

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