

Molecular Innovations, Inc.

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Certificate of Analysis

Product: IgG depleted human serum – HPLA-SER-GF

Date: February, 2013

Lot: HPLA-SER-GF-213

Physical Specifications:

Physical Appearance: clear amber liquid

Considerations:

Storage Conditions: Store frozen at -70°C – stability > 1yr

Antigen Concentration:

Total human IgG < 0.3 mg/ml

NO TEST METHOD CAN PROVIDE TOTAL ASSURANCE THAT HEPATITIS B VIRUS, HEPATITIS C VIRUS, HUMAN IMMUNODEFICIENCY VIRUS OR OTHER INFECTIOUS AGENTS ARE ABSENT. THUS, ALL BLOOD PRODUCTS THAT WE PROVIDE SHOULD BE HANDLED AT THE BIO-SAFETY LEVEL 2 AS RECOMMENDED BY THE CDC/NIH MANUAL: BIO-SAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES, FOR POTENTIALLY INFECTIOUS HUMAN SERUM OR BLOOD SPECIMENS.

EACH DONOR UNIT SUPPLIED TO YOUR FACILITY HAS BEEN TESTED ACCORDING TO FDA GUIDELINES FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN, ANTIBODIES TO HIV, ANTIBODIES TO HEPATITIS C, HIV-1 ANTIGEN (S) AND SYPHILIS. ALL UNITS YIELDED NON-REACTIVE/NEGATIVE RESULTS FOR EACH TEST PERFORMED. ALL BLOOD IS COLLECTED IN THE UNITED STATES OF AMERICA FROM HUMAN DONORS IN FDA LICENSED CENTERS AND TESTED WITH FDA APPROVED TEST KITS.

<u>TEST</u>	<u>NAME OF TEST KIT</u>	<u>MANUFACTURER/ METHOD</u>
HBsAg	AUZYME MONOCLONAL	ABBOTT
ANTI-HCV	ELISA HCV 3.0	ORTHO
ANTI-HIV 1/2	HIVAB EIA	ABBOTT
HIV-1 p24 Ag	HIVAG-1 MONOCLONAL	ABBOTT
Syphilis	RAPID PLASMA REAGIN	ARLINGTON SCIENTIFIC

ALL BLOOD PRODUCTS ARE NOT FOR USE IN PRODUCTS SUBJECT TO LICENSE UNDER SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT

Duane E. Day

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