

Certificate of Analysis

Product: Pooled Normal Human Serum

Description: All lots have been tested by A FDA approved method and found to be negative by a test for Human Immunodeficiency Virus RNA (HIV-1 RNA), Antibodies to Human Immunodeficiency Virus (Anti-HIV 1/2), Antibodies to Hepatitis C Virus (HCV), Hepatitis C Virus RNA (HCV RNA), non-reactive for Hepatitis B Surface Antigen (HbsAg), and Non-reactive by a screening test for syphilis. Not for use in products subject to license under section 351 of the public health service act.

Because no test methods can guarantee with 100% certainty the absence of an infectious agent, human derived products should be handled as suggested in the U.S. Department of Health and Human Services Manual on BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES, FOR POTENTIALLY INFECTIOUS HUMAN SERUM OR BLOOD SPECIMENS.

Expiration: Based upon evaluation of the stability of "signal chemistries" (critical parameters of the sera from the biochemical profile) serum and plasma is stable for 3 years from date of manufacture when stored in unopened containers at temperatures of -20°

Storage: -20° to -80°

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 by IBBI according to FDA guidelines for the detection of Hepatitis B surface antigen, antibodies to HIV, antibodies to Hepatitis C, HIV-1 RNA, Hepatitis C RNA, and syphilis. All units yielded non-reactive/negative results for each test performed. All blood is collected in the United States from human donors in FDA licensed centers and tested with FDA approved test kits

TEST	NAME OF TEST KIT	MANUFACTURER
HBsAg	Auzyme Monoclonal	Abbott
ANTI-HCV	Elisa HCV 3.0	Ortho
ANTI-HIV ½	HIVAB EIA	Abbott
HIV-1 RNA	HIV-1 Nat v1.5	Roche
HCV RNA	HCV NAT v2.0	Roche
Syphilis	Rapid Plasma Reagin	Arlington Scientific

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