



## Certificate of Analysis

PRODUCT: Single Donor Human Plasma ACD

CATALOG NUMBER: IPLA-0S-N-05

LOT NUMBER: Sample

NUMBER OF UNITS:

VOLUME OF UNITS:

STORAGE: -20 °

- 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.
- All materials are obtained from FDA licensed facilities (USA). The reagents that you purchase from Innovative Research, Inc are clearly labeled "For Research Use Only". To comply with U.S. Food and Drug Administration (FDA) Regulations, these products are Not for use in Clinical, Diagnostic or Therapeutic Procedures. As your supplier, we advise our customers and monitor the use of these products to ensure that they are used for research purposes only. If you have any questions, do not hesitate to contact us. Thank you for your interest in Innovative Research Inc.

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 |

- All blood products are not for use in products subject to license under section 351 of the Public Health Service Act.

## DONOR INFORMATION

|              |     |      |     |
|--------------|-----|------|-----|
| Donor Number | Age | Race | Sex |
| Sample       | 44  | B    | M   |

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