

**Molecular Innovations, Inc.**

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# Certificate of Analysis

**Product:** Human C1 Inhibitor Depleted Plasma – HPLA-SC-C1INH

**Date of Manufacture:** October, 2019

**Lot:** HPLA-SC-C1INH-5574

**Physical Specifications:**

Physical Appearance: clear amber liquid

**Antigen Concentration:**

Total Human C1 Esterase Inhibitor Antigen = <0.01 IU/ml

Prothrombin Time (PT) = 11.6 sec

Activated Partial Thromboplastin Time (aPTT) = 39.9 sec

**Considerations:**

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

Other: Depleted by immunoaffinity chromatography

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 AND FOUND NEGATIVE BY FDA AND/OR CE MARKED TESTS FOR ANTI-HIV-1/2, ANTI-HCV, HBSAG, SYPHILIS, HIV-1, AND HCV RNA. THE DONORS WERE SCREENED AND FOUND NEGATIVE FOR CREUTZFELDT-JAKOB DISEASE (CJD). ALL BLOOD IS COLLECTED IN 3.2% CITRATE FROM HUMAN DONORS OF BOTH SEXES.

**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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