

ImmunoVision

A member of Erba Mannheim

CERTIFICATE OF ANALYSIS

Product Number: HCT-0100

Description: Positive Control Sera: Human antibody against Centromere, buffered with 0.01M phosphate, 0.13 M NaCl, 0.02% NaN₃. Titer is between 1:1000 and 1:5000 ANA by IFA.

Lot Number: 6294

Amount: 2 mL

Appearance: Lyophilized Powder

Shelf Life: Store at <15°C, good for 24 months after reconstitution while stored at <15°C

Instructions: Reconstitute with 2 ml deionized H₂O

Manufacturing Method:

Single donor human plasma is delipidized and defibrinated, then the immunoglobulin fraction is precipitated and collected. Antibody concentration is adjusted for consistent lot to lot titer.

Assays:

ELISA:

Test	Results
ANA on Hep-2	Centromere titer 1080

Interpretation of Results:
Neg<40

Infectious Disease Testing:

This product has tested non-reactive for HBsAg, HIVAg, α -HIV, α -HBC, and α -HCV.


Quality Director

05/09/2022
Date