



Certificate of Analysis

Reason for Submission: Release Corrected Amended

LOT NUMBER:

PRODUCT NAME: Recombinant Hepatitis C nucleocapsid protein (p22)

DESCRIPTION: Recombinant Hepatitis C nucleocapsid protein (p22) produced in *Pichia pastoris*. Amino terminal 120 amino acids encodes a 16 kDa protein. Appears as a monomer at ~19 kDa on Western blots (also a dimer at ~34 kDa at higher loads). Reacts with patient sera, polyclonal and monoclonal antibodies as determined by ELISA / Western blot.

STORAGE: Supplied frozen and should be stored at -70°C or below. Aliquots should be dispensed to avoid multiple freeze thaws.

PACKAGING: Supplied in cryovials or other suitable container. Vials are filled to contain the exact amount of protein state on the label. Losses will occur when aliquoting.

DATE OF MFG:

EXPIRY DATE: Greater than one year form date of receipt

I. BULK PRODUCT ANALYSIS

	Attribute	Specification	Result
1.	Physical Characteristics		
1.1	Appearance	Colorless clear solution	
1.2	Formulation	6 M Urea, 0.25 M NaCl, 0.05 M Tris-HCl	
1.3	pH	7.5 to 8.5	

	Attribute	Specification	Result
2	Identity / Purity		
2.1	Molecular Weight by SDS-PAGE	Major band at ~19 kDa. Minor band at ~34 kDa. Comparable to reference lot.	
2.2	Immunospecificity by Western Blot	Major band at ~19 kDa. Minor bands ~34 kDa and two to three minor bands betwe 14 and 19 kDa. Comparable to reference lot.	
3	Potency		
3.1	Protein Concentration by Pierce BCA	Greater than or equal to 1 mg/ml \pm 10%	

Comments: All tests reported as pass

Production Manager or Scientific Director

Date

**NOT A FINISHED PRODUCT
INTENDED FOR FURTHER MANUFACTURING PROCESSING ONLY**

**BIOHAZARD INFORMATION
No physical or health hazards under OSHA definitions (NOT HAZARDOUS)**