



Certificate of Analysis

Reason for Submission: ☐ Release ☐ Corrected ☐ Amendment

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 stated on the label. Losses will occur when aliquoting.

DATE OF MFG:

EXPIRATION DATE: Greater than one year from date of receipt

I. BULK PRODUCT ANALYSIS

	Attribute	Specification	Result
1.	Physical Characteristics		
1.1	Appearance	Colorless or off-white, clear to opalescent solution	
1.2	Formulation	0.05 Sodium Phosphate, 0.15 M NaCl	
1.3	pH	6.5 – 8.5	

	Attribute	Specification	Result
2	Identity / Purity		
2.1	Molecular Weight by SDS-PAGE	Major band migrating at between 14 and 20 kDa. Comparable to reference lot.	
2.2	Immunospecificity by Western Blot	Major band between 14 and 20 kDa, comigrating with major band on stained gel, required. Minor bands allowed. Comparable to reference lot.	
3	Potency		
3.1	Protein Concentration by Coomassie Plus	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)**