



Product Overview

PRODUCT:	Hepatitis Negative, Delipidized, Human Serum
PART NUMBER:	5349
FORM / APPEARANCE:	Liquid, amber to straw, free of visible foreign matter, clots or precipitates
FILTRATION:	0.22 micron-filtered
ADDITIVES:	None
STORAGE:	< - 10 °C
EXPIRATION:	5 years from date of manufacture

Analytical Properties

ANALYTE	VALUE
TOTAL PROTEIN:	5.5 – 6.0 g/dL
aHBs:	≤ 0.8 mIU/mL
aHBc:	< 0.5 S/CO
aHBc IgM:	< 0.8 S/CO
aHAV:	≤ 1.0 S/CO
aHBe:	Nonreactive
HBeAg:	Nonreactive
HBsAg:	Nonreactive
aTP:	Negative
TRIGLYCERIDES:	< 20 mg/dL
CHOLESTEROL:	< 25 mg/dL
CALCIUM:	< 10 mg/dL
SODIUM	130 – 148 mmol/L
CHLORIDE:	90 – 110 mmol/L
POTASSIUM:	3.2 – 5.4 mmol/L
AMMONIA:	< 0.5 mg/dL
IRON:	< 500 µg/dL
HEMOGLOBIN:	< 15 mg/dL
ALK. PHOSPHOTASE:	< 120 U/L
pH:	7.0 – 7.5
TURBIDITY (O.D. @ 546nm):	< 0.16
BIOBURDEN:	< 10 CFUs/mL

FOR IN VITRO DIAGNOSTIC MANUFACTURING USE ONLY

All human plasma units used to prepare this product have been tested by FDA approved tests and found to be non-reactive for HbsAg, Anti-HIV I/II, Anti-HCV, HIV-1 RNA, and HCV RNA. Donors of human plasma units used in the making of this product were tested and found negative for Syphilis according to FDA guidelines.

CAUTION: FOR USE IN RESEARCH OR REMANUFACTURE OF NON-INJECTABLE PRODUCTS NOT SUBJECT TO LICENSE UNDER PHS ACT SECTION 351, ONLY.

CAUTION: ALL BLOOD PRODUCTS SHOULD BE HANDLED AND TREATED AS POTENTIALLY INFECTIOUS.

