

## **Product Overview**

| PRODUCT: | Hepatitis Negative, Human Serum    |
|----------|------------------------------------|
|          | riepatitis riepative, riaman seram |

| PART NUMBER:       | 5227  |
|--------------------|---|
| FORM / APPEARANCE: | Liquid, amber to straw, free of visible foreign matter, clots or precipitates |
| FILTRATION:        | 0.22 micron-filtered  |
| ADDITIVES:         | No preservatives  |
| STORAGE:           | ≤ - 10 °C   |
| EXPIRATION:        | 5 years from date of manufacture  |

## **Analytical Properties**

| ANALYTE           | VALUE             |
|-------------------|-------------------|
| TOTAL PROTEIN:    | ≥ 5.5 g/dL        |
| aHBs:             | ≤ 3.0 mIU/mL      |
| aHAV:             | < 0.8 S/CO        |
| аНВс:             | < 0.5 S/CO        |
| aHBc IgM:         | < 0.8 S/CO        |
| aHAV IgM:         | Negative          |
| TRIGLYCERIDES:    | 90 – 200 mg/dL    |
| CHOLESTEROL:      | 140 – 230 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       |
| pH:               | 7.0 – 7.5         |
| TURBIDITY (O.D. @ | < 0.180           |
| 546nm):           | <b>\(\times\)</b> |
| 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