



## Product Overview

PRODUCT:	Immunology Control, 2 Level
PART NUMBER:	5323
FORM / APPEARANCE:	Liquid, amber to straw, free of visible foreign matter, clots or precipitates
FILTRATION:	0.22 micron-filtered
ADDITIVES:	Sodium Azide
STORAGE:	2 – 8 °C
EXPIRATION:	15 months from date of manufacture

## Analytical Properties

ANALYTE	VALUES	
	Level 1	Level 2
TOTAL PROTEIN:	< 6.5 g/dL	< 15 g/dL
IgG:	730 – 1030 mg/dL	1720 – 2410 mg/dL
IgA:	153 – 235 mg/dL	367 – 500 mg/dL
C3:	66 – 90 mg/dL	200 – 280 mg/dL
C4:	12 – 21 mg/dL	35 – 57 mg/dL
CRP:	0.68 – 0.92 mg/dL	3.7 – 4.9 mg/dL
RF:	18 – 32 IU/mL	85 – 115 IU/mL
ASO:	70 – 100 IU/mL	180 – 240 IU/mL
pH:	6.5 – 7.0	6.5 – 7.0
TURBIDITY (O.D. @ 546nm):	< 0.28	< 0.28
BIOBURDEN:	< 100 CFUs/mL	< 100 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

