



Product Overview

PRODUCT:	Specialty Immunoassay Control, Lyophilized, 2 Level
PART NUMBER:	4943
FORM / APPEARANCE:	Lyophilized powder
FILTRATION:	0.22 micron-filtered
ADDITIVES:	Stabilizers
STORAGE:	2 – 8 °C
EXPIRATION:	3 years from date of manufacture

Analytical Properties

ANALYTE	VALUES	
	Level 1	Level 2
ACTH:	10 – 30 pg/mL	350 – 500 pg/mL
TSH RECEPTOR ANTIBODY (TRAb):	0 – 2 IU/mL	4 – 6 IU/mL
ANTI-TG:	40 – 100 IU/mL	300 – 500 IU/mL
ANTI-TPO:	30 – 80 IU/mL	300 – 500 IU/mL
TG:	0 – 10 ng/mL	100 – 160 ng/mL
RENIN:	10 – 30 pg/mL	60 – 100 pg/mL
ALDOSTERONE:	40 – 100 pg/mL	300 – 500 pg/mL
CALCITONIN:	5 – 15 ng/L	70 – 130 ng/L
PROCALCITONIN:	0.4 – 0.8 ng/mL	10 – 13 ng/mL
MOISTURE:	< 2%	< 2%
BIOBURDEN:	< 10 CFUs/mL	< 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.