



Product Overview

PRODUCT:	Immunoassay Verification for POC Analyzers, Liquid, 3 Levels
PART NUMBER:	4740
FORM / APPEARANCE:	Liquid, golden to straw, free of visible foreign matter, clots, or precipitate
FILTRATION:	0.22 micron-filtered
ADDITIVES:	None
STORAGE:	≤ -20°C
EXPIRATION:	1 year from date of manufacture

Analytical Properties

ANALYTE	VALUES		
	LEVEL 1	LEVEL 2	LEVEL 3
FT4:	0.45 – 0.55 ng/mL	1.5 – 2.5 ng/mL	4.5 – 5.5 ng/mL
PSA:	0.12 – 0.2 ng/mL	3 – 5 ng/mL	22.5 – 24.5 ng/mL
TESTOSTERONE:	0.25 – 0.35 ng/mL	5 – 7 ng/mL	13.5 – 14.5 ng/mL
TSH:	0.08 – 0.15 mIU/L	3 – 5 mIU/L	22.5 – 24.5 mIU/L
VITAMIN D:	12 – 40 ng/mL	32 – 48 ng/mL	90 – 105 ng/mL
BIOBURDEN:	< 100 CFUs/mL	< 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.