



## Product Overview

PRODUCT:	HbA1c Linearity, POC Methods (4-13%), 4 Levels
PART NUMBER:	4610
FORM / APPEARANCE:	Liquid
FILTRATION:	0.22 micron-filtered
ADDITIVES:	Stabilizers
STORAGE:	< -20°C
EXPIRATION:	2 years from date of manufacture

## Analytical Properties

ANALYTE	VALUES			
	Level 1	Level 2	Level 3	Level 4
HbA1c:	4.5 – 5.5 %	6.0 – 7.0 %	7.5 – 8.5 %	10.5 – 11.5 %
HEMOGLOBIN:	13 – 15 g/dL	13 – 15 g/dL	13 – 15 g/dL	13 – 15 g/dL
BIOBURDEN:	< 100 CFUs/mL	< 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.