

***Certificate of Analysis***

Product Name: Abbott Urine/CSF Protein Calibrator  
OEM Part Number: 01E7103  
OEM Lot Number: 19275UN22  
Storage: 2 - 8°C  
Qty Manufactured: 985 Kits

Abbott List Number: 01E7103  
Abbott Commodity Number: 01E7103  
Expiration Date: 2024-01-31  
Package Insert No./Rev. G95936 / R02

Description	Lot Number	Expiration Date
Level 1 (0.1 ± 0.02)	19275A	2024-01-31
Level 2 (0.2 ± 0.02)	19275B	2024-01-31
Level 3 (0.4 ± 0.02)	19275C	2024-01-31
Level 4 (0.8 ± 0.04)	19275D	2024-01-31
Level 5 (2.0 ± 0.10)	19275E	2024-01-31

Specification	Specification Limit	Result
Control L1*	±15% of Target	3 %
Control L1	Lot Number	88151
Control L2*	±10% of Target	0 %
Control L2	Lot Number	88152
Comparison Study	±5% of PRL** Calibrator	1 %
Date of Manufacture	Report	2022-01-12

For in-vitro diagnostic use.

\* Control recoveries generated on the Architect c System

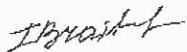
\*\* Previously Released Lot

PRECAUTIONS: This product contains source material of human origin which has been tested by FDA approved methods for the presence of antibody to HIV-1, HIV-2, HCV and Hepatitis B surface antigen and found to be non-reactive. No test method; however, can offer complete assurance that an infectious agent is absent. Therefore, all solutions containing human source material should be handled as potentially infectious and with good laboratory practice to avoid skin contact and ingestion.

This lot meets all current specifications per quality document MS.MASTER342.

The above product has been manufactured in accordance with Quality Systems Regulations, passed all Thermo Fisher final release specifications, and has met all Abbott acceptance requirements.

Reference the package insert for the standard/product to which the calibrator concentration is traceable and the methodology for calibrator value assignment.



Quality Representative

Date: 2022-03-23