

Certificate of Analysis

Product Name: ICT SERUM CALIBRATOR
OEM Part Number: 01E460004
OEM Lot Number: 50737UN22
Storage: 15 - 30°C
Qty Manufactured: 271 Kits

Abbott List Number: 01E4604
Abbott Commodity Number: 01E4604
Expiration Date: 2023-09-13
Package Insert No./Rev. G95926 / R02

Description	Lot Number	Expiration Date
Low Calibrator	450739	2023-09-13
High Calibrator	450734	2023-09-13

Specification	Specification Limit	Result
Low Calibrator: Appearance	Clear liquid free of turbidity.	Complies Pass
Low Calibrator: Na+ Concentration	119.0 - 122.0 mmol/L	120.8 Pass
Low Calibrator: K+ Concentration	3.30 - 3.40 mmol/L	3.36 Pass
Low Calibrator: Cl- Concentration	79.0 - 82.0 mmol/L	79.9 Pass
Low Calibrator: TP Concentration	6.5 - 7.5 g/dL	6.8 Pass
Low Calibrator: NH4+ Concentration	< 1.00 for each individual sample	Complies Pass
Pre-irradiated Microbial Concentration*	<=100 CFU	1 Pass
High Calibrator: Appearance	Clear liquid free of turbidity.	Complies Pass
High Calibrator: Na+ Concentration	159.0 - 162.0 mmol/L	161.1 Pass
High Calibrator: K+ Concentration	7.90 - 8.05 mmol/L	7.96 Pass
High Calibrator: Cl- Concentration	119.0 - 122.0 mmol/L	119.9 Pass
High Calibrator: TP Concentration	6.5 - 7.5 g/dL	6.8 Pass
High Calibrator: NH4+ Concentration	< 1.00 mMol/L for each individual sample	Complies Pass
Pre-irradiated Microbial Concentration*	<=100 CFU	3 Pass
Test Date	Report	06-30-22
Date of Manufacture	Report	13-JUN-22

For in-vitro diagnostic use.

This product contains animal source material. The bovine material used in the manufacture of this product is derived from bovine blood collected from U.S. sourced cattle slaughtered at a USDA licensed establishment.

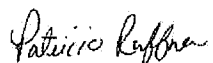
This lot meets all current release specifications per quality document MS.MASTER342.

Sodium and Potassium results traceable to NIST SRM 956d
Chloride results traceable to NIST SRM 999b

* Microbial Concentration above are based on a 50 mL Sample Size.

Fill Volume (Low and High) >= 10.0 mL Complies Pass

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



Quality Representative

Date: 2022-07-01