

Certificate of Analysis
Carbon Dioxide Calibrator

Thermo Fisher Scientific Part Number:	1E64-03	Total Quantity Manufactured:	2,064
List Number:	01E6403	Storage Temperature:	2-8°C
Kit Lot Number:	64161FD01	Package Insert Commodity # & rev #:	G95965R02
Kit Expiration Date:	2023-04-13		

Calibrator	Lot Number	Date of Manufacture	Expiration Date	Closed Vial Shelf Life	Open Vial Stability
Level 1	74564168	2022-04-13	2023-04-13	12 Months at 2-8°C from DOM	30 days at 2-8°C
Level 2	74564169	2022-04-13	2023-04-13		

	Appearance	Microbial	Fill Volume	
Specification	Clear, Colorless without particles	< 100 CFU/mL	5.0 - 5.2 mL	Pass / Fail
Level 1	Clear, Colorless without particles	0 CFU/mL	5.0 - 5.2 mL	PASS
Level 2	Clear, Colorless without particles	0 CFU/mL	5.0 - 5.2 mL	PASS

Value Assignment on ARCHITECT C-Series Systems using CO2 Reagent 03L80 using NIST SRM351a or Traceable ThermoFisher Standard				
CO2	Target	Range	Assigned Value	Pass / Fail
Level 1	22.0 mEq/L	20.8 to 23.2 mEq/L	21.2 mEq/L	PASS
Level 2	43.0 mEq/L	40.8 to 45.2 mEq/L	41.5 mEq/L	PASS

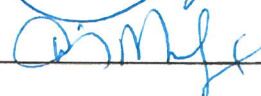
Value Verification Recovery of Previous Lot					
Previous Lot	Lot Number	Specification	Assigned Value	Result	Pass / Fail
Level 1	74476832	± 5% of Assigned Value	21.4 mEq/L	21.9 mEq/L	PASS
Level 2	74476850	± 5% of Assigned Value	41.7 mEq/L	42.2 mEq/L	PASS

Value Verification Recovery of Standard					
Standard*	Lot Number	Specification	Assigned / Nominal Value	Result	Pass / Fail
Thermo Fisher	L411306	± 5% of Nominal or Assigned Value	20.0 mEq/L	20.3 mEq/L	PASS
Thermo Fisher	L411306	± 5% of Nominal or Assigned Value	40.0 mEq/L	39.9 mEq/L	PASS

* Indicate NIST SRM351a or Thermo Fisher equivalent.

This product was manufactured in accordance with Quality System Regulations. Meets all Thermo Fisher Scientific / Microgenics Final Release Specification and Abbott Acceptance Requirements including MS. MASTER 342.

Completed by:  Date: 04/22/22

Quality Approval:  Date: 04/22/22