

Certificate of Analysis
Abbott Bilirubin Calibrator

Abbott Material Number:	08P6101
Thermo Fisher Kit Part Number:	10022591
Abbott Commodity Number:	08P6101
Abbott Kit Lot Number:	57000FD01
Expiration Date:	2023-03-31

Total Quantity Manufactured:	5,762
Package Insert Commodity# & rev#:	G71359R02
Storage Temperature:	2 - 8 °C

Item:	Lot Number	Date of Dispense / Manufacture	Expiration Date
Abbott Bilirubin Level 1	57000FD01A	2021-09-17	2023-03-31
Abbott Bilirubin Level 2	57000FD01B	2021-09-23	2023-03-31

Visual Specification:	Clean, Clear, Yellow colored Liquid	PASS / FAIL
Abbott Bilirubin Level 1	Clean, Clear, Yellow colored Liquid	PASS
Abbott Bilirubin Level 2	Clean, Clear, Yellow colored Liquid	PASS

Specification:	Fill Volume	Microbial	Homogeneity (T.Bil)	PASS / FAIL
	5.0 - 5.3 mL	No Growth	≤ 0.50 %CV	
Abbott Bilirubin Level 1	5.2 mL	No Growth	0.10 %	PASS
Abbott Bilirubin Level 2	5.2 mL	No Growth	0.40 %	PASS

Analysis on ARCHITECT C-Series Systems using BILIT Reagent LN 06L45 and BIL D Reagent LN 08G63							
Level 1	Fresh	72hr @ 41°C	Unit Change	14 Day Open	Unit Change	Specification	Pass / Fail
T-Bil (0.7 to 2.1 mg/dL)	1.6	1.6	0.00 mg/dL	1.5	-0.03 mg/dL	± 0.06 mg/dL	PASS
D-Bil (0.3 - 1.3 mg/dL)	1.0	0.9	-0.01 mg/dL	0.9	-0.02 mg/dL	± 0.04 mg/dL	PASS
Level 2	Fresh	72hr @ 41°C	Unit Change	14 Day Open	Unit Change	Specification	Pass / Fail
T-Bil (14 - 20 mg/dL)	16	16	-0.29 mg/dL	16	-0.24 mg/dL	± 0.75 mg/dL	PASS
D-Bil (6.6 - 9.8 mg/dL)	8.5	8.5	0.04 mg/dL	8.4	-0.04 mg/dL	± 0.43 mg/dL	PASS

Raw materials used in this product were collected entirely from animals that have received ante and post-mortem inspections under a veterinarian's supervision and were apparently free from infectious and contagious diseases including BSE (Bovine Spongiform Encephalopathy). Veterinary Certificates are maintained on file at the manufacturing site. The material does not contain, nor is derived from Specified Risk Materials as defined in Commission decision 97/534/EC. This is to certify that the listed product meets all Abbott specifications/criteria and was manufactured in accordance with United States Good Manufacturing Practices.

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

Completed by: *Asheley Chung*

Date: 12/09/21

Quality Approval: *[Signature]*

Date: 12/09/21

Legal Entity: Microgenics Corporation