

Product Name:	Alinity c Total Bilirubin Reagent Kit		
Sekisui Cat. No.:	04V5121	Abbott List No.:	04V5121
Sekisui Lot Number:	61238UQ12	Abbott Commodity Number:	04V5121
Storage Temperature:	2-8°C	Expiration Date (YYYY-MM-DD):	2023-05-31
Quantity Manufactured:	1723 kits	Package Insert No./Rev.:	G99838R02

Reagent Information				
Total Bilirubin Reagent R1 Bulk Part No. IT285-30-AR		Lot No.:	61239	
Total Bilirubin Reagent R2 Bulk Part No. IT243-10-DR		Lot No.:	61240	
Test performed on Alinity c-Series analyzers using	Technopath Multichem S Plus 1 (08P88-10)	Lot No.:	0196091901	
	Technopath Multichem S Plus 2 (08P88-11)	Lot No.:	0196091902	
	Technopath Multichem S Plus 3 (08P88-12)	Lot No.:	0196091903	
	Bio-Rad Pediatric Liquichek 2 (355)	Lot No.:	44372	
	Abbott Bilirubin Calibrator Level 1 and 2 (08P6101)			10976FD01
Test Date:		18-Mar-2022		
Test	Specification Limit	Results	Pass/Fail	
Minimum Fill Volume (R1)	≥ 53.5 mL	Complies	Pass	
Minimum Fill Volume (R2)	≥ 17.0 mL	Complies	Pass	
Label Claim volume	52.9 mL	Complies	Pass	
Label Claim volume	16.8 mL	Complies	Pass	
Instrument Testing (using barcode scanned reagent cartridge)	Technopath S L1	0.55 - 1.11 mg/dL	0.89 mg/dL	Pass
	Technopath S L2	2.64 - 3.20 mg/dL	2.81 mg/dL	Pass
	Technopath S L3	5.89 - 7.13 mg/dL	6.24 mg/dL	Pass
	Bio-Rad Pediatric L2	14.41 - 17.59 mg/dL	17.14 mg/dL	Pass
	Standard L3	% difference within ±10% of expected value	-8 %	Pass
	Instrument	Alinity c	Complies	Pass
UV/VIS Testing (OD)	Beginning (R1)	≤ 0.75 OD @ 365 nm	0.07 OD	Pass
	Middle (R1)	≤ 0.75 OD @ 365 nm	0.07 OD	Pass
	End (R1)	≤ 0.75 OD @ 365 nm	0.07 OD	Pass
Barcode Scan	Acceptance verification on Alinity c	Complies	Pass	
Barcode Verification Requirements				
Barcode	Reagent Lot Number		61238UQ12	Pass
	Expiration Date		2023.05.31	Pass
	Onboard Stability (hrs) 0504		Complies	Pass
	Assay/Number	Bili Total/1094	Complies	Pass
Component Information				
S/N	R1 =	02311	Pass	

For in vitro diagnostic use only.

Sekisui Diagnostics, LLC
 One Wall Street
 Burlington, MA 01803
 Tel: 1-800-332-1042 Fax: 781-652-7901

Sekisui Diagnostics (UK) Ltd
 Liphook Way, Allington
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Sekisui Diagnostics P.E.I. Inc.
 70 Watts Avenue
 Charlottetown, Prince Edward Island
 C1E 2B9 Canada
 Tel: 1-800-565-0265 Fax: 902 628 6504

Certificate of Analysis

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

Has this lot been reworked? Yes No

23-Mar-2022

Date

[Signature]

Quality Control

The above product has been manufactured in accordance with ISO 9001:2015 and ISO 13485:2016 quality management system regulations, passed all Sekisui Diagnostics P.E.I. Inc. final release specifications and has met all Abbott acceptance requirements.

The above reagent has been released for distribution.

24-Mar-2022

Date

[Signature]

Quality Assurance

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