SEKISUI DIAGNOSTICS

Cruz Bella Rose Navarro

Digitally signed by Cruz Bella Rose Navarro
DN: c=VN, st=THÀNH PHỐ HÀ NỘI, o=Văn phòng đại diện ABBOTT LABORATORIES GMBH tại thành phố Hà Nội, title=Trưởng Đại Diện, cn=Cruz Bella Rose Navarro, 0.9.2342.19200300.100.1.1=MST:P5954425A
Date: 2022.05.11 17:30:24 +07'00'

Certificate of Analysis

Product Name:	Total Bilirubin	Abbott List No.:	06L4522
Sekisui Cat. No.:	6L45-22	Abbott Commodity Number:	06L4522
Sekisui Lot Number:	60977UQ01	Expiration Date (YYYY-MM-DD):	2023-06-30
Storage Temperature:	2-8°C	Package Insert No./Rev.:	G96043R01
Quantity Manufactured:	1716 kits		

Reagent Information					
Total Bilirubin Reagent R1 Bulk Part No. IT285-30-AR		Lot No.:	60978		
Total Bilirubin Reagent R2 Bulk Part No. IT243-10-DR		Lot No.:	60979		
Test performed on Architect analyzers using	Bio-Rad Serum Lyphochek 1 (C-320-10)	Lot No.:	55911	Test Date:	07-Mar-2022
	Bio-Rad Serum Lyphochek 2 (C-325-10)	Lot No.:	55912		
	Bio-Rad Pediatric Liquichek 1 (354)	Lot No.:	44371	Test Date:	07-Mar-2022
	Bio-Rad Pediatric Liquichek 2 (355)	Lot No.:	44372		
	Abbott Bilirubin Calibrator Level 1 and 2 (1E66)	Lot No.:	25822FD01	Instrument Calibration Factor:	118
					109

Test	Specification Limit		Results	Pass/Fail
Minimum Fill Volume (R1)	≥ 53 mL		Complies	Pass
Minimum Fill Volume (R2)	≥ 17 mL		Complies	Pass
Label Claim volume (R1)	53 mL		Complies	Pass
Label Claim volume (R2)	17 mL		Complies	Pass
Instrument Testing (using barcode scanned reagent cartridge)	Bio-Rad Serum L1	1.1 - 1.5 mg/dL	1.3 mg/dL	Pass
	Bio-Rad Serum L2	4.1 - 4.8 mg/dL	4.3 mg/dL	Pass
	Bio-Rad Pediatric L1	5.0 - 6.1 mg/dL	5.9 mg/dL	Pass
	Bio-Rad Pediatric L2	14.4 - 17.6 mg/dL	16.8 mg/dL	Pass
	Standard L3	% difference within ±10% of expected value	-7 %	Pass
	Instrument	ARCHITECT cSystem	c8000	Pass
UV/VIS Testing (OD)	Beginning (R1)	≤ 0.75 OD @ 365 nm	0.09 OD	Pass
	Middle (R1)	≤ 0.75 OD @ 365 nm	0.08 OD	Pass
	End (R1)	≤ 0.75 OD @ 365 nm	0.08 OD	Pass
Barcode Scan	Acceptance verification on c8000		Complies	Pass

Sekisui Diagnostics, LLC
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C1E 2B9 Canada
Tel: 1-800-565-0265 Fax: 902 628 6504

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Certificate of Analysis

Barcode Verification Requirements				
Barcode	Reagent Lot Number		60977UQ01	Pass
	Expiration Date		2023.06.30	Pass
	Onboard Stability (hrs) 0504		Complies	Pass
	Assay/Number	BiliT/1094	Complies	Pass
Component Information				
Position	R1 =		C1	Pass
	R2 =		C1	Pass
S/N	R1 =		09622	Pass
	R2 =		10669	Pass

For in vitro diagnostic use only.

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

Has this lot been reworked? ☐ Yes ☑ No

10 Mar 2022
Date

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.

10-Mar-2022
Date

Quality Assurance

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