



**Certificate of Analysis for i2000SR
Template**

Flextronics Manufacturing (Singapore) Pte. Ltd.
1 Kallang Place
Singapore 339211
Main: +65 6507 6507
www.flextronics.com

**ARCHITECT i2000SR
Certificate of Analysis**

Serial No: ISR64824

Product Name: Architect i2000SR
 Test Procedure: TP 94000 Rev: AW
 Tested Date: 30 Aug 2021

Item	Criteria	Result	Judge
Calibration of Pipettes	1) 1111 Sample Pipettor Calibration Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<u>Pass</u> Fail
	2) 1112 R1 Pipettor Calibration Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<u>Pass</u> Fail
	3) 1113 R2 Pipettor Calibration Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<u>Pass</u> Fail
	4) 1117 STAT Pipettor Calibration Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<u>Pass</u> Fail
System Start-up	1) 2130 Flush Fluids Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<u>Pass</u> Fail
Temperature Status Check	3520 Temperature Status		
	A) P Path Zone 1	36.4 – 37.6 °C	A) <u>37.0</u> °C
	B) P Path Zone 2	36.4 – 37.6 °C	B) <u>37.0</u> °C
	C) P Path Zone 3	36.4 – 37.6 °C	C) <u>37.0</u> °C
	D) P Path Zone 4	36.4 – 37.6 °C	D) <u>37.0</u> °C
	E) P Path Zone 5	36.4 – 37.6 °C	E) <u>37.0</u> °C
	F) P Path Zone 6	36.4 – 37.6 °C	F) <u>37.0</u> °C
	G) Pre-trigger	32.0 – 37.6 °C	G) <u>35.8</u> °C
	H) Trigger	32.0 – 37.6 °C	H) <u>35.8</u> °C
	I) Wash Zone 1	34.0 – 36.5 °C	I) <u>35.5</u> °C
	J) Wash Zone 2	34.0 – 36.5 °C	J) <u>35.5</u> °C
K) Reagent Cooler	2.0 – 12.0 °C	K) <u>5.4</u> °C	

COMPANY CONFIDENTIAL

This Document is controlled in QDMS. All Copies (electronic or printed) are considered uncontrolled.



**Certificate of Analysis for i2000SR
Template**

Flextronics Manufacturing (Singapore) Pte. Ltd.
1 Kallang Place
Singapore 339211
Main: +65 6507 6507
www.flextronics.com

**ARCHITECT i2000SR
Certificate of Analysis**

Serial No: iSR64824

Item	Criteria	Result	Judge	
Optics Tests	1020 Optics Background Test			
	A) No RV, open position	3 - 500	66	Pass
	B) Empty RV	3 - 500	44	
	C) RV with Fluid	3 - 500	50	
	1045 Optics Verification Test			
	A) Mean 1 : Target Value (RLU) ±18%			Pass
	LSL Target Value USL			
	26403 ~ 32199 ~ 37995		31601 RLU	
	B) Mean 2 : Target Value (RLU) ±18%			
	LSL Target Value USL			
	110251 ~ 134452 ~ 158653		131777 RLU	
C) Mean 3 : Target Value (RLU) ±18%				
LSL Target Value USL				
2130328 ~ 2597961 ~ 3065594		2555758 RLU		
	LSL	USL		
D) %CV 1	0.00	5.00	0.85 %	
E) %CV 2	0.00	5.00	0.64 %	
F) %CV 3	0.00	5.00	0.79 %	
G) Range Deviation (%)	0.00	21.50	0.36 %	
Electrical Safety Tests	1) Ground Continuity Test Test passes all the test point without errors	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	Pass Fail	
	2) Hypot Test Test passes without error	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	Pass Fail	

The above product has been manufactured in accordance with Abbott operating procedures and conforms in all respects with the specific final product specifications as tested and inspected by Product Test.

Final Disposition	PASS	FAIL
-------------------	-------------	------

Data Verification By	<u>Thong Choi Choi</u>	<u>[Signature]</u>	<u>22 Mar 2022</u>
	Printed Name	Signature	Date
QA Approval By	<u>Duraisamy Dayalan</u>	<u>[Signature]</u>	<u>22 MAR 2022</u>
	Printed Name	Signature	Date

COMPANY CONFIDENTIAL

This Document is controlled in QDMS. All Copies (electronic or printed) are considered uncontrolled.