



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	☒ Completed ☐ Not completed	Pass Fail
	2) 1112 R1 Pipettor Calibration Procedure	☒ Completed ☐ Not completed	Pass Fail
	3) 1113 R2 Pipettor Calibration Procedure	☒ Completed ☐ Not completed	Pass Fail
	4) 1117 STAT Pipettor Calibration Procedure	☒ Completed ☐ Not completed	Pass Fail
System Start-up	1) 2130 Flush Fluids Procedure	☒ Completed ☐ Not completed	Pass 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
			Pass Fail

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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	Fail
	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	☒ Pass ☐ Fail	Pass Fail	
	2) Hypot Test Test passes without error	☒ Pass ☐ 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
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Data Verification By	Thong Choi Choi		22 Mar 2022
	Printed Name	Signature	Date
QA Approval By	Duraisamy Dayalan		22 MAR 2022
	Printed Name	Signature	Date

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Item	Criteria	Result	Judge
Calibration of Pipettes	1) 1111 Sample Pipettor Calibration Procedure	☒ Completed ☐ Not completed	Pass Fail
	2) 1112 R1 Pipettor Calibration Procedure	☒ Completed ☐ Not completed	Pass Fail
	3) 1113 R2 Pipettor Calibration Procedure	☒ Completed ☐ Not completed	Pass Fail
	4) 1117 STAT Pipettor Calibration Procedure	☒ Completed ☐ Not completed	Pass Fail
System Start-up	1) 2130 Flush Fluids Procedure	☒ Completed ☐ Not completed	Pass 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>35.7</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>7.6</u> °C
			Pass Fail

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ARCHITECT i2000SR Certificate of Analysis

Serial No: ISR64825

Item	Criteria	Result	Judge	
Optics Tests	1020 Optics Background Test			
	A) No RV, open position	3 - 500	39	Pass
	B) Empty RV	3 - 500	37	
	C) RV with Fluid	3 - 500	31	Fail
	1045 Optics Verification Test			
	A) Mean 1 : Target Value (RLU) ±18%			Pass
	LSL Target Value USL			
	26403 ~ 32199 ~ 37995	32933	RLU	
	B) Mean 2 : Target Value (RLU) ±18%			
	LSL Target Value USL			
	110251 ~ 134452 ~ 158653	136260	RLU	
	C) Mean 3 : Target Value (RLU) ±18%			
	LSL Target Value USL			
	2130328 ~ 2597961 ~ 3065594	2607818	RLU	
	LSL	USL		
D) %CV 1	0.00	5.00	0.33	%
E) %CV 2	0.00	5.00	1.09	%
F) %CV 3	0.00	5.00	0.61	%
G) Range Deviation (%)	0.00	21.50	1.89	%
Electrical Safety Tests	1) Ground Continuity Test Test passes all the test point without errors	☒ Pass ☐ Fail	Pass Fail	
	2) Hypot Test Test passes without error	☒ Pass ☐ 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
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Data Verification By	Thong Choi Choi	Coching	22 Mar 2022
	Printed Name	Signature	Date
QA Approval By	Duraismy Dayalan	Duraismy	22 MAR 2022
	Printed Name	Signature	Date

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Declaration of Conformity

Certificate Identification: 3M74
Legal Manufacturer's Name: Abbott Laboratories
Legal Manufacturer's Address: 1915 Hurd Drive, Irving TX 75038 USA

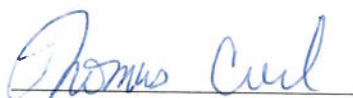
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
03M74-02	56701	ARCHITECT i2000 _{SR} PROCESSING MODULE	Self-declared

Authorized European Representative (name and address)	Abbott GmbH, Max Planck Ring-2, 65205, Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, United States
Physical manufacturer (name and address)	Flextronics Manufacturing (SINGAPORE) PTE LTD 1 Kallang Place Singapore, SINGAPORE 339211
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states, and Directive 2011/65/EU, and amending Directive (EU) 2015/863, the restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS).

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:



Full Name:

Thomas Creel

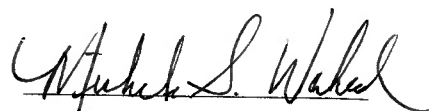
Position:

Director Quality Assurance

Date of Approval:

30-Nov-2021

Signature:



Full Name:

Michele Smith-Waheed

Position:

Associate Director, Regulatory Affairs

Date of Approval:

30-Nov-2021

Date Issued:

30-Nov-2021

Place Issued:

1915 Hurd Dr., Irving, Texas, USA

Supersedes:

31 August 2021

Effective (Date or Lot Number):

30-Nov-2021

ARCHITECT



ARCHITECT | *ci-series*

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www.corelab.abbott



THE EXTENSIVE MENU FOR CLINICAL CHEMISTRY AND IMMUNOASSAYS ON ARCHITECT SYSTEMS

CLINICAL CHEMISTRY

GENERAL CHEMISTRIES

Acid Phosphatase
Albumin BCG
Albumin BCP
Alkaline Phosphatase
ALT
ALT (activated)
Amylase
Amylase (pancreatic)
AST
AST (activated)
Bilirubin, Direct
Bilirubin, Total
Calcium
Cholesterol
CK
CO₂
Creatinine
Enzymatic Creatinine
Direct LDL
GGT
Glucose
HDL, Ultra
ICT Cl⁻ (Chloride)
ICT K⁺ (Potassium)
ICT Na⁺ (Sodium)
Iron
LDH (Lactate Dehydrogenase)
Lactic Acid
Lipase
Magnesium (Arsenazo)
Magnesium (Enzymatic)
Phosphorous
Total Protein
Triglyceride
UIBC
Urea Nitrogen
Uric Acid
Urine/CSF Protein

CARDIAC

CK-MB
Myoglobin

SPECIAL CHEMISTRIES

Ammonia
Bile Acids
Cholinesterase
Cholinesterase/Dibucaine
Copper
Cystatin C
D-Dimer
Fructosamine
HbA1c
HBDH

SPECIFIC PROTEINS

Alpha-1 Antitrypsin
Alpha-1 Glycoprotein
Apolipoprotein A1
Apolipoprotein B
ASO
Beta 2-Microglobulin
Ceruloplasmin
Complement C3
Complement C4
CRP Vario (High Sensitivity, Standard, Wide Range)
Ferritin
Haptoglobin
IgA
IgE
IgG
IgM
Lp(a)
Microalbumin
Prealbumin
RF
Transferrin
κ Light Chains
λ Light Chains

THERAPEUTIC DRUGS

Amikacin
Carbamazepine
Digitoxin
Digoxin
Gentamicin
Lithium
Phenobarbital
Phenytoin
Quinidine
Theophylline
Tobramycin
Valproic Acid
Vancomycin

DRUGS OF ABUSE/ TOXICOLOGY

Acetaminophen
Amphetamine/
Methamphetamine
Barbiturates
Benzodiazepines
Benzodiazepines Serum
Cannabinoids
Cocaine
Ecstasy
Ethanol
Methadone
Opiates
Phencyclidine (PCP)
Propoxyphene
Salicylate
Tricyclic Antidepressants



IMMUNOASSAY

CANCER

AFP
CA 125 II
CA 15-3
CA 19-9 (CA 19-9 XR)
CEA
CYFRA 21-1
HE-4
Pepsinogen I
Pepsinogen II
PIVKA-II
ProGRP
PSA, Free
PSA, Total
ROMA (HE4/CA125)
SCC

CARDIAC

BNP
CK-MB
Galectin-3
Homocysteine
Myoglobin
NT-proBNP
Troponin-I (high sensitive)

FERTILITY/PREGNANCY

DHEA-S
Estradiol
FSH
hCG (total beta-hCG)
LH
Progesterone
Prolactin
SHBG
Testosterone 2nd Generation

INFLAMMATORY DISORDERS

Procalcitonin (BRAHMS)

HEPATITIS

Anti-HAV IgG
Anti-HAV IgM
Anti-HBc
Anti-HBc IgM
Anti-HBe
HBeAg Qualitative/Quantitative
Anti-HBs
HBsAg Qualitative
HBsAg Qualitative Confirmatory
HBsAg Quantitative
Anti-HCV
HCVAg

RETROVIRUS

HIV Ag/Ab Combo
Anti-HTLV I/II

CONGENITALS

CMV IgG
CMV IgG Avidity
CMV IgM
Rubella IgG
Rubella IgM
Toxo IgG
Toxo IgG Avidity
Toxo IgM

OTHER INFECTIOUS DISEASE

Chagas
EBV EBNA-1 IgG
EBV VCA IgG
EBV VCA IgM
Syphilis TP

METABOLIC

Active-B12
Anti-CCP
B12
C-Peptide
Cortisol
Ferritin
Folate
HbA1c
Insulin
Intact PTH
Vitamin D

RENAL

NGAL

THERAPEUTIC DRUG MONITORING

Carbamazepine
Digoxin
Gentamicin
Methotrexate
Phenobarbital
Phenytoin
Theophylline
Valproic Acid
Vancomycin

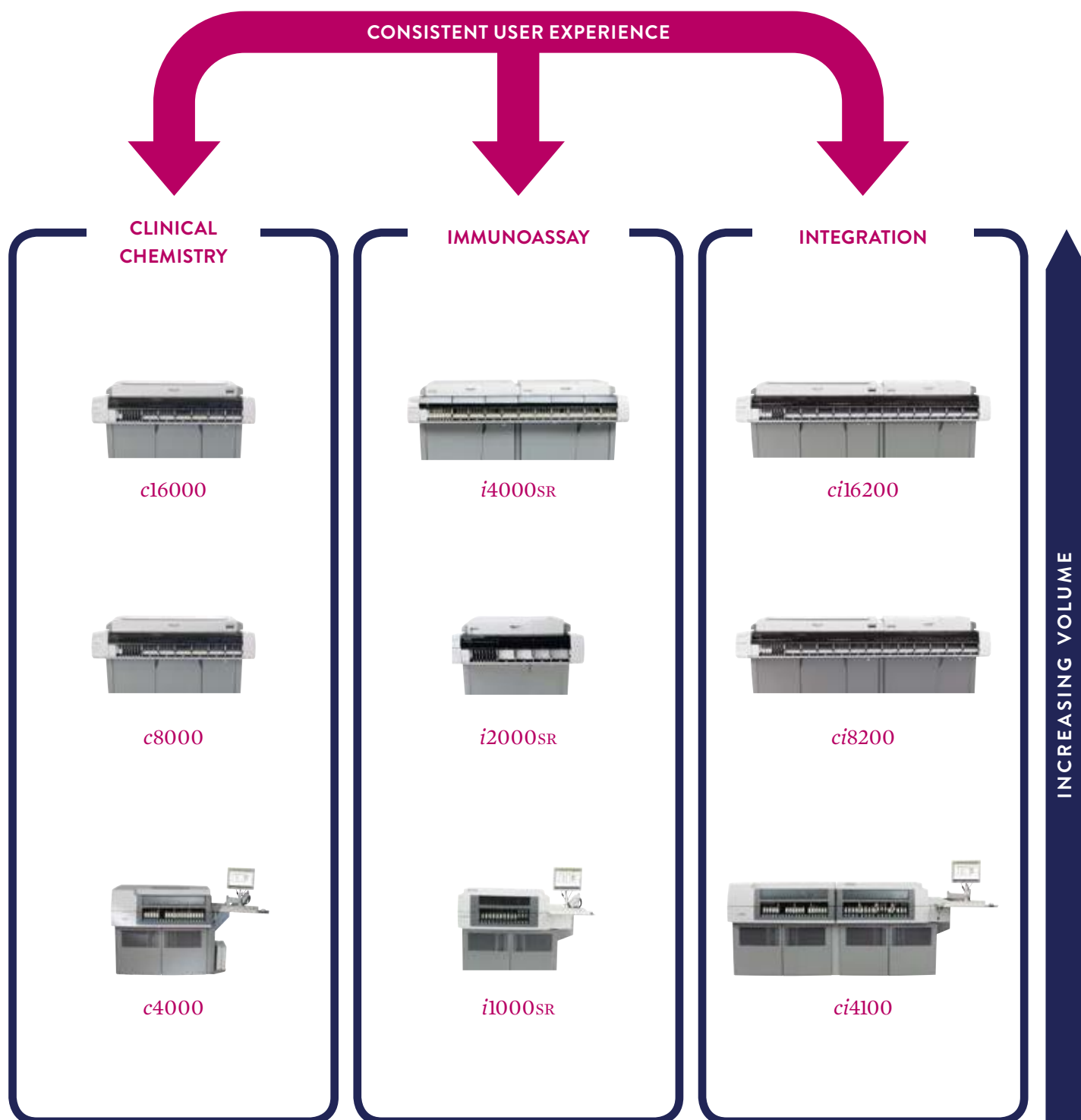
THYROID

Anti-Tg
Anti-TPO
Free T3
Free T4
Total T3
Total T4
TSH
T-Uptake

TRANSPLANT

Cyclosporine
Sirolimus
Tacrolimus

ARCHITECT SYSTEM FAMILY



WWW.CORELAB.ABBOTT

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All ARCHITECT instruments are Class 1 laser products.



ARCHITECT i2000SR

High-speed immunoassay testing with the ARCHITECT solution

HIGH PRODUCTIVITY AND SEAMLESS CONSOLIDATION



- **No clinically significant** sample-to-sample carryover (<0.1 ppm tube-to-tube)
- **Robotic Sample Handler (RSH)** eliminates bottlenecks and prioritizes urgent requests
- **Immediate STAT processing** for fast and consistent turnaround time
- **25 refrigerated** reagent positions and flexible kit sizes of 100 or 500 tests provide high reagent test capacity to optimize walkaway time
- **Continuous sample access** allows loading of up to 135 samples via priority (35) and routine (100) positions

ENHANCED SYSTEM AND ASSAY DYNAMICS



- **CHEMIFLEX** provides excellent low-end sensitivity and expanded dynamic ranges
- **Maximum throughput** of up to 200 tests per hour
- **Pressure differential technology** enables detection of clots, bubbles and insufficient sample volume to reduce analytical error and improve patient safety
- **Certainty and confidence** in the clinical results

TRUE FAMILY COMMONALITY



- **Identical technology**, reagents and assay protocols
- **Identical software** that is intuitive to operate
- **Universal ARCHITECT** sample carrier
- **Equivalent results** across all ARCHITECT iSystems

ARCHITECT i2000_{SR} can be integrated with the ARCHITECT c16000 to consolidate clinical chemistry and immunoassay on one platform.



ARCHITECT i2000_{SR}



ARCHITECT c16000

ARCHITECT Integration Achieves Testing Consolidation

- Excellent STAT turnaround time
- Ease of use
- Improved workflow
- Confidence in results
- Reduced costs



ARCHITECT ci16200

CHOOSE TRANSFORMATION™

Achieve measurably better healthcare performance.

ABBOTTDIAGNOSTICS.com

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ARCHITECT *i2000SR*

High-speed immunoassay testing uniquely designed for you

- STATs prioritized fast
- Advanced CHEMIFLEX technology
- Equivalent results across all ARCHITECT *i*Systems



CHOOSE TRANSFORMATION

Answers when you need them. Advanced systems deliver swift results.

TRUE FAMILY COMMONALITY

- Identical technology, reagents and assay protocols
- Identical software that is intuitive to operate
- ARCHITECT Universal Sample Carrier

The benefits: equivalent patient results across all ARCHITECT *i*Systems



ARCHITECT Universal
Sample Carrier

HIGH PRODUCTIVITY AND SEAMLESS CONSOLIDATION OPTIMIZE PERFORMANCE

- No clinically significant sample-to-sample carryover (<0.1 ppm)
- Robotic Sample Handler (RSH) eliminates bottlenecks and prioritizes urgent requests
- Immediate STAT processing for fast and consistent turnaround time
- 25 refrigerated reagent positions
- Continuous sample access, load up to 135 samples via priority (35) and routine (100) areas
- Throughput up to 200 immunoassay tests per hour



Up to 25 color-coded, refrigerated onboard reagent positions and flexible kit sizes of 100 or 500 tests provide high reagent test capacity to optimize walkaway time

The benefits: unique approach to consolidation

ENHANCED SYSTEM AND ASSAY DYNAMICS

- CHEMIFLEX provides excellent low-end sensitivity and expanded dynamic ranges
- Pressure differential technology detects clots, bubbles and insufficient sample volumes to reduce errors

The benefits: certainty and confidence in the clinical results



ARCHITECT *i*2000SR

can be integrated with ARCHITECT c8000 and c16000 to consolidate clinical chemistry and immunoassay on a single platform.

ARCHITECT *i*2000SR



ARCHITECT c16000



ARCHITECT ci16200



Refer to the Operations Manual for operational precautions, limitations and hazards. Manuals can be found on www.abbottdiagnostics.com.

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