Abbott (Diagnostics Division)
405, KIRTI SHIKHAR BUILDING,
JANAKPURI DISTT. CENTRE,
NEW DELHI - 110 058
TEL : +91 11 25619194 FAX: +91 11 25613392

Dated- 23rd Oct 2021

Certificate of Calibration

This is to certify that the below mentioned instrument installed in **Shri Mata Sheetla Devi Swarna Jayanti Diagnostic Centre, Gurgaon (HR)** calibrated by us on 23rd Oct 2021. The next calibration is due on or before 22nd Oct 2022. The values are falling within the specified range.

Instrument Model- **Architect Plus C4000**
Serial No. –**C461943**
Software Version – **9.45**

For Abbott Healthcare Pvt Ltd

Deepak Arya
Technical Service Specialist
Abbott Diagnostic Division

Abbott (Diagnostics Division)
405, KIRTI SHIKHAR BUILDING,
JANAKPURI DISTT CENTRE,
NEW DELHI - 110 058
TEL. : +91 11 25619194 FAX: +91 11 25613392
MOB :

SERVICE REPORT

REPORT NO

WARRANTY ◯ CONTRACT ◯ CHARGE ◯ RAP ◯ OTHERS ◯

CUSTOMER NAME AND ADDRESS	CALL STARTED	MODEL
HLL GURGAON SHRI MATA SHEETLA DEVI SWARNA JAYANTI DIAGNOSTIC CENTRE Sec-39 Jharsa, Gurugram-122003	DATE: 23/10/2021 TIME : 8:30AM	C4000
SERVICE REQUESTED BY : Dr Vijay Sharma	**CALL FINISHED** DATE: 23/10/2021 TIME: 02:30PM	**SERIAL NUMBER** C461943

PROBLEM :	OBSERVATIONS:
Preventive maintenance	Preventive Maintenance 159159RA1575403

SOLUTIONS :

- Performed preventive maintenance as per standard procedure.
  Replaced pm kit spares. Done Robotics calibration and verification.
  Run quality control all values in range

PART NO	DESCRIPTION	D.C. NO.	QTY	REMARK	FOR BILLING UNIT PRICE	VALU
02969-01	PM KIT c4000		1			
					LABOUR	
					TOTAL	

CUSTOMER'S REMARK

23/10/21

CUSTOMER SIGN AND STAMP — DATE

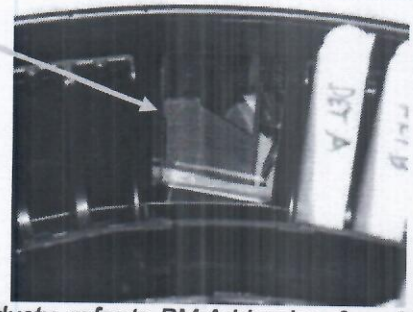
ENGINEER'S SIGN — 23-10-2021 — DATE

c4000 Preventive Maintenance Procedure

Customer Name	HLL LAB GURGAON	Serial Number	C461943
Customer Number		Ticket Number	15915RA157403
City	GURGAON	FSR Name	Pankaj Dimri
Telephone	8595659668	Date	23/10/2021

Pre-site Investigative Procedures	Completed
Interview customer for any on-going issues and order parts as necessary. ***Note:*** *If the instrument is experiencing ongoing assay imprecision or accuracy issues, perform the ISA ARCH-018 ARCHITECT Clinical Chemistry Systems Assay Troubleshooting prior to completing the PM.*	☑
Ensure PM parts are available per the parts list at the end of this procedure.	☑
Verify Abbott Link connection status & review message history log for issues.	☑
On-site Investigative Procedures	**Completed**
Verify TSB status of instrument.	☑
Verify customer has performed a recent software back-up and current system back-up CD is available.	☑
Review Maintenance & Message History Logs and advise customer on replacing the following list number (L/N) parts. • 01G48-04, Sample Probe- *if last replacement is > 1 year.* • 02P77-01, Sample Probe Tubing- *if last replacement is > 1 year.* • 01G47-04, Reagent Probe- *if last replacement is > 1 year.* • 02P76-01, Reagent Probe Tubing- *if last replacement is > 1 year.* • 09D36-02, Poppet Valve Set- *if last replacement is > 1 year.* • 09D51-02, Cuvette Drying Tip- *if last replacement is > 4 months.* • 09D34-03, Check Valve, Wash Solution- *if last replacement is > 1 year.* • 09D35-03, Check Valve ICT- *if last replacement is > 1 year.* • 09D43-02, Ref/Wash solution Line Filters- *if last replacement is > 1 year.* • 09D42-02, Cuvette Wiper - *if last replacement is > 1 year.* The removal and replacement instructions for L/N parts are available on the System Control Center (SCC) online Operations Manual. ***Note:*** *Follow local Service Organization processes if it is necessary to charge customer for LN parts and/or labor.*	☑
Decontamination & Cleaning	**Completed**
Log in as **FSE**, select **Maintenance/As needed**, perform **M&D 2183 Clean Wash Cups** and perform the following during the sodium hypochlorite soak time. • **P-625 Pre-service Decontamination** • Inspect the upper instrument deck area and pump/supply center area for evidence of leaks, spraying, splattering, etc… Clean and troubleshoot as necessary. • Gently wipe the Reagent Supply Center barcode reader window with a lint free tissue/cloth.	☑

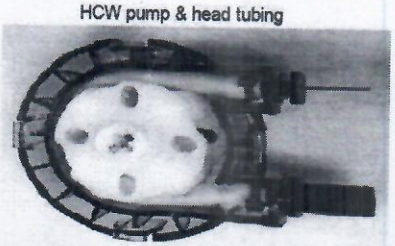
Wipe the inside & outside of window with lint free tissue



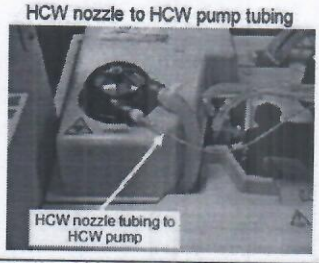
Note: *If the lab environment is dusty, refer to PM Addendum for additional cleaning instructions.*

High & Low Concentration Waste	Completed
Replace high concentration waste peristaltic pump tubing and HCW WSH NZL TO HCW PUMP IN tubing if last replacement is > 6 months. • 7-35009685-02 Tubing, Peristaltic Head **E8.03 Tubing, Peristaltic Head** • 7-205611-01 HCW WSH NZL TO HCW PUMP IN	☑
Inspect and clean LCW manifold and LCW tank as necessary.	☑
Inspect HCW and LCW external waste tubing & connections. Clean as needed.	☑
Inspect external waste pump (if present) tubing & connections. Power off external waste pump and clean as needed.	☑ NA
Probes & Tubing	**Completed**
Advise customer on replacing the Sample Probe & Tubing if last replacement is > 1 year. • 01G48-04 Sample Probe • 02P77-01 Sample Probe Tubing	☑
Advise customer on replacing the Reagent Probe & Tubing if last replacement is > 1 year. • 01G47-04, Reagent Probe • 02P76-01 Reagent Probe Tubing	☑

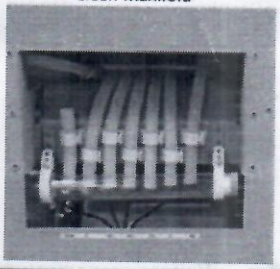
HCW pump & head tubing



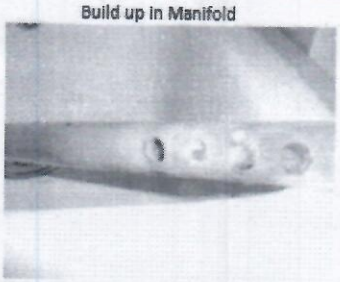
HCW nozzle to HCW pump tubing



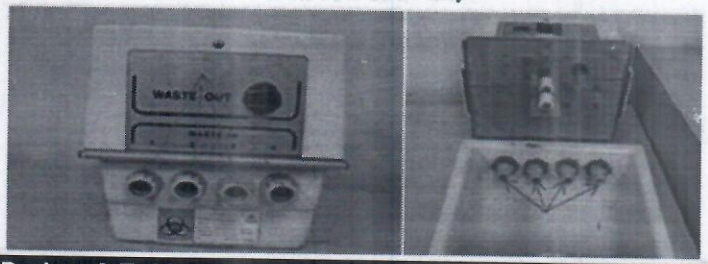
Clean Manifold

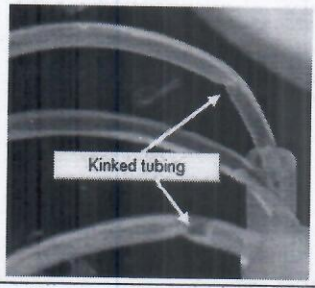
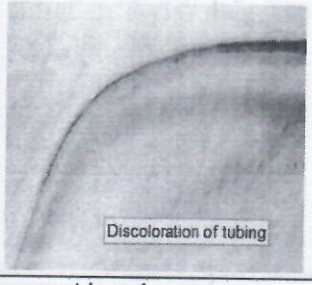


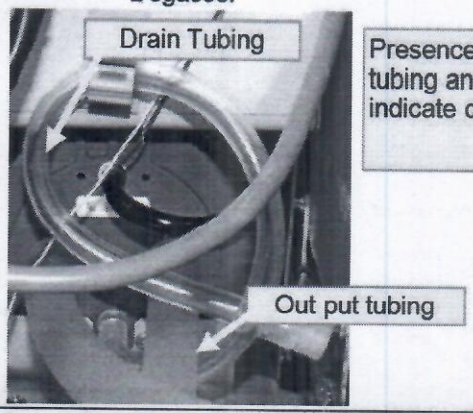
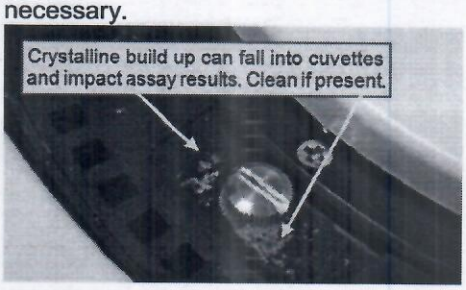
Build up in Manifold

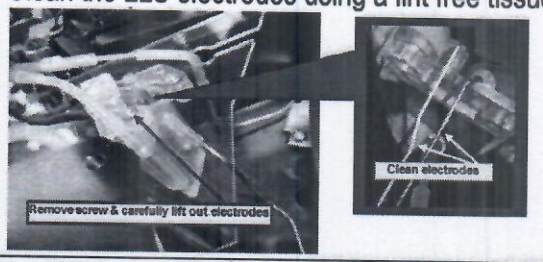


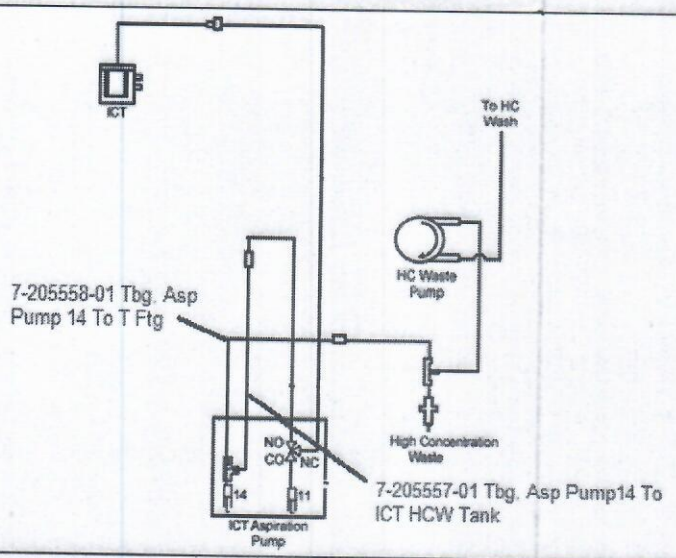
External Waste Pump



 	
Replace Cuvette Washer Pump bellows if last replacement is > 1year. • 2-89055-02 Bellows set, including rod & fitting **E9.03 Bellows, Cuvette Wash Pump** Or • 2-89054-02 Bellows, bellows only	☐
Advise customer on replacing the Cuvette Washer Pump poppets if last replacement is > 1year. • 09D36-02 Poppet Valve set	☐
Advise customer on replacing dryer tip if last replacement is > 4 months. • 09D51-02 Cuvette Drying Tip (pkg of 2).	☐
Advise customer on replacing the Wash Solutions straw filters if last replacement is > 1 year. • 09D43-02 Ref/Wash Solution Line Filter (pkg of 3).	☐
Advise customer on replacing Wash Solution Pump check valves if last replacement is > 1year. • 09D34-03 Check Valve, wash solution (pkg of 4).	☐
Log On as **FSE**, select **System/Diagnostics/Fluidics Wash** and perform **M&D 1260 Cuvette Washer Test.** Follow the on screen instructions and perform the following if the M&D fails. Replace nozzle(s) if damaged/bent or an uneven spray pattern is observed due to a clogged port that cannot be cleared. • **R6.03 Nozzle, #1, #4, & #5, R6.05 Nozzle, #6 Blank, R6.06 Nozzle, #7, Suction, R6.04 #2 & #3, Wash Solution** Replace Dryer Tip, inspect nozzle tubing for crimps, perform Cuvette Washer Alignment and rebuild vacuum pump if there is fluid in a cuvette that should be dry. • **R6.08 Cuvette Drying Tip** • **P-621 Cuvette Washer Alignment** • 2-94796-02 Diaphragm, Vacuum Pump New Style **K1.02 Diaphragm, Vac. Pump** • 2-94797-02 Sheet Valve for Vacuum Pump New Style (pkg of 2) **K1.03 Sheet Valve, Vac. Pump** • 2-94798-02 O-Ring for Vacuum Pump New Style (pkg of 2) **K1.04 O-ring, Vacuum Pump**	☐
Select **System/Maintenance/As needed** and perform: • **M&D 2155 Flush Bulk Solutions.** • **M&D 6052 Wash Cuvettes**. Observe the cuvette wash operation. Ensure water is not rising to the top of the cuvette and that the dryer tip moves down into the cuvette smoothly and does not deflect off the cuvette wall. Perform **P-621 Cuvette Washer Alignment** if necessary.	☐
Water Bath/Optics	**Completed**
Replace water bath fill pump peristaltic tubing if last replacement is > 1year. • 7-35009681-01 Tubing, Pump Head Water Bath fill **E3.05 Tubing, Pump Head Water Bath Fill**	☐
Advise customer on replacing Cuvette Wipers if last replacement is > 1year. • 09D42-02 Cuvette Wiper **N1.02 Cuvette Wiper**	☐
Clean the water bath float switch. • **P-648 Clean Water Bath Float Switch**	☐
• M&D 3526 Check Water Bath Temperature	☐
Perform P-662 Optics Check. If shutter open ranges are high (typically below 50), change lamp	☐

Probe Wash Internal/External	Completed
Replace Inner Probe Wash Pump bellows if last replacement is > 1year or signs of leakage are observed. • 2-89055-02 Bellows set, including rod & fitting **E7.02 Complete Bellows Set, Probe Wash Pump** Or • 2-89054-02 Bellows, bellows only use **E7.06 Bellow, Probe Wash Pump (c8000) as reference.**	☑
Advise customer on replacing Inner Probe Wash Pump poppets if last replacement is > 1year. • 09D36-02 Poppet Valve set	☑
Check sample & reagent syringes and degasser output for air/bubbles. Drain degasser canister if water is observed in the drain tubing. **P-609 Degasser Canister Draining** ***Note:*** *Presence of bubbles in syringes & degasser output tubing may indicate a degasser failure.* Degasser  	☑
Select **System/Maintenance/As needed** and perform **M&D 2132 Flush Water Lines.**	☑
Log on as **FSE** and select **System/Diagnostics/Fluidics Wash** and perform **M&D 1175 Wash Cup Test.**	☑
Cuvette Washer	**Completed**
Advise customer on manually cleaning cuvettes per **M&D 6310 Clean cuvettes-manually** if last completion is > 6 months. Inspect the cuvette segments for Crystalline build up and clean if necessary.  	☑
Inspect Cuvette Washer nozzle tubing for kinks, leaks, debris & discoloration. Replace as needed.	☑

and/or perform water bath clean with alkaline solution. • **P-662 Optics Check** • **P-671 Water Bath Clean with Alkaline Solution** • **P-641 Clean Water Bath Lens**	
Replace Water Bath filter if last replacement is > 1year. • 7-202500-01 Filter, Water Bath **E3.03 Filter, Water Bath**	☑
ICT	**Completed**
Advise customer on replacing the ICT check valves if last replacement is > 1year. • 09D35-03 Check Valve, ICT (pkg of 2).	☑
Advise customer on replacing the ICT Reference Solution straw filters if last replacement is > 1 year. • 09D43-02 Ref/Wash Solution Line Filter (pkg of 3).	☑
Clean the ICT Reference Cup and LLS Electrodes. • Remove the IRef cup electrodes & clean inside cup with a cotton tip swab. • Clean the LLS electrodes using a lint free tissue moistened with purified water. 	☑
Inspect the ICT Probe tubing at top of ICT module. Look for collapsed tubing, crimps, clogs, discoloration and replace as needed. • 7-205555-01 TBG, ICT MOD TO ICT ASP PUMP 11 NC ICT Probe Tubing 	☑ NA
Replace ICT aspiration pump pinch valve tubing if last replacement is > 1year. • 7-204068-01 Tubing, ICT Pinch Valve **E6.03 ICT Pinch Valve Tubing**	☐
Replace ICT waste cup tubing if last replacement is > 1year. • 7-205558-01Tbg, Asp Pump 14 To T Ftg • 7-205557-01Tbg, Asp Pump14 To ICT HCW Tank	☐



Select **System/Maintenance/As Needed** and perform **M&D 6063 Flush ICT Module.**	☐
Instrument Checks	**Completed**
Refer to the PM Addendum and perform the optional procedures as necessary.	✓
Log on as **FSE**, select **System/Diagnostics/Modules**, perform **M&D 1101 Robotics Test** and verify robotic positions for: • Sample Pipettor • R1 Pipettor • R2 Pipettor • ICT Assembly at cuvette and reference cup • Mixer position at cuvette and wash cup • M&D 3126 Mixer Vibration Test	✓
Test Front & Rear Top Covers • **P-646 Top Cover Counterbalance Adjustment** • Test the top rear cover by moving to the full open position & release. The cover should stay up. If the cover moves down; ensure the instrument is level. Replace both rear hinges if the instrument is level. • Test the top rear cover by moving to the half way closed position & release. The cover should slowly close. Replace both rear hinges if the cover immediately closes.	✓
Verify Instrument Performance	**Completed**
Ensure appropriate Quality Control meets specification and calibrate as necessary.	✓

PM Addendum Procedures
List optional procedures performed per the PM Addendum (if needed):

Comments: _____

Field Engineer Signature: _____ 23.10.2021

Customer Signature: _____ 23/10/21

Field Service PM Parts List			
Part #	Description	Qty	Criteria
7-35009685-02	Tubing, Peristaltic Head	1	If last replacement is > 6 months
7-205611-01	HCW WSH NZL TO HCW PUMP IN	1	If last replacement is > 6 months
2-89055-02 Or 2-89054-02	Bellows set, including rod & fitting Bellows, bellows only	2	If last replacement is > 1year
7-35009681-01	Tubing, Pump Head Water Bath fill	1	If last replacement is > 1year
7-10006378-01	Filter, Water Bath	1	If last replacement is > 1year
7-204068-01	Tubing, ICT Pinch Valve	1	If last replacement is > 1year
7-205557-01	Tbg, Asp Pump14 To ICT HCW Tank	1	If last replacement is > 1year
7-205558-01	Tbg, Asp Pump 14 To T Ftg	1	If last replacement is > 1year

Customer Parts List			
L/N Part #	Description	Qty	Criteria
01G48-04	Sample Probe	1	Advise customer to replace if last replacement is > 1 year.
02P77-01	Sample Probe Tubing	1	Advise customer to replace if last replacement is > 1 year.
01G47-04	Reagent Probe	2	Advise customer to replace if last replacement is > 1 year.
02P76-01	Reagent Probe Tubing	2	Advise customer to replace if last replacement is > 1 year.
09D36-02	Poppet Valve Set (Inner probe Wash pump, Cuvette wash pump)	2	Advise customer to replace if last replacement is > 1 year.
09D51-02	Cuvette Drying Tip	1	Advise customer to replace if last replacement is > 4 months.
09D34-03	Check Valve, Wash Solution	1	Advise customer to replace if last

		(pkg 4)	replacement is > 1 year.
09D35-03	Check Valve ICT	2 (pkg 2)	Advise customer to replace if last replacement is > 1 year.
09D43-02	Ref/Wash solution Line Filters (replace in all bulk solutions)	1 (pkg 3)	Advise customer to replace if last replacement is >1 year
09D42-02	Cuvette Wiper	1 (pkg 32	Advise customer to replace if last replacement is > 1 year.

Procedure Report

Procedure: 1121 R1 Pipettor Calibration

Procedure version: 10
Module no.: 1
Serial no.: c461943
Operator ID: FSE

Date: 23.10.2021
Time: 13:55:51
Status: Completed

Results:

Calibration Point	Theta	Z	Carousel
Wash Cup	-1	NA	NA
Reaction Carousel	-1	NA	3
Outer Segment	-2	-7	38
Inner Segment	-2	-4	23

Calibration passed

Procedure Report

Procedure: 1120 Sample Pipettor Calibration

Procedure version: 12
Module no.: 1
Serial no.: c461943
Operator ID: FSE

Date: 23.10.2021
Time: 13:46:51
Status: Completed

Results:

Calibration Point	Theta	Z	Carousel	Carrier Position
Reaction Carousel	-1	30	3	NA
Wash Cup	-2	NA	NA	NA
Sample Handler	2	12	NA	70

Calibration passed.

Procedure Report

Procedure: 1122 R2 Pipettor Calibration

Procedure version: 9
Module no.: 1
Serial no.: c461943
Operator ID: FSE

Date: 23.10.2021
Time: 14:04:34
Status: Completed

Results:

Calibration Point	Theta	Z	Carousel
Wash Cup	3	NA	NA
Reaction Carousel	2	NA	3
Outer Segment	1	-6	36
Inner Segment	1	-2	29

Calibration passed

QC Results List Report

Released

Operator ID: admin

System serial number: 81095

C / P	Module	SID	Control name	Assay	Result	Flags	Code	Date / Time
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	UA	4.7 mg/dL			22.10.2021 10:13
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	ALT	24 U/L			22.10.2021 10:13
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	UHDL	79 mg/dL			22.10.2021 10:12
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	BilD	0.40 mg/dL			22.10.2021 10:11
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	AST	35 U/L			22.10.2021 10:11
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	Urea	32 mg/dL			22.10.2021 10:11
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	Chol	258 mg/dL			22.10.2021 10:11
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	CreaC	2.32 mg/dL			22.10.2021 10:10
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	AlkP	89 U/L			22.10.2021 10:09
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	BiliT	0.93 mg/dL			22.10.2021 10:08
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	TP	7.0 g/dL			22.10.2021 10:06
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	GluC	80 mg/dL			22.10.2021 10:06
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	Trig	187 mg/dL			22.10.2021 10:05
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	CaC	8.4 mg/dL			22.10.2021 10:05
A835/1	1	BIORAD CCLevel 1	BIORAD CC - Level 1	AlbG	4.1 g/dL			22.10.2021 10:03

Sonja
22.10.21

Printed on: 28.03.2022
4:22:42PM

ARCHITECT

QC Results List Report

Released

Operator ID: admin

System serial number: 81095

C / P	Module	SID	Control name	Assay	Result	Flags	Code	Date / Time
A835/4	1	RANDOX-1Level 3	RANDOX-1 - Level 3	CRP32	68.5 mg/L			22.10.2021 10:15
A835/4	1	RANDOX-1Level 3	RANDOX-1 - Level 3	IgE	212.6 IU/mL			22.10.2021 10:15

QC Results List Report

Released

Operator ID: admin
System serial number: 81095

C / P	Module	SID	Control name	Assay	Result	Flags	Code	Date / Time
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	Lip	83 U/L			22.10.2021 10:16
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	UA	9.7 mg/dL			22.10.2021 10:15
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	ALT	83 U/L			22.10.2021 10:15
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	UHDL	25 mg/dL			22.10.2021 10:14
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	BilD	1.16 mg/dL			22.10.2021 10:14
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	AST	163 U/L			22.10.2021 10:14
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	Urea	97 mg/dL			22.10.2021 10:13
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	Chol	101 mg/dL			22.10.2021 10:13
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	CreaC	5.48 mg/dL			22.10.2021 10:12
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	AlkP	357 U/L			22.10.2021 10:12
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	BilT	3.85 mg/dL			22.10.2021 10:10
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	TP	4.2 g/dL			22.10.2021 10:08
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	GluC	270 mg/dL			22.10.2021 10:08
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	Trig	98 mg/dL			22.10.2021 10:08
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	Amy	384 U/L			22.10.2021 10:07
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	CaC	10.4 mg/dL			22.10.2021 10:07
A835/2	1	BIORAD CCLevel 2	BIORAD CC - Level 2	AlbG	2.5 g/dL			22.10.2021 10:06