

AU480

Installation / Operation / Performance Qualification

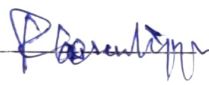

3.2 Approval certification

According to the assay results that are comprised in this document the AU480 system can be approved for routine operation.

System Released for routine operation. N/A Complete

Kopran Representatives:

Date : 05/02/2024

Engineer Signature :  Application Specialist Signature : 

SM Name: PARTHA SENGUPTA. Application Specialist Signature Name : ABHISHEK D

Adgyl Lifesciences Private Limited Representative:

Date: _____

Signature: _____

Facility Name: Adichunchanagiri Hospital and Research Centre.

Date: 05/02/2024

Signature: 

Comments:

Analyzer working ok now.

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1.3. System Initialization check list

Check level of Water. – OK

Empty waste container. - OK

Click on AU480 s/w, verify for all field should be in green - OK

Prepare all required reagents and controls according to the package insert. -OK

Select parameter to be calibrated. - OK

Verify curve. – OK

Run QC's. –OK

THIS IS TO CERTIFY THAT THE INSTALLATION SPACE IS MEETING ALL THE ABOVE MENTIONED REQUIREMENT FOR OPERATING THE AU480 FULLY AUTOMATED BIOCHEMISTRY ANALYZER IN THE CUSTOMER PLACE.

Date: 05/02/2024

Engineer Signature: _____

Engineer Printed Name: Abhishek D.

Comments: Instrument Working Satisfactorily

INSTALLATION COMPLETED SUCESSFULLY.INSTALLATION QUALIFICATION PASSED.

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SYSTEM INFORMATION
SERIAL NO
AU SOFTWARE VERSION
OS VERSION

:Beckman Coulter AU480
:2022120180
:V 1.0A1
: Windows 10 SP 2

2.1 MECHANISM MOVEMENT CHECK

RACK MOVEMENT CHECK

REMARK

- | | |
|--|----|
| <input type="checkbox"/> SAMPLE FEEDER MOVEMENT | OK |
| <input type="checkbox"/> SAMPLE RACK DETECTOR | OK |
| <input type="checkbox"/> SAMPLE BARCODE DETECTOR | OK |
| <input type="checkbox"/> SAMPLE BARCODE CLAW FEED UNIT | OK |
| <input type="checkbox"/> SAMPLE CUP DETECTOR | OK |
| <input type="checkbox"/> SAMPLE POSITION CLAW FEEDER | OK |
| <input type="checkbox"/> SAMPLE RECEIVER (AFTER MEASUREMENT) | OK |
| <input type="checkbox"/> RACK RECEIVER FULL DETECTOR | OK |
| <input type="checkbox"/> REPEAT RUN RECEIVER | OK |

STAT TABLE UNIT

- | | |
|---|----|
| <input type="checkbox"/> SAMPLE CUP SENSOR | OK |
| <input type="checkbox"/> STAT SAMPLE BARCODE READER | OK |
| <input type="checkbox"/> STAT SAMPLE ROTATION | OK |

REAGENT COMPARTMENT

- | | |
|---|------|
| <input type="checkbox"/> BOTTLE SENSOR | GOOD |
| <input type="checkbox"/> REAGENT BARCODE READER | GOOD |
| <input type="checkbox"/> REAGENT ROTATION | OK |

REACTION CUVETTE UNIT

- | | |
|--|---------------|
| <input type="checkbox"/> CUVETTE CONDITION | GOOD |
| <input type="checkbox"/> CUVETTE ROTATION | GOOD |
| <input type="checkbox"/> LAMP | GOOD |
| <input type="checkbox"/> BATH TEMPERATURE | OK |
| <input type="checkbox"/> CUVETTE WASHING | GOOD |
| <input type="checkbox"/> CUVETTE OVERFLOW | NOT HAPPENING |

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REAGENT PROBE MECHANISM

- | | |
|--|----|
| <input type="checkbox"/> WASH POT ALIGNMENT | OK |
| <input type="checkbox"/> REAGENT ASPIRATION POSITION (INNER) | OK |
| <input type="checkbox"/> REAGENT ASPIRATION POSITION (OUTER) | OK |
| <input type="checkbox"/> PRE DILUTION BOTTLE ASPIRATION POSI | OK |
| <input type="checkbox"/> CUVETTE DISPENSE POSITION | OK |
| <input type="checkbox"/> PROBE WAHING | OK |
| <input type="checkbox"/> PROBE LIQUID LEVEL DETECTION | OK |

SAMPLE PROBE MECHANISM

- | | |
|---|------|
| <input type="checkbox"/> WASH POT ALIGNMENT | OK |
| <input type="checkbox"/> SAMPLE ASPIRATION POSITION | OK |
| <input type="checkbox"/> STAT ASPIRATION POSITION | OK |
| <input type="checkbox"/> ISE DISPENSING POSITION | OK |
| <input type="checkbox"/> CUVETTE DISPENSE POSITION | OK |
| <input type="checkbox"/> PRE DILUTION DISPENSE POSITION | OK |
| <input type="checkbox"/> PROBE WASH | OK |
| <input type="checkbox"/> SAMPLE LEVEL DETECTION | OK |
| <input type="checkbox"/> SAMPLE CLOT DETECTION | GOOD |

WATER AND DETERGENT TANK

- | | |
|--|----|
| <input type="checkbox"/> WATER LEVEL SENSORS | OK |
| <input type="checkbox"/> DETERGENT LEVEL SENSORS | OK |
| <input type="checkbox"/> WATER FILTERS | OK |


SYRINGE CONDITION

- | | |
|---|----|
| <input type="checkbox"/> SAMPLE SYRINGE MOVEMENT | OK |
| <input type="checkbox"/> SAMPLE SYRINGE LEAK | NO |
| <input type="checkbox"/> REAGENT SYRINGE MOVEMENT | OK |
| <input type="checkbox"/> REAGENT SYRINGE LEAK | OK |
| <input type="checkbox"/> ISE SYRINGE MOVEMENT | OK |
| <input type="checkbox"/> ISE SYRINGE LEAK | NO |

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Date: 05/02/2024

Signature: 

Comments: Checked all hardware and alignments and no problem found.

Online

Print Time [05/03/2024 10:55 AM]

[Set Up]

<Test Requisition Information Receive>
 Routine Normal : None
 Routine Repeat : None
 Emergency Normal : None
 Emergency Repeat : None
 STAT Normal : None
 STAT Repeat : None

<Result Transfer>
 Routine Normal : Realtime
 Routine Repeat : Realtime
 Emergency Normal : Realtime
 Emergency Repeat : Realtime
 STAT Normal : None
 STAT Repeat : None
 STAT Quick : None
 Reagent Blank : None
 Calibration : None
 QC : None

[Protocol]

Upper Protocol
 T.R.I receive Error Control : Stop
 Results Transfer Error Control : Stop

Lower Protocol

<Character Format>
 Character Length : 7 bits
 Parity Bit : No
 Stop Bit : 1 bits

<Basic Data Format>
 Start Code 1st. : 02h:STX 2nd. : None
 End Code 1st. : 03h:ETX 2nd. : None
 Text Length : 256 bytes
 Device No. Use : No Device No.: ---
 ETB Use : No

<Communication Control>
 Bit/Sec. : 9600 bps.
 Class : Class A
 Retry : 3
 BCC Check : No

<Time Out [x100msec.]>
 T1 : 20
 T2 : 15
 T3 : 15
 T4 : 20
 T5 : 20
 T6 : 10
 T7 : 20

[Format Configuration]

<Used/Unused>
 Rack No./Cup pos. : Yes
 Type : Yes
 Dilution Inf. : Yes
 Reagent Inf. : No
 Zero Suppress : Yes

<Others>
 Rack No. Digit : 4 Digits
 Online Test No. Digit : 3 Digits
 Result Digit : 6 Digits
 No. of Data Marks : 2
 Cal No./Control No. Digit : 3 Digits

[Online Test No.]

Test Name	Test No.	Test Name	Test No.	Test Name	Test No.	Test Name	Test No.	Test Name	Test No.
1. ALB S	001	2. ALP B	002	3. ALT S	003	4. AST S	004	5. DBIL B	005
6. TBIL B	006	7. CHOL S	007	8. GLU B	008	9. TP S	009	10. TGL S	010
11. UREA S	011	12. URIC S	012	13. CREAT	013	14. PHOS S	014	15. IRON S	015
16. UIBC S	016	17. HDL S	017	18. CA B	018	19. GGT S	019	20. MG S	020
21. CRP S	021	22. THB S	022	23. ALCS	023	24. DBIL C	024	25. TBIL C	025
26. %HBAIC	026	27. LDL S	027	28. LIP	028	29. ADA	029	30.	030
31.	031	32.	032	33.	033	34.	034	35.	035
36.	036	37.	037	38.	038	39.	039	40.	040
41.	041	42.	042	43.	043	44.	044	45.	045
46.	046	47.	047	48.	048	49.	049	50.	050
51.	051	52.	052	53.	053	54.	054	55.	055
56.	056	57.	057	58.	058	59.	059	60.	060
61.	061	62.	062	63.	063	64.	064	65.	065
66.	066	67.	067	68.	068	69.	069	70.	070
71.	071	72.	072	73.	073	74.	074	75.	075
76.	076	77.	077	78.	078	79.	079	80.	080
81.	081	82.	082	83.	083	84.	084	85.	085
86.	086	87.	087	88.	088	89.	089	90.	090
91.	091	92.	092	93.	093	94.	094	95.	095
96. LIH	096	97. Na	097	98. K	098	99. Cl	099	100. -----	---
101. -----	---	102. -----	---	103.	103	104.	104	105.	105
106.	106	107.	107	108.	108	109.	109	110.	110
111.	111	112.	112	113.	113	114.	114	115.	115
116.	116	117.	117	118.	118	119.	119	120.	120

CARRYOVER

S.no	parameters	carry over low 1	carry over high 1	carry over low 2	percentage difference
1	ALB S	4.18	3.2	4.01	4.07
2	ALP B	229.39	426.26	226.21	1.39
3	ALT S	36.71	153.52	35.63	2.94
4	DBIL C	1.01	1.32	0.98	2.97
5	TBIL C	1.72	5.03	1.67	2.91
6	CHOL S	150.81	289.65	145.69	3.40
7	GLU B	105.68	285.51	105.39	0.27
8	TP S	5.54	4.61	5.44	1.81
9	TGL S	52.5	124.42	51.63	1.66
10	UREA S	44.82	117.43	44.52	0.67
11	URIC S	5.89	9.37	5.83	1.02
12	CREAT	1.55	4.01	1.53	1.29
13	IRON S	143.42	270.32	129.38	9.79
14	UIBC S	140.36	27.24	150.47	-7.20
15	HDL S	46.08	82.46	45.18	1.95
16	GGT S	48.38	175.47	48.23	0.31
17	MG S	1.85	3.56	1.88	-1.62
18	LIP	51	88	47	7.84
19	CRP S	0.14	0.17	0.15	-7.14
20	ADA	7	9	7	0.00
21	LDL	81	141	79	2.47

PRECISION

S.no	parameters	precision 1	precision 2	precision 3	precision 4	precision 5	Mean	SD	% RSD
1	ALB S	4.51	4.48	4.12	4.26	4.21	4.32	0.17	3.97
2	ALP B	247.81	245.41	230.53	230.11	231.37	237.05	8.78	3.71
3	ALT S	40.23	39.5	36.76	38.11	37.94	38.51	1.37	3.55
4	DBIL C	1.11	1.1	1.01	1.03	1.03	1.06	0.05	4.32
5	TBIL C	1.86	1.87	1.71	1.75	1.74	1.79	0.07	4.13
6	CHOL S	164.11	162.21	147.68	153.28	150.56	155.57	7.24	4.65
7	GLU B	109.53	112.99	106.28	107.76	106.91	108.69	2.69	2.48
8	TP S	6.01	6.02	5.4	5.69	5.67	5.76	0.26	4.53
9	TGL S	56.25	55.78	51.9	53.64	52.57	54.03	1.92	3.56
10	UREA S	45.68	46.53	44.18	45.34	44.57	45.26	0.93	2.05
11	URIC S	6.13	6.34	5.86	6.15	6	6.10	0.18	2.94
12	CREAT	1.54	1.61	1.49	1.54	1.52	1.54	0.04	2.87
13	IRON S	133.56	139.63	145.68	152.65	131.44	140.59	8.74	6.22
14	UIBC S	167.07	147.21	156.73	157.5	143.76	154.45	9.23	5.97
15	HDL S	50.76	40.97	45.46	47.92	47.76	46.57	3.65	7.84
16	GGT S	53.05	52.4	47.67	50.32	49.84	50.66	2.15	4.24
17	MG S	2.05	2.05	1.84	1.93	1.83	1.94	0.11	5.55
18	LIP	55	53	47	47	48	50.00	3.74	7.48
19	CRP S	0.15	0.16	0.14	0.15	0.15	0.15	0.01	4.71
20	ADA	7	8	7	8	7	7.40	0.55	7.40
21	LDL	88	88	80	84	83	84.60	3.44	4.06