

Appendix 1: Verification reports, Methods and Equipment

Equipment / Method	BECKMAN AU480
Performed by	Gugu Ditshego
Date of Verification	February 2021
Date of Report	February 2021
Reviewed by	Gugu Ditshego 
Approved by	Jabulani Kubheka 
Date Approved	16 March 2021

Introduction : Au480 Accuracy

Results: CV% were acceptable using hierarchy

Statistical analysis: See SOP

Limitations of the method: Limitation of methods include not enough data to complete validation. However, the validation data will be reviewed in 3-6months.

Conclusion:

Accuracy was also done using IQC samples for other analyte that were no compared with another similar method /analyser. Within- Run was performed, whereby both (level 1 & 2) were processed for 3 days with 3 runs each. And SDI, CV% were established & measured against:

Analyte that did not meet manufacturer's claims were within the CLIA allowable arrear. And therefore acceptable. The data will be reviewed further in the next Quarter to accumulate more data.

Proteus Laboratories Au480 is deemed fit for purpose.

CALIBRATOR & CONTROLS USED

System Calibrator use Lot no. 1121

Serum Level 1: Lot no. 1043

Serum Level 2: Lot no. 1044

HDL & LDL Calibrator: Lot no. 1057 & 1061

HDL & LDL L1 & L2: Lot no. 1028

Bicarbonate Calibrator: 2689

Synchron CO2 L1&2&3: Lot no.M901102

AU480 Precision

The Au480 2012121907 was validated using Beckman IQC (level 1, 2)

The IQC material was analysed on different days and SDI, CV% established.

Precision was acceptable based on the CV% which was within set target. Both with-in and between precision was performed for analytes that did not have data method comparison.

Hierarchy

- Manufacturers claims
- CLIA
- RIQAS EQA

AU480 Accuracy

The Au480 20212121907 was validated using EQA, IQC & patient samples. Accuracy was acceptable based on:

- the correlation factor (r-value) of ≥ 0.975
- slope of 1.0 (closeness to 1.0)
- y-intercept
- bias
- SD diff

Accuracy using IQC

Accuracy was also done using IQC samples for other analytes that were not compared with another similar method /analyser. Within- Run was performed, whereby both (level 1 & 2) were processed for 3 days with minimum 3 runs each. And SDI, CV% were established & measure against:

Hierarchy

- Manufacturers claims
- CLIA

Notes:

Analytes that did not meet manufacturer's claims were within the CLIA allowable arrear. And therefore acceptable.

Proteus Laboratories Au480 is deemed fit for purpose.

Total Protein								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	38.20	70.60	1	39.2	72.5	1	33.6	59.4
2	39.10	71.10	2	38.8	70.9	2	34.7	62.4
3	41.20	71.00	3	37.8	68.9	3	33.3	59.9
Total	118.50	212.70	Total	115.80	212.30	Total	101.60	181.70
Mean	39.50	70.90	Mean	38.60	70.77	Mean	33.87	60.57
SDI	1.54	0.26	SDI	0.72	1.80	SDI	0.74	1.61
CV%	3.90	0.37	CV%	1.87	2.55	CV%	2.18	2.65
Analyte performance accepted due to CLIA allowable % CV								

Sodium								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	124.00	162.60	1	121	157.2	1	118.4	154.6
2	119.40	157.10	2	120.1	155.4	2	121.6	154.7
3	124.90	156.20	3	120.9	153.1	3	116.9	154
Total	368.30	475.90	Total	362.00	465.70	Total	356.90	463.30
Mean	122.77	158.63	Mean	120.67	155.23	Mean	118.97	154.43
SDI	2.95	3.46	SDI	0.49	2.06	SDI	2.40	0.38
CV%	2.40	2.18	CV%	0.41	1.32	CV%	2.02	0.25
Analyte performance accepted due to CLIA allowable % CV								

ALP								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	111.30	444.90	1	127.7	498.5	1	109.6	445.1
2	115.30	444.00	2	122.00	482.10	2	136.5	472.4
3	118.50	450.30	3	118	471.5	3	111.6	455.9
Total	345.10	1339.20	Total	367.70	1452.10	Total	357.70	1373.40
Mean	115.03	446.40	Mean	122.57	484.03	Mean	119.23	457.80
SDI	3.61	3.41	SDI	4.87	13.60	SDI	14.99	13.75
CV%	3.14	0.76	CV%	3.98	2.81	CV%	12.57	3.00
Analyte performance accepted due to CLIA allowable % CV								

GLUC								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	5.53	12.40	1	5.41	12.55	1	4.66	11.58
2	5.50	12.04	2	5.35	12.6	2	5.78	14.08
3	5.48	12.28	3	5.17	12.16	3	5.15	12.43
Total	16.51	36.72	Total	15.93	37.31	Total	15.59	38.09
Mean	5.50	12.24	Mean	5.31	12.44	Mean	5.20	12.70
SDI	0.03	0.18	SDI	0.12	0.24	SDI	0.56	1.27
CV%	0.46	1.50	CV%	2.35	1.94	CV%	10.80	10.01
Analyte performance accepted due to CLIA allowable % CV								

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PO4								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	2.12	3.32	1	2.077	3.617	1	1.833	3.264
2	1.943	3.378	2	2.100	3.674	2	2.034	3.36
3	1.997	3.346	3	2.073	3.535	3	1.951	3.454
Total	6.06	10.04	Total	6.25	10.83	Total	5.82	10.08
Mean	2.02	3.35	Mean	2.08	3.61	Mean	1.94	3.36
SDI	0.09	0.03	SDI	0.01	0.07	SDI	0.10	0.10
CV%	4.38	0.94	CV%	0.70	1.94	CV%	5.21	2.83
Analyte performance accepted due to CLIA allowable % CV								

FE								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	11.70	36.60	1	11.9	37.2	1	10.9	35.6
2	11.50	35.10	2	12.1	36.5	2	11.3	35
3	11.70	35.80	3	11.7	35.8	3	11.5	36.4
Total	34.90	107.50	Total	35.70	109.50	Total	33.70	107.00
Mean	11.63	35.83	Mean	11.90	36.50	Mean	11.23	35.67
SDI	0.12	0.75	SDI	0.20	0.70	SDI	0.31	0.70
CV%	0.99	2.09	CV%	1.68	1.92	CV%	2.72	1.97
Analyte performance accepted due to CLIA allowable % CV								

GGT								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	63.10	156.80	1	60.2	154.8	1	63.9	167.7
2	64.50	157.80	2	60.4	155	2	65.3	169.4
3	65.10	158.90	3	59.6	153.3	3	64.3	167.4
Total	192.70	473.50	Total	180.20	463.10	Total	193.50	504.50
Mean	64.23	157.83	Mean	60.07	154.37	Mean	64.50	168.17
SDI	1.03	1.05	SDI	0.42	0.93	SDI	0.72	1.08
CV%	1.60	0.67	CV%	0.69	0.60	CV%	1.12	0.64
Analyte performance accepted due to CLIA allowable % CV								

ALB								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	24.20	43.50	1	24.10	45.00	1	23.5	42.4
2	25.20	43.30	2	24.00	43.00	2	23.9	43.8
3	24.80	43.20	3	23.4	43	3	23.2	42.9
Total	74.20	130.00	Total	71.50	131.00	Total	70.60	129.10
Mean	24.73	43.33	Mean	23.83	43.67	Mean	23.53	43.03

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SDI	0.50	0.15	SDI	0.38	1.15	SDI	0.35	0.71
CV%	2.03	0.35	CV%	1.59	2.64	CV%	1.49	1.65

Analyte performance accepted due to CLIA allowable % CV

DBILPC								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	17.70	96.70	1	17.5	91.2	1	17.2	92.4
2	17.90	94.20	2	17.6	93.8	2	17.1	93.3
3	17.70	95.00	3	16.8	90	3	17	92.2
Total	53.30	285.90	Total	51.90	275.00	Total	51.30	277.90
Mean	17.77	95.30	Mean	17.30	91.67	Mean	17.10	92.63
SDI	0.12	1.28	SDI	0.44	1.94	SDI	0.10	0.59
CV%	0.65	1.34	CV%	2.52	2.12	CV%	0.58	0.63

Analyte performance accepted due to CLIA allowable % CV

CK								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	160.70	355.80	1	169.4	386.1	1	328.6	252.9
2	163.50	355.10	2	168.2	392.4	2	841.8	395.8
3	155.20	331.30	3	168.7	392.1	3	166.4	393.6
Total	479.40	1042.20	Total	506.30	1170.60	Total	1336.80	1042.30
Mean	159.80	347.40	Mean	168.77	390.20	Mean	445.60	347.43
SDI	4.22	13.95	SDI	0.60	3.55	SDI	352.57	81.88
CV%	2.64	4.01	CV%	0.36	0.91	CV%	79.12	23.57

Analyte performance accepted due to CLIA allowable % CV

AMY								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	108.30	272.20	1	105.60	262.50	1	106.70	259.10
2	114.30	286.80	2	105.30	262.90	2	106.60	276.60
3	107.30	275.00	3	101.30	157.30	3	112.1	283.6
Total	329.90	834.00	Total	312.20	682.70	Total	325.40	819.30
Mean	109.97	278.00	Mean	104.07	227.57	Mean	108.47	273.10
SDI	3.79	7.75	SDI	2.40	60.85	SDI	0.07	12.37
CV%	3.44	2.79	CV%	2.31	26.74	CV%	0.07	4.53

Analyte performance accepted due to CLIA allowable % CV

CL								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	93.20	118.30	1	90.4	113.8	1	88.1	112.1
2	97.30	111.50	2	89.4	111.9	2	90.2	112.1

3	93.00	112.70	3	90.1	110.7	3	86.7	111.4
Total	283.50	342.50	Total	269.90	336.40	Total	265.00	335.60
Mean	94.50	114.17	Mean	89.97	112.13	Mean	88.33	111.87
SDI	2.43	3.63	SDI	0.51	1.56	SDI	1.76	0.40
CV%	2.57	3.18	CV%	0.57	1.39	CV%	1.99	0.36
Analyte performance accepted due to CLIA allowable % CV								

ALT								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	43.60	120.80	1	41.90	119.00	1	50.6	127
2	44.40	123.10	2	40.00	116.30	2	53.8	1969.9
3	45.10	122.20	3	40.1	115.6	3	42	118.6
Total	133.10	366.10	Total	122.00	350.90	Total	146.40	2215.50
Mean	44.37	122.03	Mean	40.67	116.97	Mean	48.80	738.50
SDI	0.75	1.16	SDI	1.07	1.80	SDI	6.10	1066.43
CV%	1.69	0.95	CV%	2.63	1.53	CV%	12.51	144.41
Analyte performance accepted due to CLIA allowable % CV								

CHOL								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	3.98	7.26	1	3.84	7.16	1	3.72	7.00
2	4.18	7.30	2	3.82	7.05	2	3.9	7.17
3	3.98	7.32	3			3	3.73	7.08
Total	12.14	21.88	Total	7.66	14.21	Total	11.35	21.25
Mean	4.05	7.29	Mean	2.55	4.74	Mean	3.78	7.08
SDI	0.12	0.03	SDI	0.01	0.08	SDI	0.10	0.09
CV%	2.85	0.42	CV%	0.55	1.64	CV%	2.67	1.20
Analyte performance accepted due to CLIA allowable % CV								

TBILPC								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	22.70	110.70	1	21.7	107.4	1	21.7	106.4
2	23.80	108.70	2	22.4	108.8	2	22.4	109.2
3	22.70	108.60	3	21.6	106.6	3	21.7	106.4
Total	69.20	328.00	Total	65.70	322.80	Total	65.80	322.00
Mean	23.07	109.33	Mean	21.90	107.60	Mean	21.93	107.33
SDI	0.64	1.18	SDI	0.44	1.11	SDI	0.40	1.62
CV%	2.75	1.08	CV%	1.99	1.03	CV%	1.84	1.51
Analyte performance accepted due to CLIA allowable % CV								

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Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	2.135	3.056	1	2.157	3.178	1	2.08	2.996
2	2.218	2.937	2	2.153	2.999	2	2.149	3.059
3	2.153	2.923	3	2.117	3.005	3	2.082	3.035
Total	6.51	8.92	Total	6.43	9.18	Total	6.31	9.09
Mean	2.17	2.97	Mean	2.14	3.06	Mean	2.10	3.03
SDI	0.04	0.07	SDI	0.02	0.10	SDI	0.04	0.03
CV%	2.01	2.46	CV%	1.03	3.32	CV%	1.87	1.05

Analyte performance accepted due to CLIA allowable % CV

UA								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	0.35	0.52	1	0.351	0.529	1	0.331	0.523
2	0.345	0.523	2	0.347	0.528	2	0.348	0.544
3	0.350	0.521	3	0.341	0.521	3	0.336	0.53
Total	1.05	1.57	Total	1.04	1.58	Total	1.02	1.60
Mean	0.35	0.52	Mean	0.35	0.53	Mean	0.34	0.53
SDI	0.00	0.00	SDI	0.01	0.00	SDI	0.01	0.01
CV%	0.83	0.22	CV%	1.45	0.83	CV%	2.58	2.01

Analyte performance accepted due to CLIA allowable % CV

AST								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	54.10	143.90	1	51.9	145.9	1	55.5	162.4
2	52.10	146.00	2	51.4	139.7	2	58.1	155.8
3	54.10	143.90	3	50.6	138.6	3	57	140.3
Total	160.30	433.80	Total	153.90	424.20	Total	170.60	458.50
Mean	53.43	144.60	Mean	51.30	141.40	Mean	56.87	152.83
SDI	1.15	1.21	SDI	0.66	3.94	SDI	1.31	11.34
CV%	2.16	0.84	CV%	1.28	2.78	CV%	2.30	7.42

Analyte performance accepted due to CLIA allowable % CV

TRIG								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	1.56	3.55	1	1.65	3.56	1	1.52	3.4
2	1.70	3.40	2	1.63	3.55	2	1.6	3.65
3	1.64	3.39	3	1.58	3.48	3	1.55	3.53
Total	4.90	10.34	Total	4.86	10.59	Total	4.67	10.58
Mean	1.63	3.45	Mean	1.62	3.53	Mean	1.56	3.53
SDI	0.07	0.09	SDI	0.04	0.04	SDI	0.04	0.13
CV%	4.30	2.60	CV%	2.23	1.23	CV%	2.60	3.55

Analyte performance accepted due to CLIA allowable % CV

MG								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	1.048	1.628	1	1.044	1.621	1	0.984	1.537
2	1.100	1.590	2	1.026	1.590	2	1.016	1.567
3	1.091	1.614	3	1.002	1.579	3	0.992	1.554
Total	3.24	4.83	Total	3.07	4.79	Total	2.99	4.66
Mean	1.08	1.61	Mean	1.02	1.60	Mean	1.00	1.55
SDI	0.03	0.02	SDI	0.02	0.02	SDI	0.02	0.02
CV%	2.57	1.19	CV%	2.06	1.36	CV%	1.67	0.97
Analyte performance accepted due to CLIA allowable % CV								

CRE-E								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	113.40	476.70	1	114.8	476.3	1	103.4	449.5
2	115.60	455.00	2	114.3	417.1	2	116.6	463.7
3	110.20	541.00	3	109.6	453.2	3	108.2	455.1
Total	339.20	1472.70	Total	338.70	1346.60	Total	328.20	1368.30
Mean	113.07	490.90	Mean	112.90	448.87	Mean	109.40	456.10
SDI	2.72	44.72	SDI	2.87	29.84	SDI	6.68	7.15
CV%	2.40	9.11	CV%	2.54	6.65	CV%	6.11	1.57
Analyte performance accepted due to CLIA allowable % CV								

BUN								
Quality Control Day 1			Quality Control Day 2			Quality Control Day 3		
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
1	6.82	27.21	1	6.62	27.50	1	6.73	27.26
2	6.38	27.02	2	6.64	27.49	2	7.00	23.89
3	6.82	27.21	3	6.47	26.84	3	6.36	27.52
Total	20.02	81.44	Total	19.73	81.83	Total	20.09	78.67
Mean	6.67	27.15	Mean	6.58	27.28	Mean	6.70	26.22
SDI	0.25	0.11	SDI	0.09	0.38	SDI	0.32	2.02
CV%	3.81	0.40	CV%	1.41	1.39	CV%	4.80	7.72
Analyte performance accepted due to CLIA allowable % CV								