HUMAN ANALYSIS CENTRE & CO.

(Department of Laboratory Services)

Root cause analysis of outlier parameter for EQAS performance

EQAS Cycle /17347
Sample No:Round–7

Format No: HAC/FM/87

BIOCHEMISTRY DEPARTMENT

Points to be analysis	Check point by lab(Please√)			Remarks
	Yes/Follow	NO/NOT Follow (If NO/NOT Follow Remarks is required)	N/A	
A)POINTS TO BE CHECKED BEFORE EQAS SAMPLE RUN				
PRE-ANALYTICAL				
Trytoperform thetestsasearlyaspossiblefromthedateofreceipt ofEQAsamples. The lyophilized/stabilized samples should bestoredinarefrigerator(2-8°C)untiltesting. Donotfreezethelyophilizedsamples	**Followed**			
All EQAS samples must be treated in the same Manner as a routine patient specimen	**Followed**			
Most programs provide lyophilized/stabilized samples. Follow instructions carefully about there constitution and preparationof sample. If exact volume of water is not used for reconstitution,theresultingsamplemaybemorediluteor concentrated. Use of a calibrated volumetricpipetteisrecommended.	**Followed**			
Mixgentlytoavoid frothing .After reconstitution,thesampleshouldbekeptatroomtemperaturefort hePrescribedperiodoftime.	**Followed**			
The testing should be performed within therecommended period of time after reconstitution.If samples have been reconstituted and left forlong periods of time at room temperature,refrigeratedorfrozenandthawed,theresultswill becomeunreliable.	**Followed**			
ANALYTICAL				
The procedure for testing must be identical tothatforall thepatient samples.No additionalprecautionsshouldbeperformedpriorto testing EQA materials except at thepreparatory stage. This is because the test isbeing done to determine the quality of routineproceduresbeingfollowedinthelaboratory (being followed for any random patient sample).For as instance if the laboratory repeats the teston the EQA sample whereas routine patients aretested onlyoncethenthepurposeofparticipationinEQASisdefeated.	**Followed**			

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EQAS Cycle / 17347 **Department Of Biochemistry** **Format No: HAC/FM/87**

Sample No: Round - 7

Points to be analysis	Check point by lab (Please √)			Remarks
	Yes/ Follow	NO/NOT Follow (If NO/NOT Follow Remarks is required)	N/A	
The laboratory using any form of automation should not perform non-routine quality/maintenance procedures on the analyzer prior to testing the FQA material.	Followed			
For laboratory that performs manual testing, it is preferable that the same analyst who carries out the routine testing also performs the proficiency test. If this is not done, then the laboratory will fail to get a true reflection of its practices related to patient specimens.	Followed			
POST ANALYTICAL				
The reporting of EQA result should be in the same manner as used for reporting patient results. Some of the routine laboratory methods of reporting such a reviewing patient's prior results may not apply in these situations.	Followed			
Precautions must be taken to ensure that there are transcription errors.	Followed			
Reconstituted EQA samples should not be stored for future testing as they tend to deteriorate and will act provide accurate results.	Followed			
Lyophilized samples if available may be stored in a refrigerator for up to one year. Prior to use check for the presence of liquid in the vial or discoloration of the pellet. These are Indicators of deterioration. Do not freeze lyophilized specimens.	Followed			
B) A SIMPLE APPROACH WOULD BE TO CLASSIFY THE PROBLEM				
Clerical error				
Transcription error (may be pre or post-analytical factors).	Followed			
Situations where wrong method has been registered for analysis or method change not updated.	Followed			
Methodological problem				
Instrument function checks (e.g., blank readings, pressures) not performed as necessary, or results not within acceptable range.	Checked ok			
Scheduled instrument maintenance not performed appropriately.	Checked ok			
Incorrect instrument calibration.	OK			
Standards or reagents improperly reconstituted and stored or inadvertently used beyond expiration date.	OK			
Instrument probes misaligned.	OK			
Problem with instrument data processing functions. The laboratory may need to contact the manufacturer.	OK			

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Sample No: Round - 7

Points to be analysis	Check point by lab (Please √)			Remarks
	Yes/ Follow	NO/NOT Follow (If NO/NOT Follow Remarks is required)	N/A	
To evaluate such problems.	Followed			
Problem in manufacture of reagents/standards, or with instrument settings specified by manufacturer.	Followed			
Carry-over from previous specimen.	Followed			
Automatic pipette not calibrated to acceptable precision and accuracy.	Followed			
Imprecision from result being close to detection limit of method.	Followed			
Instrument problem not detected by quality control: • QC material not runs within expiration date, or method improperly stored. • QC material not runs at relevant analyte concentration.	Followed			
Result not within reportable range (linearity) for Instrument/reagent system.	Followed			
Obstruction of instrument tubing/orifice by clot or protein.	Followed			
Technical problem				
EQA material improperly reconstituted.	CHECKED			
Testing delayed after reconstitution of EQA material (with problem from evaporation or deterioration).	CHECKED			
Sample not placed in proper order on instrument.	CHECKED			
Result released despite unacceptable QC data.	CHECKED			
QC data within acceptable limits but showed trend suggestive of problem with the assay.	CHECKED			
Inappropriate quality control limits/rules. If the acceptable QC range is too wide, the probability increases that a result will fall within the acceptable QC range yet exceed acceptable limits for EQA.	CHECKED			
Manual pipetting/diluting performed inaccurately, at an incorrect temperature or with incorrect diluents.	CHECKED			
Calculation error or result reported using too few significant digits.	CHECKED			
Secondary specimen tubes incorrectly labeled.	CHECKED			
In addition to above discipline specific errors may also occur.	CHECKED			

HUMAN ANALYSIS CENTRE & CO.

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Root cause analysis of outlier parameter for EQAS performance

EQAS Cycle /17347 **Department of Biochemistry** **Format No: HAC/FM/87**

Sample No: Round – 7 Of 2024

Points to be analysed	Check point by lab (Please √)			Remarks
	Yes/ Follow	NO/NOT Follow (If NO/NOT Follow Remarks is required)	N/A	
Problem with proficiency testing materials				
Matrix effects: The performance of some instrument/ method combinations may be affected by the matrix of the PT sample. This can be overcome to some extent by assessing participants in peer groups-to be done by the PT provider.			✓	
Non-homogenous test material due to variability infill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens.			✓	
Non-viable samples for microbiology PT program.			✓	
Haemolysis on an immune-hematology program samples.			✓	
Problem with evaluation of results by the PT provider				
Peer group not appropriate.			✓	
Inappropriate target value: Target values developed from participant consensus can be inappropriate from non-homogeneous testing material or lingering ("masked") outliers. However, occasional inappropriate target values occur in every PT program. Inappropriate evaluation interval: An evaluation interval may be inappropriately narrow e.g., if ±2 standard deviation units are used with an extremely precise method, the acceptable range may be much narrower than needed for clinical usefulness.			✓	
Incorrect data entry by PT provider.			✓	
No explanation after investigation				
All identifiable sources of error have been excluded, single unacceptable result may be attributed to random error, particularly when the result of repeat analysis is acceptable. In such cases, no corrective action should be taken; as such an action may actually increase the probability of a future unacceptable result.		After the RCA of this EQAS result it was found that no error occurred and it will follow the same CAPA routinely.		
Conclusion and proposed action				
Checked By: QM	Date:08.08.2024			Reviewed By
Corrective Action: NO CORRECTIVE ACTION REQUIRED AS THE RESULTS ARE WITHIN Z SCORE.				
Done By LAB TECH.	Date	08.082024		

CHRISTIAN MEDICAL COLLEGE

VELLORE, TAMIL NADU - 632004. INDIA

DEPARTMENT OF CLINICAL BIOCHEMISTRY

CMC EXTERNAL QUALITY ASSURANCE SCHEME

PC-1024

MONTHLY SUMMARY REPORT - JULY 2024

LAB NO: 17347

LAB NAME: **HUMAN ANALYSIS CENTRE & CO**

CONSTITUENT GROUP

Chemistry II

Date of Result Entered: 23/07/2024

Date of Result Published: 08/08/2024

PT Item: Lyophilized human serum based

S. No.	Analyte	Method / Principle	Analyser	No. of Participants	AV	Participants		Your Value	Z Score	u*
						CV	SDPA			
1	GLUCOSE II	GOD-POD II	Any Analyser (Automation / Semi Automation)	1863	159 64	11.11	17.73	169 mg/dL	0 53	0 82
2	UREA II	Urease UV / GLDH II	Any Analyser (Automation / Semi Automation)	1341	56.68	13.56	7.69	71 mg/dL	1.86	0.42
3	CREATININE II	Jaffes Kinetic-Alkaline Picrate II	Any Analyser (Automation / Semi Automation)	1394	2.91	12.65	0.37	2.9 mg/dL	-0.03	0.02
4	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Any Analyser (Automation / Semi Automation)	1670	3.9	18.38	0.72	3.9 mg/dL	0	0 04
5	T-PROTEIN II	Biuret - Colorimetric II	Any Analyser (Automation / Semi Automation)	1500	5.52	10.7	0.59	6.7 g/dL	2	0.03
6	ALBUMIN II	BCG - Colorimetric II	Any Analyser (Automation / Semi Automation)	1459	3.3	10.15	0.34	3.5 g/dL	0.59	0.02
7	URIC ACID II	Enzymatic / Uricase Colorimetric II	Any Analyser (Automation / Semi Automation)	1671	7.05	14.79	1.04	6.6 mg/dL	-0 43	0 05
8	CHOLESTROL II	CHOD-PAP II	Any Analyser (Automation / Semi Automation)	1829	119.63	12.35	14.77	98 mg/dL	-1.46	0.69
9	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Any Analyser (Automation / Semi Automation)	1634	115.23	16.87	19.44	82 mg/dL	-1.71	0.96

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DEPARTMENT OF CLINICAL BIOCHEMISTRY

CMC EXTERNAL QUALITY ASSURANCE SCHEME

PC-1024

MONTHLY SUMMARY REPORT - JUNE 2024

LAB NO: 17347

LAB NAME: **HUMAN ANALYSIS CENTRE & CO**

CONSTITUENT GROUP

Chemistry II

Date of Result Entered: 20/06/2024

Date of Result Published: 27/06/2024

PT Item: Lyophilized human serum based

S. No.	Analyte	Method / Principle	Analyser	No. of Participants	AV	Participants		Your Value	Z Score	u*
						CV	SDPA			
1	GLUCOSE II	GOD-POD II	Any Analyser (Automation / Semi Automation)	1689	258.68	9.56	24.72	297 mg/dL	1.55	1.2
2	UREA II	Urease UV / GLDH II	Any Analyser (Automation / Semi Automation)	1215	102.06	12.93	13.2	98 mg/dL	-0.31	0.76
3	CREATININE II	Jaffes Kinetic-Alkaline Picrate II	Any Analyser (Automation / Semi Automation)	1302	4.08	12.64	0.52	4.4 mg/dL	0.62	0.03
4	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Any Analyser (Automation / Semi Automation)	1397	2.3	18.45	0.42	2.5 mg/dL	0.48	0.02
5	T-PROTEIN II	Biuret - Colorimetric II	Any Analyser (Automation / Semi Automation)	1439	5.27	10.52	0.55	5.9 g/dL	1.15	0.03
6	ALBUMIN II	BCG - Colorimetric II	Any Analyser (Automation / Semi Automation)	1379	3.19	9.79	0.31	3.3 g/dL	0.35	0.02
7	URIC ACID II	Enzymatic / Uricase Colorimetric II	Any Analyser (Automation / Semi Automation)	1563	6.22	14.8	0.92	6.1 mg/dL	-0.13	0.05
8	CHOLESTROL II	CHOD-PAP II	Any Analyser (Automation / Semi Automation)	1666	108.42	11.01	11.94	102 mg/dL	-0.54	0.59
9	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Any Analyser (Automation / Semi Automation)	1430	173.75	11.61	20.18	153 mg/dL	-1.03	1.07

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DEPARTMENT OF CLINICAL BIOCHEMISTRY
CMC EXTERNAL QUALITY ASSURANCE SCHEME

PC-1024

MONTHLY SUMMARY REPORT - MAY 2024

LAB NO: 17347

LAB NAME: **HUMAN ANALYSIS CENTRE & CO**

CONSTITUENT GROUP
Chemistry II

Date of Result Entered: 21/05/2024

PT Item: Lyophilized human serum based

Date of Result Published: 30/05/2024

S. No.	Analyte	Method / Principle	Analyser	No. of Participants	AV	Participants CV	Participants SDPA	Your Value	Z Score	u*
1	GLUCOSE II	GOD-POD II	Any Analyser (Automation / Semi Automation)	1744	127.17	9.22	11.72	131 mg/dL	0.33	0.56
2	UREA II	Urease UV / GLDH II	Any Analyser (Automation / Semi Automation)	1258	74.7	13.84	10.34	62 mg/dL	-1.23	0.58
3	CREATININE II	Jaffes Kinetic-Alkaline Picrate II	Any Analyser (Automation / Semi Automation)	1323	1.8	13.34	0.24	1.7 mg/dL	-0.42	0.01
4	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Any Analyser (Automation / Semi Automation)	1455	3.44	15.69	0.54	1.9 mg/dL	-2.85	0.03
5	T-PROTEIN II	Biuret - Colorimetric II	Any Analyser (Automation / Semi Automation)	1414	5.27	10.05	0.53	5.7 g/dL	0.81	0.03
6	ALBUMIN II	BCG - Colorimetric II	Any Analyser (Automation / Semi Automation)	1396	3.22	9.51	0.31	3.4 g/dL	0.58	0.02
7	URIC ACID II	Enzymatic / Uricase Colorimetric II	Any Analyser (Automation / Semi Automation)	1562	4.76	19.82	0.94	3.7 mg/dL	-1.13	0.05
8	CHOLESTROL II	CHOD-PAP II	Any Analyser (Automation / Semi Automation)	1689	112.28	10.99	12.34	88 mg/dL	-1.97	0.6
9	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Any Analyser (Automation / Semi Automation)	1501	95.35	18	17.17	65 mg/dL	-1.77	0.89

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DEPARTMENT OF CLINICAL BIOCHEMISTRY
CMC EXTERNAL QUALITY ASSURANCE SCHEME

PC-1024

MONTHLY SUMMARY REPORT - APRIL 2024

LAB NO: 17347

LAB NAME: **HUMAN ANALYSIS CENTRE & CO**

CONSTITUENT GROUP
Chemistry II

Date of Result Entered: 20/04/2024

PT Item: Lyophilized human serum based

Date of Result Published: 08/05/2024

S. No.	Analyte	Method / Principle	Analyser	No. of Participants	AV	Participants		Your Value	Z Score	u*
						CV	SDPA			
1	GLUCOSE II	GOD-POD II	Any Analyser (Automation / Semi Automation)	1687	204.86	9.48	19.41	172 mg/dL	-1.69	0.95
2	UREA II	Urease UV / GLDH II	Any Analyser (Automation / Semi Automation)	1184	36.72	11.85	4.35	83 mg/dL	10.64	0.25
3	CREATININE II	Jaffes Kinetic-Alkaline Picrate II	Any Analyser (Automation / Semi Automation)	1310	3.59	12.77	0.46	3.2 mg/dL	-0.85	0.03
4	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Any Analyser (Automation / Semi Automation)	1477	5.85	14.57	0.85	5.06 mg/dL	-0.93	0.04
5	T-PROTEIN II	Biuret - Colorimetric II	Any Analyser (Automation / Semi Automation)	1415	5.38	10.36	0.56	6.4 g/dL	1.82	0.03
6	ALBUMIN II	BCG - Colorimetric II	Any Analyser (Automation / Semi Automation)	1388	3.23	9.87	0.32	3 g/dL	-0.72	0.02
7	URIC ACID II	Enzymatic / Uricase Colorimetric II	Any Analyser (Automation / Semi Automation)	1522	6.77	14.81	1	5.4 mg/dL	-1.37	0.05
8	CHOLESTROL II	CHOD-PAP II	Any Analyser (Automation / Semi Automation)	1705	112.26	12.27	13.78	88 mg/dL	-1.76	0.67
9	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Any Analyser (Automation / Semi Automation)	1472	314.39	13.86	43.57	246 mg/dL	-1.57	2.27

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DEPARTMENT OF CLINICAL BIOCHEMISTRY
CMC EXTERNAL QUALITY ASSURANCE SCHEME

PC-1024

MONTHLY SUMMARY REPORT - MARCH 2024

LAB NO: 17347

LAB NAME: **HUMAN ANALYSIS CENTRE & CO**

CONSTITUENT GROUP
Chemistry II

Date of Result Entered 21/03/2024

Date of Result Published 06/04/2024

PT Item: Lyophilized human serum based

S. No.	Analyte	Method / Principle	Analyser	No. of Participants	AV	Participants		Your Value	Z Score	u*
						CV	SDPA			
1	GLUCOSE II	GOD-POD II	Any Analyser (Automation / Semi Automation)	1640	385.53	10.46	40.34	328 mg/dL	-1.43	1.99
2	UREA II	Urease UV / GLDH II	Any Analyser (Automation / Semi Automation)	1166	64.17	12.02	7.71	52 mg/dL	-1.58	0.45
3	CREATININE II	Jaffes Kinetic-Alkaline Picrate II	Any Analyser (Automation / Semi Automation)	1233	6.66	11.71	0.78	5.9 mg/dL	-0.97	0.04
4	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Any Analyser (Automation / Semi Automation)	1435	2.6	16.3	0.42	1.81 mg/dL	-1.88	0.02
5	T-PROTEIN II	Biuret - Colorimetric II	Any Analyser (Automation / Semi Automation)	1251	4.33	12.37	0.54	3.2 g/dL	-2.09	0.03
6	ALBUMIN II	BCG - Colorimetric II	Any Analyser (Automation / Semi Automation)	1285	2.65	11.67	0.31	2.5 g/dL	-0.48	0.02
7	URIC ACID II	Enzymatic / Uricase Colorimetric II	Any Analyser (Automation / Semi Automation)	1238	4.3	14.99	0.64	2.8 mg/dL	-2.34	0.04
8	CHOLESTROL II	CHOD-PAP II	Any Analyser (Automation / Semi Automation)	1453	90.3	11.84	10.69	87 mg/dL	-0.31	0.56
9	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Any Analyser (Automation / Semi Automation)	1296	81.75	17.62	14.41	63 mg/dL	-1.3	0.8

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DEPARTMENT OF CLINICAL BIOCHEMISTRY

CMC EXTERNAL QUALITY ASSURANCE SCHEME

PC-1024

MONTHLY SUMMARY REPORT - FEBRUARY 2024

LAB NO: 17347

LAB NAME: **HUMAN ANALYSIS CENTRE & CO**

CONSTITUENT GROUP

Chemistry II

Date of Result Entered: 22/02/2024

Date of Result Published: 05/03/2024

PT Item: Lyophilized human serum based

S. No.	Analyte	Method / Principle	Analyser	No. of Participants	AV	Participants		Your Value	Z Score	u*
						CV	SDPA			
1	GLUCOSE II	GOD-POD II	Any Analyser (Automation / Semi Automation)	1627	96.57	9.21	8.9	86 mg/dL	-1.19	0.44
2	UREA II	Urease UV / GLDH II	Any Analyser (Automation / Semi Automation)	1168	26.64	15.95	4.25	39 mg/dL	2.91	0.25
3	CREATININE II	Jaffes Kinetic-Alkaline Picrate II	Any Analyser (Automation / Semi Automation)	1273	2.26	12.99	0.29	1.8 mg/dL	-1.59	0.02
4	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Any Analyser (Automation / Semi Automation)	1130	1.76	16.01	0.28	1.04 mg/dL	-2.57	0.02
5	T-PROTEIN II	Biuret - Colorimetric II	Any Analyser (Automation / Semi Automation)	1322	5.99	9.6	0.57	4.8 g/dL	-2.09	0.03
6	ALBUMIN II	BCG - Colorimetric II	Any Analyser (Automation / Semi Automation)	1294	3.61	9.21	0.33	3.4 g/dL	-0.64	0.02
7	URIC ACID II	Enzymatic / Uricase Colorimetric II	Any Analyser (Automation / Semi Automation)	1499	5.37	17.7	0.95	3.6 mg/dL	-1.86	0.05
8	CHOLESTROL II	CHOD-PAP II	Any Analyser (Automation / Semi Automation)	1685	125.93	11.88	14.96	89 mg/dL	-2.47	0.73
9	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Any Analyser (Automation / Semi Automation)	1488	159.25	13.19	21.01	110 mg/dL	-2.34	1.09