CHRISTIAN MEDICAL COLLEGE

DEPARTMENT OF CLINICAL BIOCHEMISTRY

CMC EXTERNAL QUALITY ASSURANCE SCHEME

MONTHLY SUMMARY REPORT - AUGUST 2023

PC-1024

Lab Name	**LUPIN DIAGNOSTICS**	**Lab No**	**16047**
Constituent Group	**Chemistry I**	**Date of Result Entered :**	**16/08/2023**
PT item	**Lyophilized human serum based**	**Date of Report Published :**	**01/09/2023**

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants CV	Participants SD	Your Value	SDI	U
1	GLUCOSE	Dry Chemistry	Fuji Dry Chemistry series	47	58.14	5.20	3.02	60 mg/dL	0.62	0.88
2	UREA	Dry Chemistry	Fuji Dry Chemistry series	59	17.87	6.08	1.09	17.97 mg/dL	0.09	0.28
3	CREATININE	Dry Chemistry	Fuji Dry Chemistry series	60	0.84	5.87	0.05	0.97 mg/dL	2.65	0.01
4	T.BILIRUBIN	Dry Chemistry	Fuji Dry Chemistry series	56	0.80	12.33	0.10	0.7 mg/dL	-1.01	0.03
5	T-PROTEIN	Dry Chemistry	Fuji Dry Chemistry series	65	5.51	4.70	0.26	5.6 g/dL	0.35	0.06
6	ALBUMIN	Dry Chemistry	Fuji Dry Chemistry series	60	3.46	6.00	0.21	3.6 g/dL	0.67	0.05
7	CALCIUM	Dry Chemistry	Fuji Dry Chemistry series	77	8.54	5.58	0.48	8.8 mg/dL	0.55	0.11
8	URIC ACID	Dry Chemistry	Fuji Dry Chemistry series	71	3.79	4.77	0.18	3.8 mg/dL	0.06	0.04
9	CHOLESTEROL	Dry Chemistry	Fuji Dry Chemistry series	60	121.66	4.92	5.98	124 mg/dL	0.39	1.54
10	TRIGLYCERIDE	Dry Chemistry	Fuji Dry Chemistry series	63	127.87	7.04	9.00	135 mg/dL	0.79	2.27
11	HDL	Dry Chemistry	Fuji Dry Chemistry series	61	23.21	7.23	1.68	24 mg/dL	0.47	0.43
12	SODIUM	Dry Chemistry	Fuji Dry Chemistry series	77	128.87	2.38	3.06	132 mmol/L	1.02	0.70
13	POTASSIUM	Dry Chemistry	Fuji Dry Chemistry series	75	2.48	5.08	0.13	2.5 mmol/L	0.16	0.03
14	CHLORIDE	Dry Chemistry	Fuji Dry Chemistry series	73	94.08	3.37	3.17	95 mmol/L	0.29	0.74
15	AST	Dry Chemistry	Fuji Dry Chemistry series	62	36.02	9.50	3.42	28 U/L	-2.34	0.87
16	ALT	Dry Chemistry	Fuji Dry Chemistry series	60	29.65	12.28	3.64	19 U/L	-2.93	0.94
17	ALP	Dry Chemistry	Fuji Dry Chemistry series	57	131.71	13.88	18.28	190 U/L	3.19	4.84
18	MAGNESIUM	Dry Chemistry	Fuji Dry Chemistry series	45	1.52	7.74	0.12	1.5 mg/dL	-0.17	0.04

SDI Range	Interpretation
Within -1.00 to +1.00	Excellent.
Within ±1.01 to ±2.00	Good.
Within ±2.01 to ±2.99	Accept with caution. Warning Signal.
Beyond ±3.0	Unacceptable performance. Action Signal.

LAB ADDRESS :
LUPIN DIAGNOSTICS
SHOBHA NURSING HOME, OPP TO SEWA SADAN SCHOOL, SARASWATI CHOWK
SOLAPUR
MAHARASHTRA413003

Pamela Christudoss

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Dr. Pamela Christudoss
CMC EQAS Coordinator
Christian Medical College, Vellore

Homogeneity and Stability of the sample is passed.
Data in CMC EQAS reports is confidential
CMC EQAS does not sub contract any components
********* End of Report ********

Title	PT/ EQAS EVALUATION RECORD
Document Number	FRM.QCM.03
Version	02
Amendment No	00
Effective Date	02.06.2023

LUPIN DIAGNOSTICS
Good health starts here

Date of Investigation: 02/09/23.

PT/EQAS Set Identification:	CMC, vellore chemistry-1.
Date of PT/EQAS:	16/08/23.
Acceptable/ Unacceptable Results	Creatinine.
Acceptable Result Range:	0.80 ± 0.10.

Previous Trends/ Unacceptable Results from this Analyte/ Test:

No.

Classification of Problems: (Please tick)

Clerical:

- Transcription error (may be pre- or post-analytical factors)
- Wrong method has been registered for analysis or method change not updated.

Details of Investigation: No.

Methodological

- Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range.
- Scheduled instrument maintenance not performed appropriately.
- Incorrect instrument calibration.
- Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date.
- Instrument probes misaligned.
- Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems.
- Problem in manufacture of reagents / standards, or with instrument settings specified by manufacturer
- Carry-over from previous specimen.
- Automatic pipettor not calibrated to acceptable precision and accuracy.
- Imprecision from result being close to detection limit of method.
- QC material not run within expiration date, or improperly stored.

QC material not run at relevant analyte concentration.

Result not within reportable range (linearity) for instrument / reagent system.

Obstruction of instrument tubing / orifice by clot or protein.

Incorrect incubation times.

Details of Investigation: No.

Technical

EQA material improperly reconstituted.

Testing delayed after reconstitution of EQA material (with problem from evaporation or deterioration).

Sample not placed in proper order on instrument.

Result released despite unacceptable QC data.

QC data within acceptable limits but showed trend suggestive of problem with the assay.

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.

Manual pipetting / diluting performed inaccurately, at an incorrect temperature or with incorrect diluent.

Calculation error or result reported using too few significant digits.

Secondary specimen tubes incorrectly labeled.

In addition to above discipline specific errors may also occur

Details of Investigation: No.

Problem with PT/EQAS Material

Matrix effects: The performance of some instrument / method combinations may be affected by the matrix of the PT/EQAS sample. This can be overcome to some extent by assessing participants in peer groups – to be done by the PT/EQAS provider.

Non-homogenous test material due to variability infill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens.

Non-viable samples for microbiology PT/EQAS program.

Haemolysis on an immune-haemtology program samples.

Details of Investigation:

Problem with PT/EQAS Evaluation

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.

Details of Investigation: No.

No Explanation: Attributed to Random Error

Any Others (explain)

Summary of Investigation:

No any deviation in IQC performance.
No any issue with respect to reagent, analyser.
Previous EQAS performance within a acceptable range.

Was patient data affected? & Corrective action taken if Patient data was affected.

Corrective/ Preventive action taken to prevent Reoccurrence

performance of creatinine parameters closely monitor in next sample.

Conclusions No any specific issue found. Suspected outlier due to be random error.
Quality Manager/ Team Leader [signature] Date: 02/09/23
Lab Head [signature] Date: 02/09/23.

Date of Investigation: 02/09/23.

PT/EQAS Set Identification:	CMC Vellore Chemistry- 7.
Date of PT/EQAS:	16/08/23.
Acceptable/ Unacceptable Results	AST.
Acceptable Result Range:	36.02 ± 3.42.

Previous Trends/ Unacceptable Results from this Analyte/ Test:

No.

Classification of Problems: (Please tick)

Clerical:

Transcription error (may be pre- or post-analytical factors)

Wrong method has been registered for analysis or method change not updated.

Details of Investigation: No.

Methodological

Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range.

Scheduled instrument maintenance not performed appropriately.

Incorrect instrument calibration.

Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date.

Instrument probes misaligned.

Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems.

Problem in manufacture of reagents / standards, or with instrument settings specified by manufacturer

Carry-over from previous specimen.

Automatic pipettor not calibrated to acceptable precision and accuracy.

Imprecision from result being close to detection limit of method.

QC material not run within expiration date, or improperly stored.

- QC material not run at relevant analyte concentration.
- Result not within reportable range (linearity) for instrument / reagent system.
- Obstruction of instrument tubing / orifice by clot or protein.
- Incorrect incubation times.

Details of Investigation: No.

Technical

- EQA material improperly reconstituted.
- Testing delayed after reconstitution of EQA material (with problem from evaporation or deterioration).
- Sample not placed in proper order on instrument.
- Result released despite unacceptable QC data.
- QC data within acceptable limits but showed trend suggestive of problem with the assay.
- 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.
- Manual pipetting / diluting performed inaccurately, at an incorrect temperature or with incorrect diluent.
- Calculation error or result reported using too few significant digits.
- Secondary specimen tubes incorrectly labeled.
- In addition to above discipline specific errors may also occur

Details of Investigation: No.

Problem with PT/EQAS Material

- Matrix effects: The performance of some instrument / method combinations may be affected by the matrix of the PT/EQAS sample. This can be overcome to some extent by assessing participants in peer groups – to be done by the PT/EQAS provider.
- Non-homogenous test material due to variability infill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens.
- Non-viable samples for microbiology PT/EQAS program.
- Haemolysis on an immune-haemtology program samples.

Details of Investigation:

Problem with PT/EQAS Evaluation

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.

Details of Investigation: No.

No Explanation: Attributed to Random Error

Any Others (explain)

Summary of Investigation:

No any deviation in IQC performance.
No any issue with respect to reagent, analyser.
previous EQAs performance within a acceptable range.

Was patient data affected? & Corrective action taken if Patient data was affected.

Corrective/ Preventive action taken to prevent Reoccurrence

performance of AST parameters closely monitor in next sample.

Conclusions No any Specific issue found. Suspected outlier due to be random error.
Quality Manager/ Team Leader Apurva Date: 02/09/23
Lab Head Date: 02/09/23.

Date of Investigation: 02/09/23.

PT/EQAS Set Identification: QMC, Vellore chemistry - I.

Date of PT/EQAS: 18/08/23.

Acceptable/ Unacceptable Results: ALT.

Acceptable Result Range: 29.65 I 3.64

Previous Trends/ Unacceptable Results from this Analyte/ Test:

No.

Classification of Problems: (Please tick)

Clerical:

- Transcription error (may be pre- or post-analytical factors)
- Wrong method has been registered for analysis or method change not updated.

Details of Investigation: No.

Methodological

- Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range.
- Scheduled instrument maintenance not performed appropriately.
- Incorrect instrument calibration.
- Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date.
- Instrument probes misaligned.
- Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems.
- Problem in manufacture of reagents / standards, or with instrument settings specified by manufacturer
- Carry-over from previous specimen.
- Automatic pipettor not calibrated to acceptable precision and accuracy.
- Imprecision from result being close to detection limit of method.
- QC material not run within expiration date, or improperly stored.

- ☐ QC material not run at relevant analyte concentration.
- ☐ Result not within reportable range (linearity) for instrument / reagent system.
- ☐ Obstruction of instrument tubing / orifice by clot or protein.
- ☐ Incorrect incubation times.

Details of Investigation: No.

Technical

- ☐ EQA material improperly reconstituted.
- ☐ Testing delayed after reconstitution of EQA material (with problem from evaporation or deterioration).
- ☐ Sample not placed in proper order on instrument.
- ☐ Result released despite unacceptable QC data.
- ☐ QC data within acceptable limits but showed trend suggestive of problem with the assay.
- ☐ 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.
- ☐ Manual pipetting / diluting performed inaccurately, at an incorrect temperature or with incorrect diluent.
- ☐ Calculation error or result reported using too few significant digits.
- ☐ Secondary specimen tubes incorrectly labeled.
- ☐ In addition to above discipline specific errors may also occur

Details of Investigation: No.

Problem with PT/EQAS Material

- ☐ Matrix effects: The performance of some instrument / method combinations may be affected by the matrix of the PT/EQAS sample. This can be overcome to some extent by assessing participants in peer groups – to be done by the PT/EQAS provider.
- ☐ Non-homogenous test material due to variability infill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens.
- ☐ Non-viable samples for microbiology PT/EQAS program.
- ☐ Haemolysis on an immune-haemtology program samples.

Details of Investigation:

Problem with PT/EQAS Evaluation

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.

Details of Investigation: No.

No Explanation: Attributed to Random Error

Any Others (explain)

Summary of Investigation:

No any deviation in IQC performance.
No any issue with respect to reagent analyser.
previous EQAS performance within a acceptable range.

Was patient data affected? & Corrective action taken if Patient data was affected.

Corrective/ Preventive action taken to prevent Reoccurrence

performance of ALT parameters closely monitor in next sample.

Conclusions No any specific issue found suspected outlier due to the random error.
Quality Manager/ Team Leader Date: 02/09/23
Lab Head Date: 02/09/2023

Date of Investigation: 02/09/23.

PT/EQAS Set Identification:	CMC Vellore Chemistry - I.
Date of PT/EQAS:	16/08/23.
Acceptable/ Unacceptable Results	ALP.
Acceptable Result Range:	131.71 ± 18.25.

Previous Trends/ Unacceptable Results from this Analyte/ Test:

No.

Classification of Problems: (Please tick)

Clerical:

- Transcription error (may be pre- or post-analytical factors)
- Wrong method has been registered for analysis or method change not updated.

Details of Investigation: No.

Methodological

- Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range.
- Scheduled instrument maintenance not performed appropriately.
- Incorrect instrument calibration.
- Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date.
- Instrument probes misaligned.
- Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems.
- Problem in manufacture of reagents / standards, or with instrument settings specified by manufacturer
- Carry-over from previous specimen.
- Automatic pipettor not calibrated to acceptable precision and accuracy.
- Imprecision from result being close to detection limit of method.
- QC material not run within expiration date, or improperly stored.

- QC material not run at relevant analyte concentration.
- Result not within reportable range (linearity) for instrument / reagent system.
- Obstruction of instrument tubing / orifice by clot or protein.
- Incorrect incubation times.

Details of Investigation: No.

Technical

- EQA material improperly reconstituted.
- Testing delayed after reconstitution of EQA material (with problem from evaporation or deterioration).
- Sample not placed in proper order on instrument.
- Result released despite unacceptable QC data.
- QC data within acceptable limits but showed trend suggestive of problem with the assay.
- 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.
- Manual pipetting / diluting performed inaccurately, at an incorrect temperature or with incorrect diluent.
- Calculation error or result reported using too few significant digits.
- Secondary specimen tubes incorrectly labeled.
- In addition to above discipline specific errors may also occur

Details of Investigation: No.

Problem with PT/EQAS Material

- Matrix effects: The performance of some instrument / method combinations may be affected by the matrix of the PT/EQAS sample. This can be overcome to some extent by assessing participants in peer groups – to be done by the PT/EQAS provider.
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- Haemolysis on an immune-haemtology program samples.

Details of Investigation:

Problem with PT/EQAS Evaluation

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.

Details of Investigation: No.

✓ No Explanation: Attributed to Random Error

Any Others (explain)

Summary of Investigation:

No any deviation in IQC performance.
No any issue with respect to reagent, analyser.
Previous EQAS performance with a acceptable range.

Was patient data affected? & Corrective action taken if Patient data was affected.

No.

Corrective/ Preventive action taken to prevent Reoccurrence

performance of ALP parameters closely monitor in next sample.

Conclusions No any Specific issue found suspected outlier due to be random error.
Quality Manager/ Team Leader Date: 02/09/23
Lab Head Date: 02/09/23