



CHRISTIAN MEDICAL COLLEGE

DEPARTMENT OF CLINICAL BIOCHEMISTRY

CMC EXTERNAL QUALITY ASSURANCE SCHEME

MONTHLY SUMMARY REPORT - JANUARY 2023



PC-1024

Lab Name **LUPIN DIAGNOSTICS**Lab No **16041**Constituent Group **Chemistry I**Date of Result Entered : **18/01/2023**PT item **Lyophilized Serum**Date of Report Published : **09/02/2023**

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants		Your Value	SDI	U
						CV	SD			
1	GLUCOSE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	287	163.72	3.48	5.70	171 mg/dL	1.28	0.67
2	UREA	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	292	30.94	4.95	1.53	29.3 mg/dL	-1.07	0.18
3	CREATININE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	287	1.33	4.05	0.05	1.4 mg/dL	1.30	0.01
4	T.BILIRUBIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	284	2.86	8.07	0.23	3 mg/dL	0.61	0.03
5	T-PROTEIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	285	5.04	4.96	0.25	4.8 g/dL	-0.96	0.03
6	ALBUMIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	288	2.98	5.17	0.15	3.1 g/dL	0.78	0.02
7	CALCIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	281	8.75	4.95	0.43	8.6 mg/dL	-0.35	0.05
8	PHOSPHORUS	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	230	6.14	5.13	0.32	5.9 mg/dL	-0.76	0.04
9	URIC ACID	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	280	4.24	3.30	0.14	4.1 mg/dL	-1.00	0.02
10	CHOLESTEROL	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	262	105.27	4.62	4.86	113 mg/dL	1.59	0.60
11	TRIGLYCERIDE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	264	126.62	4.42	5.60	132 mg/dL	0.96	0.69
12	HDL	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	257	21.75	7.70	1.68	24 mg/dL	1.34	0.21
13	SODIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	223	129.48	2.36	3.06	131 mmol/L	0.50	0.41
14	POTASSIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	225	3.49	2.75	0.10	3.6 mmol/L	1.15	0.01
15	CHLORIDE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	186	96.39	2.63	2.53	99 mmol/L	1.03	0.37
16	AST	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	287	63.15	5.13	3.24	63 U/L	-0.05	0.38
17	ALT	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	286	68.70	8.03	5.52	74 U/L	0.96	0.65
18	ALP	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	283	88.74	8.53	7.57	102 U/L	1.75	0.90
19	AMYLASE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	157	40.67	17.53	7.13	55 U/L	2.01	1.14

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

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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	01
Amendment No	01
Effective Date	01.09.2022

Date of Investigation:

10/02/23

PT/EQAS Set Identification:	C.M.C. Vellore Chemistry I - (1)
Date of PT/EQAS:	18/01/23.
Acceptable/ Unacceptable Results	55 U/L
Acceptable Result Range:	26.41 - 54.93.
Previous Trends/ Unacceptable Results from this Analyte/ Test:	- NO.
<p>Classification of Problems: (Please tick)</p> <p>Clerical:</p> <p><input type="checkbox"/> Transcription error (may be pre- or post-analytical factors)</p> <p><input type="checkbox"/> Wrong method has been registered for analysis or method change not updated.</p> <p>Details of Investigation:</p> <p>NIL</p>	
<p>Methodological</p> <p><input type="checkbox"/> Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range.</p> <p><input type="checkbox"/> Scheduled instrument maintenance not performed appropriately.</p> <p><input type="checkbox"/> Incorrect instrument calibration.</p> <p><input type="checkbox"/> Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date.</p> <p><input type="checkbox"/> Instrument probes misaligned.</p> <p><input type="checkbox"/> Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems.</p> <p><input type="checkbox"/> Problem in manufacture of reagents / standards, or with instrument settings specified by manufacturer</p> <p><input type="checkbox"/> Carry-over from previous specimen.</p>	

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- 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:

NIL

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:

NIL

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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- 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:

NIL

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:

NIL

No Explanation: Attributed to Random Error

Any Others (explain)

Summary of Investigation:

*no any specific deviation noted
in IQC*

[Signature]

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**LUPIN
DIAGNOSTICS**

Good health starts here

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

NO

Corrective/ Preventive action taken to prevent Reoccurrence

Performance monitored closely in next sample.

Conclusions

Based on investigation suspected unacceptable performance due to may be random error.

Quality Manager/ Team Leader

Sunay Loni

Date:

10/02/23.

Lab Head

Dr. Bipin Biswas

Date:

10.02.2023