CHRISTIAN MEDICAL COLLEGE

DEPARTMENT OF CLINICAL BIOCHEMISTRY

CMC EXTERNAL QUALITY ASSURANCE SCHEME

MONTHLY SUMMARY REPORT - FEBRUARY 2024

PC-1024

Lab Name	**LUPIN DIAGNOSTICS**	**Lab No**	**16726**
Constituent Group	**Chemistry I**	**Date of Result Entered :**	**20/02/2024**
PT item	**Lyophilized human serum based**	**Date of Report Published :**	**05/03/2024**

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	AV	Participants		Your Value	Z Score	u*
						CV	SDPA			
1	GLUCOSE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	270	241.84	3.24	7.84	218 mg/dL	-3.04	0.95
2	UREA	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	273	64.21	4.25	2.73	67.41 mg/dL	1.17	0.33
3	CREATININE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	275	5.65	4.66	0.26	5.96 mg/dL	1.18	0.03
4	T.BILIRUBIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	273	2.79	6.17	0.17	2.8 mg/dL	0.06	0.02
5	T-PROTEIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	281	5.15	3.83	0.20	4.8 g/dL	-1.78	0.02
6	ALBUMIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	280	3.02	5.19	0.16	3.2 g/dL	1.15	0.02
7	CALCIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	265	10.10	3.17	0.32	9.9 mg/dL	-0.62	0.04
8	URIC ACID	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	274	7.04	3.78	0.27	7.3 mg/dL	0.98	0.03
9	CHOLESTEROL	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	256	107.09	5.50	5.89	108 mg/dL	0.15	0.74
10	TRIGLYCERIDE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	259	224.57	4.81	10.81	225 mg/dL	0.04	1.34
11	HDL	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	251	23.42	6.07	1.42	23 mg/dL	-0.30	0.18
12	SODIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	230	125.29	2.49	3.12	130 mmol/L	1.51	0.41
13	POTASSIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	229	5.00	2.92	0.15	5 mmol/L	0.00	0.02
14	CHLORIDE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	195	96.80	2.88	2.79	100 mmol/L	1.15	0.40
15	AST	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	286	88.59	5.58	4.94	61 U/L	-5.58	0.58
16	ALT	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	282	103.61	7.48	7.75	90 U/L	-1.76	0.92
17	ALP	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	283	81.32	7.56	6.14	102 U/L	3.37	0.73

u* - Method of Uncertainty

Z-Score	Interpretation
$\|z\| \leq 2.0$	Acceptable
$2.0 < \|z\| < 3.0$	Warning Signal
$\|z\| \geq 3.0$	Unacceptable (action Signal)

Self-Evaluation summary report

Aim- Self-evaluation performed because of laboratory were missed to change instrument name on EQAS portal

CMC Vellore – Sample February-2024

Sl.No	Constituent Name	Method / Principle Name	Analyzer Name	No of Participants	AV	Participants		Your Value	Z Score	u*
						CV	SDPA			
1	GLUCOSE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	270	241.84	3.24	7.84	218	-3.04	0.95
			Fuji Dry Chemistry series	52	249.01	4.06	10.11		-3.07	2.8
2	UREA	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	273	64.21	4.25	2.73	67.41	1.17	0.33
			Fuji Dry Chemistry series	56	66.86	4.03	2.7		0.20	0.72
3	CREATININE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	275	5.65	4.66	0.26	5.96	1.18	0.03
			Fuji Dry Chemistry series	60	5.73	5.89	0.34		0.68	0.09
4	T.BILIRUBIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	273	2.79	6.17	0.17	2.8	0.06	0.02
			Fuji Dry Chemistry series	58	2.79	6.23	0.17		0.06	0.05
5	T-PROTEIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	281	5.15	3.83	0.2	4.8	-1.78	0.02
			Fuji Dry Chemistry series	59	5.18	4.96	0.26		-1.46	0.07
6	ALBUMIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	280	3.02	5.19	0.16	3.2	1.15	0.02
			Fuji Dry Chemistry series	58	3.21	5.26	0.17		-0.06	0.04
7	CALCIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	265	10.1	3.17	0.32	9.9	-0.62	0.04
			Fuji Dry Chemistry series	73	9.83	6.12	0.6		0.12	0.14
8	URIC ACID	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	274	7.04	3.78	0.27	7.3	0.98	0.03
			Fuji Dry Chemistry series	65	7.68	4.18	0.32		-1.19	0.08
9	CHOLESTEROL	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	256	107.09	5.5	5.89	108	0.15	0.74
			Fuji Dry Chemistry series	59	111.97	6.68	7.48		-0.53	1.95
10	TRIGLYCERIDE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	259	224.57	4.81	10.81	225	0.04	1.34
			Fuji Dry Chemistry series	62	222.57	6.17	13.72		0.18	3.49
11	HDL	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	251	23.42	6.07	1.42	23	-0.30	0.18
			Fuji Dry Chemistry series	62	23.41	6.01	1.41		-0.29	0.36
12	SODIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	230	125.29	2.49	3.12	130	1.51	0.41

Date of Investigation: 06/02/2024

PT/EQAS Set Identification:	CMC Vellore (Sample February -2024)
Date of PT/EQAS:	20/02/2024
Acceptable/ Unacceptable Results	Chloride & AST
Acceptable Result Range:	–

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: None

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: None

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: None

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: None

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:

None

No Explanation: Attributed to Random ~~Error~~

Any Others (explain)

No any issue found in all steps

Summary of Investigation:

- IQC performance within acceptable range
- No any issue of reagent, analyzer.
- No any technical error noted.

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

No

Corrective/ Preventive action taken to prevent Reoccurrence

Performance of both parameter will be monitor closely in next sample

Conclusions Concluded warning performance as random error.
Quality Manager/ Team Leader MVRaleja Date: 06/03/24
Lab Head Dhanaya Date: 8/3/24

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: 06/03/2024

PT/EQAS Set Identification:	CMC Vellore (Sample - February-2024)
Date of PT/EQAS:	22/02/2024
Acceptable/ Unacceptable Results	~~Cholesterol~~ Glucose
Acceptable Result Range:	249 ± 10.11

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:

None

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:

None

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: None

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: None

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: None

No Explanation: Attributed to Random Error

Any Others (explain)

Summary of Investigation:

- Ige performance found within range.
- No any issue noted wef analyser, calibration, reagent
- No any specific complaint received from patient on day of EQAS sample procell.

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

No

Corrective/ Preventive action taken to prevent Reoccurrence

Glucose performance will be monitor closely in next sample.

Conclusions Suspected outlier due to may be random error.
Quality Manager/ Team Leader Mustakeem Date: 05/03/2024
Lab Head Dhananjay Date: 6/3/24