



CHRISTIAN MEDICAL COLLEGE

DEPARTMENT OF CLINICAL BIOCHEMISTRY
CMC EXTERNAL QUALITY ASSURANCE SCHEME
MONTHLY SUMMARY REPORT - MARCH 2024



Lab Name **LUPIN DIAGNOSTICS** Lab No **16726**
Constituent Group **Chemistry I** Date of Result Entered : **19/03/2024**
PT item **Lyophilized human serum based** Date of Report Published : **06/04/2024**

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	AV	Participants		Your Value	Z Score	u*
						CV	SDPA			
1	GLUCOSE	Dry Chemistry	Fuji Dry Chemistry series	51	165.29	4.72	7.80	142 mg/dL	-2.99	2.18
2	UREA	Dry Chemistry	Fuji Dry Chemistry series	54	25.72	4.67	1.20	25.46 mg/dL	-0.22	0.33
3	CREATININE	Dry Chemistry	Fuji Dry Chemistry series	59	0.94	6.82	0.06	0.9 mg/dL	-0.62	0.02
4	T.BILIRUBIN	Dry Chemistry	Fuji Dry Chemistry series	55	0.77	14.19	0.11	0.8 mg/dL	0.28	0.03
5	T-PROTEIN	Dry Chemistry	Fuji Dry Chemistry series	59	5.50	5.92	0.33	5.2 g/dL	-0.92	0.08
6	ALBUMIN	Dry Chemistry	Fuji Dry Chemistry series	57	3.45	8.24	0.28	3.4 g/dL	-0.18	0.08
7	CALCIUM	Dry Chemistry	Fuji Dry Chemistry series	71	8.60	7.04	0.60	8.2 mg/dL	-0.66	0.14
8	CHOLESTEROL	Dry Chemistry	Fuji Dry Chemistry series	61	113.27	8.37	9.48	104 mg/dL	-0.98	2.43
9	HDL	Dry Chemistry	Fuji Dry Chemistry series	57	24.53	5.59	1.37	24 mg/dl	-0.39	0.36



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

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

Date of Investigation: 06/03/2024

PT/EQAS Set Identification:	CME Vellure (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:	
<input type="checkbox"/> Transcription error (may be pre- or post-analytical factors)	
<input type="checkbox"/> Wrong method has been registered for analysis or method change not updated.	
Details of Investigation:	No
Methodological	
<input type="checkbox"/> Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range.	
<input type="checkbox"/> Scheduled instrument maintenance not performed appropriately.	
<input type="checkbox"/> Incorrect instrument calibration.	
<input type="checkbox"/> Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date.	
<input type="checkbox"/> Instrument probes misaligned.	
<input type="checkbox"/> Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems.	
<input type="checkbox"/> Problem in manufacture of reagents / standards, or with instrument settings specified by manufacturer	
<input type="checkbox"/> Carry-over from previous specimen.	
<input type="checkbox"/> Automatic pipettor not calibrated to acceptable precision and accuracy.	
<input type="checkbox"/> Imprecision from result being close to detection limit of method.	
<input type="checkbox"/> QC material not run within expiration date, or improperly stored.	

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

- 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 in fill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens.
- Non-viable samples for microbiology PT/EQAS program.
- Haemolysis on an immune-haematology program samples.

Details of Investigation:

None

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

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 any steps

Summary of Investigation:

- *Isr performance within acceptable range*
- *No any issue w/ 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

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



Conclusions	
<p><i>Concluded warning performance at random error</i></p>	
Quality Manager/ Team Leader	<p><i>Mustakim</i> Date: <i>06/03/24</i></p>
Lab Head	<p><i>Shaziyah</i> Date: <i>8/3/24</i></p>

Controlled Copy

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

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:	None
Classification of Problems: (Please tick) Clerical:	
<input type="checkbox"/> Transcription error (may be pre- or post-analytical factors)	
<input type="checkbox"/> Wrong method has been registered for analysis or method change not updated.	
Details of Investigation:	None
Methodological	
<input type="checkbox"/> Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range.	
<input type="checkbox"/> Scheduled instrument maintenance not performed appropriately.	
<input type="checkbox"/> Incorrect instrument calibration.	
<input type="checkbox"/> Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date.	
<input type="checkbox"/> Instrument probes misaligned.	
<input type="checkbox"/> Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems.	
<input type="checkbox"/> Problem in manufacture of reagents / standards, or with instrument settings specified by manufacturer	
<input type="checkbox"/> Carry-over from previous specimen.	
<input type="checkbox"/> Automatic pipettor not calibrated to acceptable precision and accuracy.	
<input type="checkbox"/> Imprecision from result being close to detection limit of method.	
<input type="checkbox"/> QC material not run within expiration date, or improperly stored.	

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

- 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 in fill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens.
- Non-viable samples for microbiology PT/EQAS program.
- Haemolysis on an immune-haematology program samples.

Details of Investigation:

None

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



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:

- Ice performance found within range.
- No any issue noted w/ analyser, calibration, reagent
- No any specific complaint received from patients on day of each sample process.

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.

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



Conclusions	
<i>suspected outlier due to may be random error.</i>	
Quality Manager/ Team Leader	<i>Mustakim</i> Date: <i>06/03/2024</i>
Lab Head	<i>Sharafa</i> Date: <i>6/3/24</i>

Controlled Copy



CHRISTIAN MEDICAL COLLEGE

DEPARTMENT OF CLINICAL BIOCHEMISTRY

CMC EXTERNAL QUALITY ASSURANCE SCHEME

MONTHLY SUMMARY REPORT - JANUARY 2024



PC-1024

Lab Name LUPIN DIAGNOSTICS

Lab No

16726

Constituent Group Chemistry I

Date of Result Entered :

22/01/2024

PT item Lyophilized human serum based

Date of Report Published :

06/02/2024

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	258	121.13	2.88	3.49	121 mg/dL	-0.04	0.43
2	UREA	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	259	38.84	4.30	1.67	36.3 mg/dL	-1.52	0.21
3	CREATININE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	252	1.65	4.24	0.07	1.7 mg/dL	0.71	0.01
4	T.BILIRUBIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	250	1.94	8.20	0.16	1.7 mg/dL	-1.51	0.02
5	T-PROTEIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	260	4.96	3.18	0.16	5.3 g/dL	2.15	0.02
6	ALBUMIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	261	3.01	5.25	0.16	2.9 g/dL	-0.70	0.02
7	CALCIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	245	8.53	4.94	0.42	7.8 mg/dL	-1.73	0.05
8	URIC ACID	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	252	4.54	3.28	0.15	4.5 mg/dL	-0.27	0.02
9	CHOLESTEROL	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	233	100.13	4.87	4.88	115 mg/dL	3.05	0.64
10	TRIGLYCERIDE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	236	169.69	3.80	6.44	165 mg/dL	-0.73	0.84
11	HDL	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	232	22.57	6.28	1.42	18 mg/dL	-3.23	0.19
12	SODIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	219	129.06	2.51	3.24	130 mmol/L	0.29	0.44
13	POTASSIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	211	3.26	2.95	0.10	3.2 mmol/L	-0.62	0.01
14	CHLORIDE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	186	91.99	2.50	2.30	91 mmol/L	-0.43	0.34
15	AST	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	260	134.48	5.46	7.35	109 U/L	-3.47	0.91
16	ALT	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	262	48.45	6.79	3.29	43 U/L	-1.66	0.41
17	ALP	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	255	140.32	7.63	10.70	124 U/L	-1.53	1.34

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)

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



Date of Investigation: 06/02/2024

PT/EQAS Set Identification:	22/01/2024 (case vellore) sample-1
Date of PT/EQAS:	22/01/2024
Acceptable/ Unacceptable Results	cholesterol
Acceptable Result Range:	
Previous Trends/ Unacceptable Results from this Analyte/ Test:	NO
Classification of Problems: (Please tick) Clerical:	
<input type="checkbox"/> Transcription error (may be pre- or post-analytical factors)	
<input type="checkbox"/> Wrong method has been registered for analysis or method change not updated.	
Details of Investigation:	None
<hr/>	
<hr/>	
<hr/>	
Methodological	
<input type="checkbox"/> Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range.	
<input type="checkbox"/> Scheduled instrument maintenance not performed appropriately.	
<input type="checkbox"/> Incorrect instrument calibration.	
<input type="checkbox"/> Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date.	
<input type="checkbox"/> Instrument probes misaligned.	
<input type="checkbox"/> Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems.	
<input type="checkbox"/> Problem in manufacture of reagents / standards, or with instrument settings specified by manufacturer	
<input type="checkbox"/> Carry-over from previous specimen.	
<input type="checkbox"/> Automatic pipettor not calibrated to acceptable precision and accuracy.	
<input type="checkbox"/> Imprecision from result being close to detection limit of method.	
<input type="checkbox"/> QC material not run within expiration date, or improperly stored.	

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

- 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 in fill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens.
- Non-viable samples for microbiology PT/EQAS program.
- Haemolysis on an immune-haematology program samples.

Details of Investigation:

None

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



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:

*- No any issue noted w/ analyzer, reagent, Calibration.
- The performance found within acceptable limit*

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

No

Corrective/ Preventive action taken to prevent Reoccurrence

performance of cholesterol parameter closely monitor in next sample.

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

<p>Conclusions</p> <p><i>cholesterol outlier suspected due to may be random error</i></p>	
<p>Quality Manager/ Team Leader <u><i>Mustaficim</i></u></p>	<p>Date: <i>08/02/2024</i></p>
<p>Lab Head <u><i>Shayya</i></u></p>	<p>Date: <i>01/2/24</i></p>

Controlled Copy

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

Date of Investigation: 06/02/2024

PT/EQAS Set Identification:	Cmc vellone (sample - 1)
Date of PT/EQAS:	22/01/2024
Acceptable/ Unacceptable Results	HDL cholesterol
Acceptable Result Range:	22.57 - ± 1.42
Previous Trends/ Unacceptable Results from this Analyte/ Test:	No
Classification of Problems: (Please tick) Clerical:	<input type="checkbox"/> Transcription error (may be pre- or post-analytical factors) <input type="checkbox"/> Wrong method has been registered for analysis or method change not updated.
Details of Investigation:	None
Methodological	<input type="checkbox"/> Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range. <input type="checkbox"/> Scheduled instrument maintenance not performed appropriately. <input type="checkbox"/> Incorrect instrument calibration. <input type="checkbox"/> Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date. <input type="checkbox"/> Instrument probes misaligned. <input type="checkbox"/> Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems. <input type="checkbox"/> Problem in manufacture of reagents / standards, or with instrument settings specified by manufacturer <input type="checkbox"/> Carry-over from previous specimen. <input type="checkbox"/> Automatic pipettor not calibrated to acceptable precision and accuracy. <input type="checkbox"/> Imprecision from result being close to detection limit of method. <input type="checkbox"/> QC material not run within expiration date, or improperly stored.

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

- 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 in fill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens.
- Non-viable samples for microbiology PT/EQAS program.
- Haemolysis on an immune-haematology program samples.

Details of Investigation:

None

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

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:

- ICE performance found within acceptable range.
- No any issue noted w.r.t analyzer, calibration, reagents
- No any trend noted in HDL previously

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

No

Corrective/ Preventive action taken to prevent Reoccurrence

- HDL performance closely monitor in next sample.
- Also performance verify with ZUC study and found acceptable.

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

Conclusions	
<p><i>suspected outlier due to may be random error and monitor performance closely in next sample.</i></p>	
Quality Manager/ Team Leader	<p><i>Multalain</i> Date: <i>06/07/2024</i></p>
Lab Head	<p><i>Sharayu</i> Date: <i>01/2/24</i></p>

Controlled Copy

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



Date of Investigation: 06/07/2024

PT/EQAS Set Identification:	Cmc Vellore - (Sample - 1)
Date of PT/EQAS:	22/01/2024
Acceptable/ Unacceptable Results	AST
Acceptable Result Range:	
Previous Trends/ Unacceptable Results from this Analyte/ Test:	NA
Classification of Problems: (Please tick)	
Clerical:	
<input type="checkbox"/> Transcription error (may be pre- or post-analytical factors)	
<input type="checkbox"/> Wrong method has been registered for analysis or method change not updated.	
Details of Investigation:	None
Methodological	
<input type="checkbox"/> Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range.	
<input type="checkbox"/> Scheduled instrument maintenance not performed appropriately.	
<input type="checkbox"/> Incorrect instrument calibration.	
<input type="checkbox"/> Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date.	
<input type="checkbox"/> Instrument probes misaligned.	
<input type="checkbox"/> Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems.	
<input type="checkbox"/> Problem in manufacture of reagents / standards, or with instrument settings specified by manufacturer	
<input type="checkbox"/> Carry-over from previous specimen.	
<input type="checkbox"/> Automatic pipettor not calibrated to acceptable precision and accuracy.	
<input type="checkbox"/> Imprecision from result being close to detection limit of method.	
<input type="checkbox"/> QC material not run within expiration date, or improperly stored.	

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

- 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 in fill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens.
- Non-viable samples for microbiology PT/EQAS program.
- Haemolysis on an immune-haematology program samples.

Details of Investigation:

None

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

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:

- *No any issue found with the performance.*
- *No any issue found w/ analyser, calibration, reagent*

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

No

Corrective/ Preventive action taken to prevent Reoccurrence

As a part of corrective action performance verify with JLE and found satisfactory.

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

Conclusions	
<i>suspected unacceptable performance due to many be of systematic error.</i>	
Quality Manager/ Team Leader	<i>Mustafa</i> Date: <i>08/02/2024</i>
Lab Head	<i>S. Konev</i> Date: <i>6/2/24</i>

Controlled Copy