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: 22/05/2024

PT/EQAS Set Identification:	CMC Vellore (Sample - April-2024)
Date of PT/EQAS:	19/04/2024
Acceptable/ Unacceptable Results	Glucose
Acceptable Result Range:	119.82 ± 5.88

Previous Trends/ Unacceptable Results from this Analyte/ Test:

No any trend.

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:

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 wef analyzer, reagent, Calibration
- IQC performance found within acceptable limit on the day of EQAS proceed.
- All reagent and calibration within expiry limit.

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

No, no any complaint received

Corrective/ Preventive action taken to prevent Reoccurrence

As a part of preventive action Glucose performance verify by Inter laboratory comparision study with referal laboratory IQC performance found within acceptable limit.

Conclusions Based on the finding glucose outlier found to be due to systematic error and performance can be closely in smear sample.
Quality Manager/ Team Leader M.Wahab Date: 22/05/2024
Lab Head Dhanaji Date: 22/5/24

VIEW LAB MONTHLY SUMMARY

Lab Name	LUPIN DIAGNOSTICS
Lab No	16726
Month	April
Year	2024
Constituent Group	Chemistry I

Details About Robust Analysis

Detail About Monthly Summary

Detail about Z-Score

Click on the analyte to view Graphical Data

All Analyser Result | Print

Print Non Accredited Analytes

Date of Result Entered : 19/04/2024

Date of Report Published : 08/05/2024

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	AV	Participants CV	Participants SDPA	Your Value	Z Score	u*
1	GLUCOSE	Dry Chemistry	Fuji Dry Chemistry series	50	119.82	4.91	5.88	102 mg/dL	-3.03	1.66
2	UREA	Dry Chemistry	Fuji Dry Chemistry series	59	37.59	4.22	1.59	38.09 mg/dL	0.32	0.41
3	CREATININE	Dry Chemistry	Fuji Dry Chemistry series	58	1.79	4.97	0.09	1.74 mg/dL	-0.56	0.02
4	T.BILIRUBIN	Dry Chemistry	Fuji Dry Chemistry series	57	1.99	7.79	0.16	1.8 mg/dL	-1.23	0.04
5	D.BILIRUBIN	Dry Chemistry	Fuji Dry Chemistry series	14	0.96	12.05	0.12	1 mg/dL	0.34	0.06
6	T-PROTEIN	Dry Chemistry	Fuji Dry Chemistry series	62	5.01	4.73	0.24	4.7 g/dL	-1.31	0.06
7	ALBUMIN	Dry Chemistry	Fuji Dry Chemistry series	62	3.33	5.38	0.18	3.4 g/dL	0.39	0.05
8	CALCIUM	Dry Chemistry	Fuji Dry Chemistry series	66	7.72	6.10	0.47	7.8 mg/dL	0.17	0.12
9	URIC ACID	Dry Chemistry	Fuji Dry Chemistry series	61	4.77	3.59	0.17	4.7 mg/dL	-0.41	0.04
10	CHOLESTEROL	Dry Chemistry	Fuji Dry Chemistry series	63	106.61	7.21	7.68	106 mg/dL	-0.08	1.94
11	TRIGLYCERIDE	Dry Chemistry	Fuji Dry Chemistry series	63	164.32	4.96	8.16	169 mg/dL	0.57	2.06
12	HDL	Dry Chemistry	Fuji Dry Chemistry series	61	22.74	7.68	1.75	22 mg/dL	-0.42	0.45
13	SODIUM	Dry Chemistry	Fuji Dry Chemistry series	76	132.04	2.44	3.22	141 mmol/L	2.78	0.74
14	POTASSIUM	Dry Chemistry	Fuji Dry Chemistry series	77	3.19	4.76	0.15	3.3 mmol/L	0.72	0.03
15	CHLORIDE	Dry Chemistry	Fuji Dry Chemistry series	73	90.75	3.56	3.23	91 mmol/L	0.08	0.76
16	AST	Dry Chemistry	Fuji Dry Chemistry series	61	107.15	8.83	9.46	93 U/L	-1.50	2.42
17	ALT	Dry Chemistry	Fuji Dry Chemistry series	53	41.80	12.82	5.36	36 U/L	-1.08	1.47
18	ALP	Dry Chemistry	Fuji Dry Chemistry series	57	211.61	9.54	20.18	178 U/L	-1.67	5.35

u* - Method of Uncertainty

Z-Score	Interpretation
$\lvert z \rvert \leq 2.0$	Acceptable
$2.0 < \lvert z \rvert < 3.0$	Warning Signal

Title	INTER- INSTRUMENT / INTER-TECHNOLOGY ANALYSIS
Document Number	FRM.QCM.20
Version	02
Amendment No	00
Effective Date	02.06.2023

LUPIN DIAGNOSTICS
Good health starts here

Department Biochemistry **Month** _____ **Year** _____

Date	Sample No. & Type	Parameter/ Analyte	SI Unit	Details of Instrument/ Technology-1	Results	Details of Instrument/ Technology-2	Results	Difference	%Difference	Acceptable Criteria as per ALP/ CLIA subpart I	Acceptable/ Not Acceptable	Remarks (if any)
22/05/25	Serum	Glucose	mg/dl	Fusi	103	Cobas E801	109.60	-6.6	5.82	8%	Acceptable	Mustakim

Performed By:	**Reviewed By:**	**Approved By:**

Patient Information		Specimen Information		Client/Doctor Information	
Name	: Mrs.SHUBHANGI BALALNATH PAWAR	Visit ID	: LGRG16974	Client Code	: HLM0010
Age/Gender	: 32 Y 0 M 0 D /Female	Collected	: 21/May/2024 16:59	Client Name	: HLM LATUR FERTILITY PRIVATE LIMITED
MobileNo	: 9405400941	Received	: 22/May/2024 09:21	Client Add.	: LATUR
UHID	: LDAA01894659	Reported	: 22/May/2024 11:25	Client No.	:
Address	:	IP/OP/Barcode	:	Ref Doctor	: Dr.K B Barmade
		Report Status	: Final Report		

Test Name	Result	Bio. Ref. Range	Unit	Method
Blood Glucose Random (RBS) , *FLUORIDE PLASMA*				
Blood Glucose Random (RBS)	109.60	70.0-140.0	mg/dL	Enzymatic UV Hexokinase

Interpretation:

This test checks your blood glucose levels, at random time of the day.

Diagnosing Diabetes	
RBS value	**Interpretation**
70-140 mg/dL	Normal
>/=200	Diabetic

The above reference ranges are as per ADA guidelines.

***** End Of Report *****

Dr. Manoj Sawadkar
Consultant - MD Path

MC-5498

SIN No:BI01828887

This test has been performed at Lupin Diagnostics Laboratory, NRL MUMBAI National Reference Laboratory, Plot No.C-533, MIDC, TTC Industrial Area, Pawane,Turbhe,NAVI MUMBAI , 400705

Patient Information		Specimen Information		Client/Doctor Information	
Name	: Mrs.SHUBHANGI BALALNATH PAWAR	Visit ID	: LGRG16971	Client Code	: HLM0010
Age/Gender	: 32 Y 0 M 0 D /Female	Collected	: 21/May/2024 15:16	Client Name	: HLM LATUR FERTILITY PRIVATE LIMITED
MobileNo	: 9405400941	Received	: 21/May/2024 15:17	Client Add.	: LATUR
UHID	: LDAA01894659	Reported	: 21/May/2024 16:15	Client No.	:
Address	:	IP/OP/Barcode	: R-1500580	Ref Doctor	: Dr.K B Barmade
		Report Status	: Final Report		

PRE-OPERATIVE PANEL

Test Name	Result	Bio. Ref. Range	Unit	Method
Blood Glucose Random (RBS) , *FLUORIDE PLASMA*				
Blood Glucose Random (RBS)	103.00	70-140	mg/dL	Colorimetric End-Point

Interpretation:

This test checks your blood glucose levels, at random time of the day.

Diagnosing Diabetes	
RBS value	**Interpretation**
70-140 mg/dL	Normal
>/=200	Diabetic

The above reference ranges are as per ADA guidelines.

***** End Of Report *****

Dr. Sharayu Patil

SIN No:BI01828572

This test has been performed at Lupin Diagnostics Laboratory, HLM LATUR FERTILITY PRIVATE LIMITED Barmade Hospital Old Adarsh Colony Ausa Road,LATUR,LATUR , 413512

VIEW LAB MONTHLY SUMMARY

Lab Name LUPIN DIAGNOSTICS

Lab No 16726

Month March

Year 2024

Constituent Group Chemistry I

Details About Robust Analysis

Detail About Monthly Summary

Detail about Z-Score

Click on the analyte to view Graphical Data

All Analyser Result | Print | Print Non Accredited Analytes

Date of Result Entered : 19/03/2024

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	D.BILIRUBIN	Dry Chemistry	Fuji Dry Chemistry series	10	0.30	0.00	0.00	0.2 mg/dL	0.00	0.00
6	T-PROTEIN	Dry Chemistry	Fuji Dry Chemistry series	59	5.50	5.92	0.33	5.2 g/dL	-0.92	0.08
7	ALBUMIN	Dry Chemistry	Fuji Dry Chemistry series	57	3.45	8.24	0.28	3.4 g/dL	-0.18	0.08
8	CALCIUM	Dry Chemistry	Fuji Dry Chemistry series	71	8.60	7.04	0.60	8.2 mg/dL	-0.66	0.14
9	CHOLESTEROL	Dry Chemistry	Fuji Dry Chemistry series	61	113.27	8.37	9.48	104 mg/dL	-0.98	2.43
10	HDL	Dry Chemistry	Fuji Dry Chemistry series	57	24.53	5.59	1.37	24 mg/dL	-0.39	0.36
11	SODIUM	Dry Chemistry	Fuji Dry Chemistry series	76	139.03	2.84	3.95	141 mmol/L	0.50	0.91
12	POTASSIUM	Dry Chemistry	Fuji Dry Chemistry series	70	3.59	3.99	0.14	3.6 mmol/L	0.07	0.03
13	CHLORIDE	Dry Chemistry	Fuji Dry Chemistry series	74	101.05	3.37	3.40	102 mmol/L	0.28	0.79
14	AST	Dry Chemistry	Fuji Dry Chemistry series	58	59.17	7.91	4.68	50 U/L	-1.96	1.23
15	ALT	Dry Chemistry	Fuji Dry Chemistry series	59	94.42	12.10	11.43	80 U/L	-1.26	2.98

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

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)

Date of Investigation: 06/02/2024

PT/EQAS Set Identification: 22/01/2024 (CMC 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:

- ☐ 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:

- No any issue noted wrt analyzer, reagent, Calibration.
- IQC 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.

Conclusions cholesterol outlier suspected due to may be random error
Quality Manager/ Team Leader Muskaan Date: 08/04/2024
Lab Head Dhanya Date: 8/2/24

Date of Investigation: 06/02/2024

PT/EQAS Set Identification:	CMC vellore (Sample - 17
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:

- ☐ 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:

- IQc performance found within acceptable range.
- No any issue noted wef Analyzer, Calibration, reagent
- 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.
- New performance verify with the study and found acceptable

Conclusions Suspected outlier due to may be random error and monitor performance closely in next sample.
Quality Manager/ Team Leader Date: 06/02/2024
Lab Head Date: 6/2/24

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: 06/02/2024

PT/EQAS Set Identification: CMC Vellore -(Sample-D)
Date of PT/EQAS: 22/01/2024
Acceptable/ Unacceptable Results: Acc
Acceptable Result Range:
Previous Trends/ Unacceptable Results from this Analyte/ Test: NA

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: N/A

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 wrt 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 ILE and found satisfactory.

Conclusions suspected unacceptable performance due to many be of systematic error
Quality Manager/ Team Leader mustafeiz Date: 08/02/2024
Lab Head Shorayh Date: 6/2/24