CHRISTIAN MEDICAL COLLEGE

DEPARTMENT OF CLINICAL BIOCHEMISTRY

CMC EXTERNAL QUALITY ASSURANCE SCHEME

MONTHLY SUMMARY REPORT - MAY 2023

PC-1024

Lab Name	**LUPIN DIAGNOSTICS**	**Lab No**	**16038**
Constituent Group	**Chemistry I**	**Date of Result Entered :**	**13/05/2023**
PT item	**Lyophilized human serum based**	**Date of Report Published :**	**05/06/2023**

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants CV	Participants SD	Your Value	SDI	U
1	GLUCOSE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	305	233.10	3.35	7.81	234 mg/dL	0.12	0.89
2	UREA	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	309	80.95	3.68	2.98	79.8 mg/dL	-0.39	0.34
3	CREATININE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	307	1.53	4.51	0.07	1.5 mg/dL	-0.43	0.01
4	T.BILIRUBIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	302	3.56	7.08	0.25	3.5 mg/dL	-0.24	0.03
5	T-PROTEIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	303	4.80	3.65	0.18	5.1 g/dL	1.71	0.02
6	ALBUMIN	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	305	2.77	5.41	0.15	2.9 g/dL	0.87	0.02
7	CALCIUM	Dry Chemistry	Fuji Dry Chemistry series	69	8.15	6.87	0.56	8.4 mg/dL	0.45	0.13
8	PHOSPHORUS	Dry Chemistry	Fuji Dry Chemistry series	62	5.54	4.98	0.28	5.7 mg/dL	0.58	0.07
9	URIC ACID	Dry Chemistry	Fuji Dry Chemistry series	67	8.52	5.50	0.47	8.6 mg/dL	0.17	0.11
10	CHOLESTEROL	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	282	101.31	4.39	4.45	111 mg/dL	2.18	0.53
11	TRIGLYCERIDE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	283	154.35	4.70	7.25	149 mg/dL	-0.74	0.86
12	HDL	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	270	19.80	7.03	1.39	21 mg/dL	0.86	0.17
13	SODIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	237	132.25	2.41	3.19	127 mmol/L	-1.65	0.41
14	POTASSIUM	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	240	3.17	3.16	0.10	2.9 mmol/L	-2.70	0.01
15	CHLORIDE	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	198	96.94	2.60	2.52	90 mmol/L	-2.76	0.36
16	AST	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	309	175.75	6.61	11.62	156 U/L	-1.70	1.32
17	ALT	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	308	88.68	9.17	8.13	72 U/L	-2.05	0.93
18	ALP	Dry Chemistry	Ortho Clinical Diagnostics Dry Chemistry Series	305	215.89	7.82	16.89	187 U/L	-1.71	1.93
19	AMYLASE	Dry Chemistry	Fuji Dry Chemistry series	60	127.27	5.16	6.56	123 U/L	-0.65	1.69
20	MAGNESIUM	Dry Chemistry	Fuji Dry Chemistry series	46	2.17	5.26	0.11	2.1 mg/dL	-0.61	0.03

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
MACCARE HOSPITAL, BEHIND ZOPADI CANTEEN, SAVEDI
AHMEDNAGAR
MAHARASHTRA414003

Coordinator Contact Details:
Email:clinqc@cmcvellore.ac.in
Contact Number: 0416-2283102

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 ********

Date of Investigation: 06/06/2023

PT/EQAS Set Identification:	CMC Vellore.
Date of PT/EQAS:	13/05/2023.
Acceptable/ Unacceptable Results	ALTN.
Acceptable Result Range:	–

Previous Trends/ Unacceptable Results from this Analyte/ Test:

No any trend in previous evalution.

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 specific deviation noted in IQC performance. control calibration & reagents within a expiry limit. No any specific issue with analyzer.

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

No.

Corrective/ Preventive action taken to prevent Reoccurrence

performance will be monitored closely in next sample.

Conclusions Based on the findings suspected unaccepted performance due to random error.
Quality Manager/ Team Leader Bhulsing Mahesh Date: 06/06/23
Lab Head Dr. Sagar Kulat Date: 06/06/23

LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
Opp. Monica D.Ed. College
Savedi, Ahmednagar-414001

Date of Investigation: 06/06/23

PT/EQAS Set Identification: CMC Vellore.
Date of PT/EQAS: 13/05/23
Acceptable/ Unacceptable Results ✓ Cholesterol.
Acceptable Result Range: –
Previous Trends/ Unacceptable Results from this Analyte/ Test: No any trend in previous evaluation.

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 specific deviation noted in IQC performance control calibration & reagents within a expiry limit. No any specific issue with analyzer

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

No

Corrective/ Preventive action taken to prevent Reoccurrence

Performance will be monitored closely in next sample

Conclusions Based on the findings suspected unaccepted performance due to random error.
Quality Manager/ Team Leader Mahesh Bhalsing Date: 06/06/23
Lab Head Dr. Sagar Kulat Date: 06/06/23

LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
Opp. Monica D.Ed. College
Savedi, Ahmednagar-414001

Date of Investigation: 06/06/23

PT/EQAS Set Identification:	CMC Vellore.
Date of PT/EQAS:	13/05/23
Acceptable/ Unacceptable Results	- Potassium
Acceptable Result Range:	-

Previous Trends/ Unacceptable Results from this Analyte/ Test:

No any trend in previous evaluation.

Classification of Problems: (Please tick)

Clerical:

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

Details of Investigation: No

Methodological

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

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

Details of Investigation: 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 specific deviation noted in IQC performance control Calibrater and reagents within a expiry limit. No any specific issue with analyzer, ISE electrode found to be satisfactory.

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

Corrective/ Preventive action taken to prevent Reoccurrence

Performance will be monitored closely in next sample.

Conclusions Based on the findings suspected unaccepted performance due to random error.
Quality Manager/ Team Leader Mr. Mahesh Bhalsing Date: 06/06/23
Lab Head Dr. Sagar Kulal Date: 06/06/23

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Savedi, Ahmednagar-414001

Date of Investigation: 06/06/2023.

PT/EQAS Set Identification:	CMC Vellore.
Date of PT/EQAS:	13/5/2023.
Acceptable/ Unacceptable Results	- chloride.
Acceptable Result Range:	

Previous Trends/ Unacceptable Results from this Analyte/ Test:

No any trend in previous evaluation.

Classification of Problems: (Please tick)

Clerical:

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

Details of Investigation: No

Methodological

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

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

Details of Investigation: 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.
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- ☐ 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 specific deviation noted in IQC performance control calibrator and reagents within a expiry limits. No any specific issue with analyzer, ISE electrode found to be satisfactory.

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

Corrective/ Preventive action taken to prevent Reoccurrence
performance will be monitored closely in next sample.

Conclusions Based on the findings suspected unaccepted performance due to random error.
Quality Manager/ Team Leader Bhalsing Mahegs Date: 06/06/23
Lab Head Dr. Sagar Kulat Date: 06/06/23

LUPIN DIAGNOSTIC
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CHRISTIAN MEDICAL COLLEGE

DEPARTMENT OF CLINICAL BIOCHEMISTRY

CMC EXTERNAL QUALITY ASSURANCE SCHEME

MONTHLY SUMMARY REPORT - MAY 2023

PC-1024

Lab Name	**LUPIN DIAGNOSTICS**	**Lab No**	**16038**
Constituent Group	**HbA1c**	**Date of Result Entered :**	**13/05/2023**
PT item	**Lyophilized human whole blood based**	**Date of Report Published :**	**05/06/2023**

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants CV	Participants SD	Your Value	SDI	U
1	HbA1c	OTHERS (Any Other Principles / Methods)	Any Analyser (Automation / Semi Automation)	297	6.27	9.91	0.62	6.2 %	-0.11	0.07

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
MACCARE HOSPITAL, BEHIND ZOPADI CANTEEN, SAVEDI
AHMEDNAGAR
MAHARASHTRA414003

Pamela Christudoss

Coordinator Contact Details:
Email:clinqc@cmcvellore.ac.in
Contact Number: 0416-2283102

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 ********