

CHRISTIAN MEDICAL COLLEGE

DEPARTMENT OF CLINICAL BIOCHEMISTRY

CMC EXTERNAL QUALITY ASSURANCE SCHEME





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

SI.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Partic CV	ipants 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

Panela Christudoss

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 *******

PT/ EQAS EVALUATION RECORD
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Date of Investigation: 06 06 2093

PT/EQAS Set Identification: CMC Vellore.			
Date of PT/EQAS: 13/05/2000.			
Acceptable/ Unacceptable Results ALT 7 .			
Acceptable Result Range:			
Previous Trends/ Unacceptable Results from this Analyte/ Test:			
No any trend is 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.			

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Ü	QC material not run at relevant analyte concentration,				
П	Result not within reportable range (linearity) for instrument / reagent system.				
	Obstruction of instrument tubing / orifice by clot or protein.				
	Incorrect incubation times.				
De	etails of Investigation:				
	14011				
-					
0.					
	echnical				
	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.				
П	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.				
Ū	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.				
П	In addition to above discipline specific errors may also occur				
D	etails of Investigation:				
-	THORE				
Pı	roblem with PT/EQAS Material				
G	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.				
Ш	Non-viable samples for microbiology PT/EQAS program.				
	Haemolysis on an immune-haemtology program samples.				
D	etails of Investigation:				
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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:		
No Explanation: Attributed to Random Error Any Others (explain)		
Summary of Investigation:		
No any specific deviation noted in IQC performance. control calibration freagents within a exploy. Iimit. 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 munitored closely in next		
ecomple.		

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Conclusions

Based on the findings suspected unaccepted performance due to random error

Quality Manager/ Team Leader

Bhulsing

Date: 06\06\23

Lab Head Dr

Date:

06/06/23

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PT/ EQAS EVALUATION RECORD FRM.QCM.03
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02.06.2023



Date of Investigation: $\circ 6 \setminus \circ 6 \mid 23$

PT/EQAS Set Identification: CMC Vellanes
Date of PT/EQAS:
Acceptable/ Unacceptable Results
(b) olactor
Association Result Range:
Previous Trends/ Unacceptable Results from this Analyte/ Test:
No constant
No any trend in previous evaluation.
Classification of Problems: (Please tick)
Cionodi.
☐ Transcription error (may be pre- or post-analytical factors) ☐ Wrong method has been registered for
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.
results not within acceptable range.
Scheduled instrument maintenance not performed appropriately.
incorrect instrument calibration.
☐ Standards or reagents improperly reconstituted and standards
☐ 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.
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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 often any state of the constituted.
delayed after reconstitution of EQA material (with problems)
despite unacceptable QC data
acceptable limits but showed trond and acceptable limits but showed trond
I IIII I III A ACCOMPANIA CO
a result will fall within the acceptable QC range yet exceed acceptable limits for EQA.
I and a district perior in a contract of the c
specified 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.
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 immuno hoomatal
Haemolysis on an immune-haemtology program samples.
Details of Investigation:
None.

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Pro	oblem 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.
	None
	xplanation: Attributed to Random Error
	Others (explain)
umn	
m on op	nary of Investigation: any specific deviation noted in IQC performant trol calibration & reagents within a expiry it. No any specific issue with analyzen
m on op	
m as p	any specific deviation noted in IQC performant trol calibration & reagents within a expiry it. No any specific issue with analyzen atient data affected? & Corrective action taken if Patient data was affected.
m mas p	nary of Investigation: any specific deviation noted in IQC performant trol calibration & reagents within a expiry it. No any specific issue with analyzen atient data affected? & Corrective action taken if Patient data was affected.

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Cor	CILL	sions
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Based on the findings suspected unaccepted performance due to random essor.

Quality Manager/ Team Leader

Makesh Bhalsing

Date:

06/06/23

Date:

06 06 23

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

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Date of Investigation: 06/06/23

ate of investigation.
PT/EQAS Set Identification: CMC Veilore
Date of PT/EQAS: 13 1 0 5 1 2 3
Acceptable/ Unacceptable Results - Potassium
Acceptable Result Range:
Previous Trends/ Unacceptable Results from this Analyte/ Test:
Previous Trends/ Offacceptable 100
No any trend in previous evaluation.
Classification of Problems: (Please tick)
Olympath
□ Transcription error (may be pre- or post-analytical factors) □ Wrong method has been registered for analysis or method change not updated.
. (/)
Details of Investigation:
140
Methodological proscures) not performed as necessary, or
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.
Automatic pipettor not calibrated to acceptable pressure. Imprecision from result being close to detection limit of method.
☐ Imprecision from result being close to detection limit or the property stored. ☐ QC material not run within expiration date, or improperly stored.
QC material not run within expiration date, of improperty

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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.	
etails of Investigation:	_
None	_
	===
echnical	
EQA material improperly reconstituted.	
EQA material improperty reconstitution. Testing delayed after reconstitution of EQA material (with problem from evaporation or deterioration).	
Sample not placed in proper order on instrument.	
Devilt released despite unacceptable QC data.	
the limits but chowed trend suggestive of problem with the assay.	at
the acceptable QC range is too wide, the probability control limits / rules. If the acceptable QC range is too wide, the probability is	μę
with the acceptable OC range vet exceed acceptable limits for Educa-	
a result will fall within the acceptable Qo range years. Manual pipetting / diluting performed inaccurately, at an incorrect temperature or with incorrect diluent.	
O building error or result reported using too few significant digits.	
2 wydawiana simon tubes incorrectly labeled.	
☐ Secondary specimen tubes intervery may also occur In addition to above discipline specific errors may also occur	
Details of Investigation:	
None.	
Problem with PT/EQAS Material	x of
Matrix effects: The performance of some instrument / method combinations may be affected by the matrix	ne
Matrix effects: The performance of some instrument in meaning the PT/EQAS sample. This can be overcome to some extent by assessing participants in peer groups – to be do	J110
The bear agong test material due to variability infill volumes, inadequate mixing, or inconsistent reasons.	9 01
Iyophilized specimens.	
the complex for microbiology PT/EQAS program.	
- vy sky is an an immune-haemtology program samples.	
Haemolysis on an immune-machinology programme.	
Details of Investigation:	

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Prob	olem with PT/EQAS Evaluation
□ □ □ De	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. tails of Investigation:
Ar	Explanation: Attributed to Random Error ny Others (explain)
200	ummary of Investigation: so any specific deviation noted in to performance control alibrater and reagents within a expiry limit. No any pecific 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.

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Conclusions		
Based on the findings our due to random essos	spect-ee	I unaccepted performance
Quality Manager/ Team Leader Bhalsing	Date:	06/06/23
Lab Head Dr. Sagar Kulat	Date:	06/06/23

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Date of Investigation: 06 06 20 2 .
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 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:
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.

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Imprecision from result being close to detection limit of method.
 QC material not run within expiration date, or improperly stored.

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C material not run at relevant analyte concentration.	
esult not within reportable range (linearity) for instrument / reagent system.	
bstruction of instrument tubing / orifice by clot or protein.	
ncorrect incubation times.	
ails of Investigation:	
Nune.	-
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hnical	
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.	Le
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	
stails of Investigation:	
None.	
oblem 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 do	e
by the PT/EOAS 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.	
etails of Investigation:	
None.	

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Pro	blem with PT/EQAS Evaluation
Land House of La	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.
De	etails of Investigation:
-	
A	o Explanation: Attributed to Random Error ny Others (explain)
S	summary of Investigation: No any specific devation noted in IRC 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

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Conclusions

Based on the findings suspected unaccepted. performance due to random error.

Quality Manager/ Team Leader

Bhalfing makes Date:

06/06/23

Lab Head Dr. Sagar Kulat

Date:

06/06/23

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CHRISTIAN MEDICAL COLLEGE

DEPARTMENT OF CLINICAL BIOCHEMISTRY

CMC EXTERNAL QUALITY ASSURANCE SCHEME

MONTHLY SUMMARY REPORT - MAY 2023



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

SDI Range			SDI Range		Interpretation							
	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	
	SI.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	CV	SD	Your Value	SDI	U	

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

Panela Christudos

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 *******