



RML- Quality Assurance Program (RML-QAP)



BIO-CHEMISTRY-02

ALL METHOD REPORT

Lab Code: 1926

Cycle - 12/2023

Round No - 08

Date: 31/08/2023

Parameters	Units	No. of Participants	Robust Mean	Robust Standard deviation (SD)	Uncertainty of Assign Values	Range (± 2 SD)	Your Value	Z Score
Albumin	g/dL	120	2.9	0.2	0.02	2.5-3.3	*3.8	4.5
Alkaline Phosphatase	U/L	121	328.5	59.2	6.73	210.1-446.9	402	1.2
Bilirubin (Total)	mg/dL	121	5.1	0.6	0.07	3.9-6.3	5.2	0.2
Calcium (Total)	mg/dL	115	12.5	0.5	0.06	11.5-13.4	-	-
Cholesterol (Total)	mg/dL	121	261.5	13.7	1.55	234.2-288.8	252	-0.7
Creatinine	mg/dL	122	4.2	0.2	0.02	3.8-4.6	4.0	-1.0
Glucose	mg/dL	121	265.6	16.9	1.92	231.8-299.4	272	0.4
HDL	mg/dL	114	81.3	17.7	2.08	45.9-116.8	49.3	-1.8
Potassium	mEq/L	100	5.7	0.3	0.04	5.1-6.4	-	-
Protein (Total)	g/dl	120	4.5	0.3	0.04	3.9-5.2	4.6	0.2
Sodium	mEq/L	100	155.7	4.0	0.50	147.7-163.8	-	-
SGPT/ALT	U/L	122	134.2	11.2	1.26	111.9-156.6	120	-1.3
SGOT/AST	U/L	121	131.8	8.5	0.96	114.9-148.7	124	-0.9
Triglyceride	mg/dL	120	251.0	14.7	1.68	221.5-280.5	258	0.5
Urea	mg/dL	122	113.6	7.4	0.84	98.7-128.4	113	-0.1
Uric Acid	mg/dl	119	9.3	0.6	0.07	8.1-10.6	10.3	1.6
Chloride	mEq/L	95	115.6	4.7	0.60	106.2-125.0	-	-
Phosphorus	mg/dL	86	6.7	0.3	- 0.04	6.1-7.4	-	-
Magnesium	mg/dl	26	4.2	0.1	0.03	4.0-4.5	-	-
Iron	μ g/dL	82	217.9	14.8	2.04	188.3-247.4	-	-
Amylase	U/L	60	288.7	28.5	4.59	231.8-345.6	-	-
CK	U/L	24	449.9	94.7	24.16	260.5-639.3	-	-

Interpretation of Z Score :

Z Score Value(+/-)	$[Z] \leq 2.0$	$2.0 < [Z] < 3.0$	$[Z] \geq 3.0$
Interpretation	Satisfactory Performance No signal	Questionable Warning Signal	Unsatisfactory Performance action Signal

Legends	(*) Excluded From Group Mean	{ } Not Reported	(#)Late Result Submission	(\$)Reported in other Unit
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Chief Coordinator

Dr.Sanjay Mehrotra

Checked By:

Prepared by: A.D

Programme Director

Dr.Bandana Mehrotra

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CORRECTIVE ACTION (CA) FORM

LABORATORY NAME: CSIR-Central Drug Research Institute

EPA ID:

DEPARTMENT OR ANALYSIS TYPE: Submit corrective action report on ALB outlier in the PT report of August month 2023.

RESPONSIBLE SUPERVISOR / MANAGER: Dr Vivek V. Bhosale

PERSON COMPLETING CA FORM (NAME, TITLE): Dr (Mrs) Shail Singh

DATE: 12/09/2023

**RECORD INFORMATION BELOW OR ATTACH ADDITIONAL SHEETS.
PROVIDE DOCUMENTATION WHENEVER POSSIBLE.**

EVENT DESCRIPTION:

Problem: ALB found outlier in the PT report of RML EQAS of August month 2023.

Corrective action:

1. Our instrument found in working condition
2. I have repeated the sample with multical, Erba norm and Erba path, I found that values were in mean range.

Advice: Ask to RML EQAS from (Pear group mean)

EVENT RESPONSE / INVESTIGATION STEPS:

1. Immediate corrective action taken repeated the sample, with multical, Erba norm and Erba path. I found that values were in mean range. QA notified analysis repeated.

ROOT CAUSE DETERMINATION:

First list all possibilities of non conformities, and then select the most probable cause or causes.)

CORRECTIVE ACTION (CA) FORM

ACTION(S) TAKEN TO RESOLVE ISSUE AND PREVENT RECURRENCE: *Include SOP revision, stafftraining, purchase of standards, document/form revision, etc.*

Corrective Action(s)	Contact Person Responsible	Proposed Implementation Date	Date Completed	Evidence Of Completion
Repeated the sample with multical, Erba norm and Erba path	Dr. Mrs. Shail Singh	12 September 2023	12 September 2023	Report attached
Additional Comments/Supplemental Information:				

Submitted By:		Date:  12/9/23
Reviewed By:	Responsible Supervisor or Manager	Date:  12/9/23

By signature and comments below, the QA Manager and Laboratory Director or Technical Manager approve this corrective action plan and the proposed implementation date(s) given. The QA Manager or designee will provide followup until the corrective action is closed with documentation/evidence of completion as noted above.


Approved By: 
Quality Assurance Manager
Date: 12/9/23

Approved By: 
Laboratory Director or Technical Manager
Date: 12/09/23

Reviewer Comments or Additional Actions Recommended:

Closing the Corrective Action: The QA Manager is responsible for effectiveness review. The CA should stay OPEN for a sufficient time to ensure all stated actions were taken and address/solve the initial issue.

Follow-up Review Notes:


12/9/23

Corrective Action Closed By QA Manager:
Signature:
Date:

Date: