



# RML- Quality Assurance Program (RML-QAP)



## BIO-CHEMISTRY-02

### ALL METHOD REPORT

Lab Code: 1926

Cycle - 12/2023

Round No - 03

Date: 31/03/2023

Parameters	Units	No. of Participants	Robust Mean	Robust Standard deviation (SD)	Uncertainty of Assign Values	Range ( $\pm 2$ SD)	Your Value	Z Score
Albumin	g/dL	90	3.0	0.2	0.23	2.5-3.4	3.0	0.0
Alkaline Phosphatase	U/L	89	325.4	50.8	50.75	223.9-426.9	428	2.0
Bilirubin (Total)	mg/dL	90	5.2	0.6	0.08	4.1-6.3	5.4	0.3
Calcium (Total)	mg/dL	84	12.4	0.7	0.10	11.1-13.7	.	-
Cholesterol (Total)	mg/dL	89	266.0	11.1	1.47	243.9-288.1	264	-0.2
Creatinine	mg/dL	90	4.2	0.2	0.03	3.7-4.7	4.1	-0.5
Glucose	mg/dL	89	271.9	14.1	1.87	243.7-300.1	.	-
HDL	mg/dL	85	75.4	21.5	2.92	32.5-118.3	55.5	-0.9
Potassium	mEq/L	83	5.7	0.3	0.04	5.1-6.3	.	-
Protein (Total)	g/dl	89	4.6	0.3	0.03	4.1-5.1	4.7	0.5
Sodium	mEq/L	83	156.5	4.4	0.60	147.8-165.2	.	-
SGPT/ALT	U/L	90	136.1	8.3	1.09	119.5-152.7	117	-2.3
SGOT/AST	U/L	89	135.5	8.4	1.11	118.6-152.3	126	-1.1
Triglyceride	mg/dL	88	254.2	10.8	1.44	232.6-275.8	253	-0.1
Urea	mg/dL	89	113.5	6.9	0.91	99.6-127.3	114	0.1
Uric Acid	mg/dl	89	9.4	0.6	0.08	8.2-10.7	10.0	1.0
Chloride	mEq/L	80	115.9	3.9	0.55	108.1-123.8	.	-
Phosphorus	mg/dL	75	6.8	0.3	0.04	6.2-7.3	.	-
Magnesium	mg/dl	26	4.0	0.8	0.20	2.3-5.6	.	-
Iron	µg/dL	66	217.8	14.2	2.18	189.4-246.2	.	-
Amylase	U/L	54	287.1	22.2	3.78	242.6-331.6	.	-
CK	U/L	22	533.7	34.4	9.17	464.9-602.5	.	-

### 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

Programme Director

Dr. Bandana Mehrotra

Checked By:

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Prepared by: Sh.K

Doc. No.: ASS / FR / 03A / R 01 / Dt.: 05.01.2022



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**CORRECTIVE ACTION (CA) FORM**

**LABORATORY NAME:**CSIR-Central Drug Research Institute

**EPA ID:** 1926

**DEPARTMENT OR ANALYSIS TYPE:** Submit corrective action report on SGPT (ALT) outlier in the PT report of March month 2023.

**RESPONSIBLE SUPERVISOR / MANAGER:** Dr Vivek V.Bhosale

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

**DATE:** 10/4/2023

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

**EVENT DESCRIPTION:**

**Problem:** SGPT (ALT) found outlier in the PT report of RML EQAS of March month 2023.

**Corrective action:**

1. Instrument found in working condition.
2. I have repeated the sample with Multical, Erba norm and Erba path. I found that values were different from previous one.
3. Engineer visited and Run calibration and control both level result come within range.

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

**EVENT RESPONSE / INVESTIGATION STEPS:**

Immediate corrective action taken repeated the sample. QA notified analysis repeated.

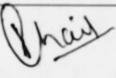
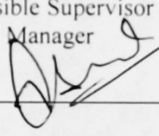
**ROOT CAUSE DETERMINATION:**

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

## CORRECTIVE ACTION (CA) FORM

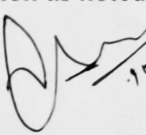
**ACTION(S) TAKEN TO RESOLVE ISSUE AND PREVENT RECURRENCE:** *Include SOP revision, stafftraining, purchase of standards, document/form revision, etc.*

Corrective Action(s)	Contact Person Responsible	Proposed Implementation Date	Date Completed	Evidence Of Completion
Repeated the sample, run calibration and control both level result come within range	Dr Mrs Shail Singh	1 April, 2023	1 April, 2021	Report attached
Engineer visited and Run calibration and control both level result come within range.	Sachin Singh	10 April, 2023	10 April, 2023	Report attached
<b>Additional Comments/Supplemental Information:</b>				

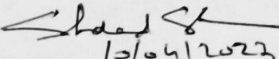
<b>Submitted By:</b>		Date: 10/4/23
<b>Reviewed By:</b>	Responsible Supervisor or Manager 	Date: 10/4/23

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 follow up until the corrective action is closed with documentation/evidence of completion as noted above.

**Approved By:**  
Quality Assurance Manager  
Date:

  
10/4/23

**Approved By:**  
Laboratory Director or Technical Manager  
Date:


  
10/04/2023

**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:

Corrective Action Closed By QA Manager:

  
Signature: \_\_\_\_\_

Date:

Date:

10/4/23