



RML – Quality Assurance Program (RML – QAP)



BIO-CHEMISTRY-02

ALL METHOD REPORT

Cycle - 12/2023

Round No - 04

Date: 29/04/2023

Lab Code: 1926

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	101	4.2	0.3	0.04	3.7-4.7	3.9	-1.0
Alkaline Phosphatase	U/L	99	172.2	23.0	2.89	126.2-218.2	179	0.3
Bilirubin (Total)	mg/dL	100	1.5	0.2	0.03	1.1-1.8	1.3	-1.0
Calcium (Total)	mg/dL	93	8.9	0.4	0.05	8.0-9.7	.	-
Cholesterol (Total)	mg/dL	99	150.7	9.1	1.14	132.4-168.9	*123	-3.0
Creatinine	mg/dL	100	1.5	0.1	0.01	1.3-1.7	1.5	0.0
Glucose	mg/dL	99	102.4	6.2	0.78	89.9-114.9	88	-2.3
HDL	mg/dL	94	48.6	6.8	0.88	35.0-62.1	33.8	-2.2
Potassium	mEq/L	90	4.0	0.2	0.03	3.6-4.5	.	-
Protein (Total)	g/dl	98	5.8	0.3	0.04	5.2-6.5	5.1	-2.3
Sodium	mEq/L	90	140.4	3.5	0.46	133.5-147.3	.	-
SGPT/ALT	U/L	100	31.3	3.5	0.44	24.2-38.3	23	-2.4
SGOT/AST	U/L	99	30.1	2.7	0.34	24.8-35.4	24	-2.3
Triglyceride	mg/dL	98	99.5	8.5	1.07	82.5-116.5	86	-1.6
Urea	mg/dL	100	42.9	2.8	0.35	37.3-48.5	39	-1.4
Uric Acid	mg/dl	98	5.9	0.4	0.05	5.0-6.7	5.3	-1.5
Chloride	mEq/L	88	99.5	3.9	0.52	91.6-107.3	.	-
Phosphorus	mg/dL	80	4.6	0.2	0.03	4.2-5.0	.	-
Magnesium	mg/dl	27	2.1	0.2	0.05	1.7-2.6	.	-
Iron	µg/dL	70	111.9	6.1	0.91	99.8-124.0	.	-
Amylase	U/L	56	83.1	9.0	1.50	65.1-101.1	.	-
CK	U/L	21	182.7	34.2	9.33	114.4-251.0	.	-

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: PS

Programme Director

Dr. Bandana Mehrotra

Page 1 of 7

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



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Email: rmlresearchfoundation@gmail.com Website: www.rmlpathology.com

Continuous Efforts And Execution Leads To Quality Excellence

CORRECTIVE ACTION (CA) FORM

LABORATORY NAME: CSIR-Central Drug Research Institute

EPA ID: 1926

DEPARTMENT OR ANALYSIS TYPE: Submit corrective action report on Total Protein outlier in the PT report of April month 2023.

RESPONSIBLE SUPERVISOR / MANAGER: Dr Vivek V. Bhosale

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

DATE: 09/05/2023

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

EVENT DESCRIPTION:

Problem: Total Protein found outlier in the PT report of RML EQAS of April 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 (Peer group mean)

EVENT RESPONSE / INVESTIGATION STEPS:

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

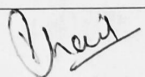
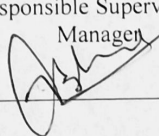
ROOT CAUSE DETERMINATION:

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

CORRECTIVE ACTION (CA) FORM

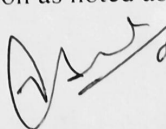
ACTION(S) TAKEN TO RESOLVE ISSUE AND PREVENT RECURRENCE: *Include SOP revision, staff training, purchase of standards, document/form revision, etc.*

Corrective Action(s)	Contact Person Responsible	Proposed Implementation Date	Date Completed	Evidence Of Completion
I have repeated the sample with multical, erba norm and erba path. I found that values were different from previous one	Dr Mrs Shail Singh	30 April 2023	30 April 2023	Report attached
Engineer visited and Run calibration and control both level result come within range	Sachin Singh	5 May 2023	5 May 2023	Report attached
Additional Comments/Supplemental Information:				

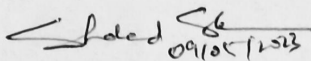
Submitted By:		Date: 9/5/23
Reviewed By:	Responsible Supervisor or Manager 	Date: 9/5/23

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:


9/5/23

Approved By:
Laboratory Director or Technical Manager
Date:


09/05/2023

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.

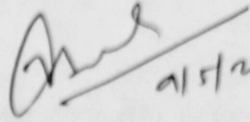
Follow-up Review Notes:

Date:

Corrective Action Closed By QA Manager:

Signature:

Date:


2/5/23

CORRECTIVE ACTION (CA) FORM

LABORATORY NAME: CSIR-Central Drug Research Institute

EPA ID: 1926

DEPARTMENT OR ANALYSIS TYPE: Submit corrective action report on Glucose outlier in the PT report of April month.

RESPONSIBLE SUPERVISOR / MANAGER: Dr Vivek V. Bhosale

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

DATE: 09/05/2023

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

EVENT DESCRIPTION:

Problem: Glucose found outlier in the PT report of RML EQAS of April 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, control both level result come within range.

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

EVENT RESPONSE / INVESTIGATION STEPS:

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

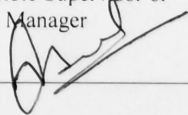
ROOT CAUSE DETERMINATION:

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

CORRECTIVE ACTION (CA) FORM

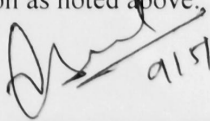
ACTION(S) TAKEN TO RESOLVE ISSUE AND PREVENT RECURRENCE: *Include SOP revision, staff training, purchase of standards, document/form revision, etc.*

Corrective Action(s)	Contact Person Responsible	Proposed Implementation Date	Date Completed	Evidence Of Completion
I have repeated the sample with Multical, Erba norm and Erba path. I found that values were different from previous one.	Dr Mrs Shail Singh	30 April 2023	30 April 2023	Report attached
Engineer visited and Run calibration, control both level result come within range.	Sachin Singh	5 May 2023	5 May 2023	Report attached
Additional Comments/Supplemental Information:				

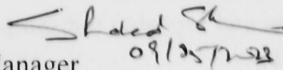
Submitted By:		Date: 9/5/23
Reviewed By:	Responsible Supervisor or Manager 	Date: 9/5/23

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Quality Assurance Manager
Date:


9/5/23

Approved By:
Laboratory Director or Technical Manager
Date:


09/05/23

Reviewer Comments or Additional Actions Recommended:

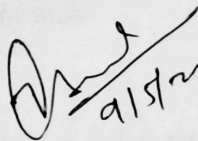
Closing the Corrective Action: The QA Manager is responsible for effectiveness review. The CA should stay OPEN for a sufficient time to ensure all stated actions were taken and address/solve the initial issue.

Follow-up Review Notes:

Corrective Action Closed By QA Manager:

Signature:

Date:


9/15/20.

Date:

CORRECTIVE ACTION (CA) FORM

LABORATORY NAME: CSIR-Central Drug Research Institute

EPA ID: 1926

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

RESPONSIBLE SUPERVISOR / MANAGER: Dr Vivek V. Bhosale

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

DATE: 9/05/2023

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

EVENT DESCRIPTION:

Problem: Cholesterol found outlier in the PT report of RML EQAS of April 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.

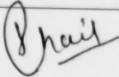

ROOT CAUSE DETERMINATION:

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

CORRECTIVE ACTION (CA) FORM

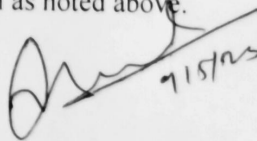
ACTION(S) TAKEN TO RESOLVE ISSUE AND PREVENT RECURRENCE: *Include SOP revision, staff training, purchase of standards, document/form revision, etc.*

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	30 April 2023	30 April 2023	Report attached
Engineer visited and Run calibration and control both level result come within range.	Sachin Singh	5 May 2023	5 May 2023	Report attached
Additional Comments/Supplemental Information:				

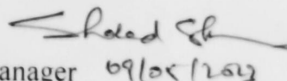
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Date:

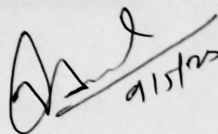

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Follow-up Review Notes:

Corrective Action Closed By QA Manager:
Signature:
Date:


9/15/20

Date:

CORRECTIVE ACTION (CA) FORM

LABORATORY NAME: CSIR-Central Drug Research Institute

EPA ID: 1926

DEPARTMENT OR ANALYSIS TYPE: Submit corrective action report on HDL outlier in the PT report of April month.

RESPONSIBLE SUPERVISOR / MANAGER: Dr Vivek V. Bhosale

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

DATE: 5/05/2023

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

EVENT DESCRIPTION:

Problem: HDL found outlier in the PT report of RML EQAS of April 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.

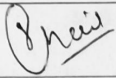
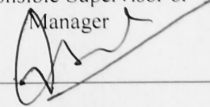
ROOT CAUSE DETERMINATION:

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CORRECTIVE ACTION (CA) FORM

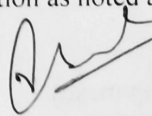
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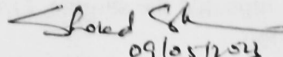
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Reviewed By:	Responsible Supervisor or Manager 	Date: 9/5/23

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Approved By:
Quality Assurance Manager
Date:

 09/05/23

Approved By:
Laboratory Director or Technical Manager
Date:

 09/05/23

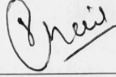
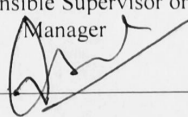
Reviewer Comments or Additional Actions Recommended:

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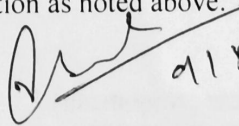
ACTION(S) TAKEN TO RESOLVE ISSUE AND PREVENT RECURRENCE: *Include SOP revision, stafftraining, purchase of standards, document/form revision, etc.*

Corrective Action(s)	Contact Person Responsible	Proposed Implementation Date	Date Completed	Evidence Of Completion
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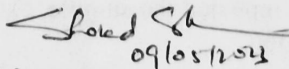
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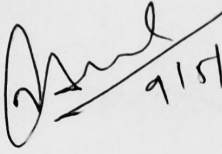
 09/05/2023

Reviewer Comments or Additional Actions Recommended:

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Follow-up Review Notes:

Corrective Action Closed By QA Manager:
Signature:
Date:


9/5/25.

Date:

CORRECTIVE ACTION (CA) FORM

LABORATORY NAME: CSIR-Central Drug Research Institute

EPA ID: 1926

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

RESPONSIBLE SUPERVISOR / MANAGER: Dr Vivek V. Bhosale

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

DATE: 09/05/2023

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

EVENT DESCRIPTION:

Problem: SGPT found outlier in the PT report of RML EQAS of April 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.

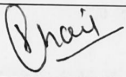
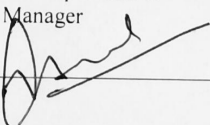
ROOT CAUSE DETERMINATION:

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CORRECTIVE ACTION (CA) FORM

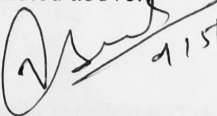
ACTION(S) TAKEN TO RESOLVE ISSUE AND PREVENT RECURRENCE: *Include SOP revision, stafftraining, purchase of standards, document/form revision, etc.*

Corrective Action(s)	Contact Person Responsible	Proposed Implementation Date	Date Completed	Evidence Of Completion
I have repeated the sample with multical, erba norm and erba path. I found that values were different from previous one.	Dr Mrs Shail Singh	30 April 2023	30 April 2023	Report attached
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Additional Comments/Supplemental Information:				

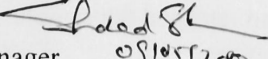
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Quality Assurance Manager
Date:


9/5/23

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Laboratory Director or Technical Manager
Date:


09/05/2023

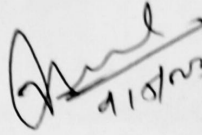
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Follow-up Review Notes:

Date:

Corrective Action Closed By QA Manager:
Signature:
Date:


9/15/2013

CORRECTIVE ACTION (CA) FORM

LABORATORY NAME: CSIR-Central Drug Research Institute

EPA ID: 1926

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

RESPONSIBLE SUPERVISOR / MANAGER: Dr Vivek V. Bhosale

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

DATE: 09/05/2023

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

EVENT DESCRIPTION:

Problem: SGOT found outlier in the PT report of RML EQAS of April 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.

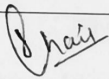
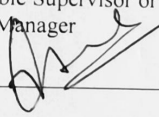
ROOT CAUSE DETERMINATION:

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

CORRECTIVE ACTION (CA) FORM

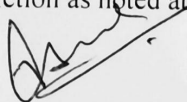
ACTION(S) TAKEN TO RESOLVE ISSUE AND PREVENT RECURRENCE: *Include SOP revision, stafftraining, purchase of standards, document/form revision, etc.*

Corrective Action(s)	Contact Person Responsible	Proposed Implementation Date	Date Completed	Evidence Of Completion
I have repeated the sample with Multical, Erba norm and Erba path. I found that values were different from previous one.	Dr Mrs Shail Singh	30 April 2023	30 April 2023	Report attached
Engineer visited and Run calibration and control both level result come within range.	Sachin Singh	05 May 2023	05 May 2023	Report attached
Additional Comments/Supplemental Information:				

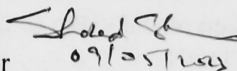
Submitted By:		Date: 9/5/23
Reviewed By:	Responsible Supervisor or Manager 	Date: 9/5/23

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:



Approved By:
Laboratory Director or Technical Manager
Date:


09/05/2023

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:

Date:

Corrective Action Closed By QA Manager:

Signature:

Date:


9/15/23