

Prepared By: Quality Manager	 TRUSTlab® DIAGNOSTICS <i>where Trust matters.</i>	Document No:	TDPL/GE/FOM-035
Approved By: Lab Head		Version No:	2.0
		Version Date:	01/10/2024
		Revision No:	00
DOCUMENT TITLE:	Corrective Action & Preventive Action log for EQAS Outliers		Revision Date: 00-00-0000

1. Date of Corrective Action Taken: 26/11/2025

2. Name of the Survey: MHL EQAS - cycle no - 240412

3. Details of Samples: Sample No - 1, 2

4. EQAS Sample Run Date: 4/11/25

5. Outlier Results: NON REACTIVE

6. EQAS Trends of last 2 cycles (if applicable): 2/2

7. Root Cause Analysis:

Sr No.	Root Cause Analysis	Acceptable	Unacceptable
1	IQC Status	✓	
2	Preventive Maintenance Status	—	
3	Calibration Status	✓	
4	Reagent Status	✓	
5	Clerical Error	.	Clerical error - entered results of ELISA.
6	Technical Problem	—	
7	Problem with EQAS Samples	—	
Any Other (Please Specify):			

Department Head Signature:

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8. Immediate Action Taken, if any:

Informed all staff to be vigilant while entering results online
— N/A —

9. Summary of re-assayed results:

Sr No.	Analyte	Previous Results/	Re-assayed Results/ ILC Result of Lab	Acceptability Limits/ Obtained CV & Acceptable Criteria of ILC

10. Comment on Re-Assayed Results:

11. Preventive Action to prevent recurrence:

To be careful while entering results online.

12. Documents Attached:

13. Conclusion:

- a. Clerical Error
- b. Methodology Error
- c. Technical Problem
- d. Problem with EQAS material
- e. Others (please Specify)

Corrective Action Taken By:

Corrective Action Reviewed Approved By:

 24/10/24
Department Head Signature:

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		Revision No:	00
		Revision Date:	00-00-0000

1. Date of Corrective Action Taken: 24/2/2025

2. Name of the Survey: MHL EQAS - cycle No - 240412.

3. Details of Samples: Sample No - 1, 2.

4. EQAS Sample Run Date: 4/2/25

5. Outlier Results: NON REACTIVE

6. EQAS Trends of last 2 cycles (if applicable): 2/2.

7. Root Cause Analysis:

Sr No.	Root Cause Analysis	Acceptable	Unacceptable
1	IQC Status	✓	
2	Preventive Maintenance Status	✓	
3	Calibration Status	—	
4	Reagent Status	✓	
5	Clerical Error	—	
6	Technical Problem	✓	Sample Recheck
7	Problem with EQAS Samples		Sample Rechecked. Showing reactive supply.
Any Other (Please Specify):			

Department Head Signature:

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8. Immediate Action Taken, if any: —

9. Summary of re-assayed results: Reactive.

Sr No.	Analyte	Previous Results/	Re-assayed Results/ ILC Result of Lab	Acceptability Limits/ Obtained CV & Acceptable Criteria of ILC
1.	Sample - 1 RPR	Reactive	Reactive	—
2.	Sample - 2 RPR	Reactive	Reactive	

10. Comment on Re-Assayed Results: Results found to be same.

11. Preventive Action to prevent recurrence: To observe in next EQAS sample.

12. Documents Attached:

13. Conclusion:

- a. Clerical Error
- b. Methodology Error
- c. Technical Problem
- d. Problem with EQAS material
- e. Others (please Specify)

Corrective Action Taken By: To be observed in next EQAS sample.

Corrective Action Reviewed Approved By:

Sanjay 26/2/25-

Department Head Signature:

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