EQAS Alert: Decoding BC-720's Platelet Outliers

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- Customer have enrolled Mindray BC-720 Analyzer in EQA Survey of ISHTM-AIIMS.
- Customer feedback: For First EQA results show precision testing (within lab) is satisfactory for PLT, but PLT parameters are showing outlier in accuracy testing (among lab)

Problem & Customer request:

What caused the EQA results of PLT parameters outlier and how to solve this?





Duration of stability testing - minimum upto 8 days at ambient temp. after dispatch of specimens

EQAP CODE No.: 2501 Instrument ID: Mindray Model Name.: 720

Month/Year: March/2025

Serial No.: BC 720

CBC and Retic Assessment

		-		Among Lab (Accuracy Testing)				Within Lab (Precision Testing)				
Test Parameters	S.No.	Your Result 1		Your Results Sum of 2 Value	Consensus result sum of 2 values (Assigned Value)	Uncertainty of Assigned Values		Yours Results Diff. of 2 Values	Consensus Result Diff. of 2 values (Assigned Value)	Uncertainty of Assigned Values		
WBC x10³/μl	1	11.09	10.89	21.98	20.73	0.116	0.37	0,2	0.19	0.012	0.06	
RBC x10 ⁶ /μl	1	4.27	4.24	8.51	8.31	0.011	0.59	0.03	0.03	0.002	-0.13	
Hb g/dl	1	11.5	11.5	23	22.4	0.033	0.58	0	0.1	0.007	-1.35	
нст%	1	39.3	39.1	78.4	71.8	0.198	1.12	0.2	0.3	0,021	-0.27	
MCV-fl	1	92.1	92.1	184.2	172.45	0.389	0.97	0	0.2	0.020	-0.64	
мсн-Рд	1	27.1	26.9	54	54.1	0.056	-0.07	0.2	0.2	0.013	0.00	
MCHC-g/dl	1	29.4	29.2	58.6	62.7	0.167	-0.81	0.2	0.3	0.018	-0.34	
Plt. x10³/μl	1	264	256	520	249	3.067	3.22	8	5	0.335	0.51	
Retic %	2	3.41	3.21	6.62	13	0.174	-1.23	0.2	0.5	0.032	-0.51	

YOUR REPORT			CONSENSUS REPORT			
DLC%	3	Nrbcs=01 , Poly=27 L=58, E=02, Mono/Promono=09 , B1=01 P.M.=02, Mye=01, Meta=0, Other=0	Lymp: 46-81, Poly: 20-30, Mono: 2-6, Eosino: 1-2, nRBC/blast/Promyelo/Myelo/Meta: 0-5			
RBC Morphology	3	NORMOCYTIC HYPOCHROMIC	Normocytic, normochromic to macrocytic; polychromatophils seen.			
Diagnosis	3	CHRONIC LYMPHOPROLIFERATIVE DISORDER THE POSSIBILITY OF HAIRY CELL LEUKAEMIA TO BE CONSIDERED. ADVISED IMMUNOPHENOTYPING	Chronic Lymphoproliferative Disorder (CLPD)			

✓ The Result reported by Lab for PLT: 520 x10^3

✓ Peer Group Assigned Values for PLT : 249 x10^3

✓ Among Lab EQA : Z Score : 3.22 : Rejected

✓ With in Lab EQA : Z Score : 0.51 : Acceptable

Z-Score Criteria as per EQAS

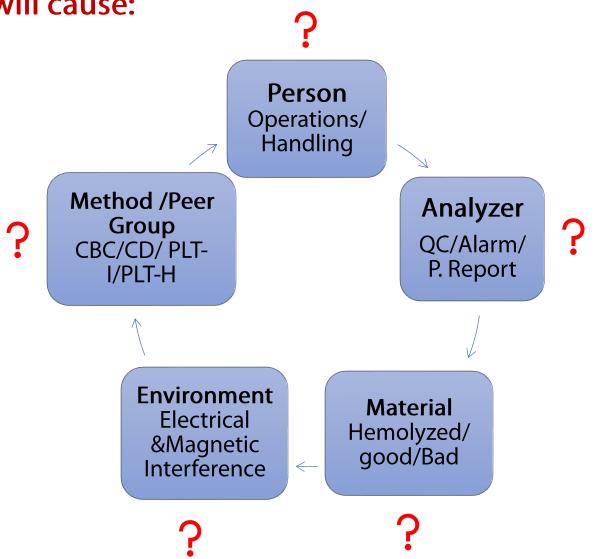
Z Score	Results
Between 0 to +-2.0	Results acceptable
Between +-2 to +- 2.5	Warning
Above +-2.5	Result unacceptable

- EQAS Report verified observed PLT parameters are showing outlier in Accuracy testing (among lab).
- Precision testing (within lab) is satisfactory for PLT.
- While the other EQAS parameters with in acceptable.
- Observed IOC and Patients results no issues observed

Ideas

Troubleshooting

What reasons will cause:





Troubleshooting

What has been verified:

Person Operations/ Handling

✓ Trained Technicians Handle the Instrument



- ✓ Verified the EQA sample Number & Details
- ✓ Followed Instruction for EQA Sample Handling Organizer

Analyzer QC/Alarm/ P. Report

- ✓ Calibration & IQC Observed satisfactory
- ✓ Maintenance & PM –Ok
- ✓ No abnormal Alarms IQC/Instrument etc.



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PLT Outlier

Material
Hemolyzed/ good/Bad

- ✓ EQA Sample Good Condition –No Trace of Hemolysis.
- ✓ No Errors : Labelling / Sample mismatch
- ✓ Reagent used are not expired



- ✓ Laboratory Temperature under control
- ✓ No Electrical / Magnetic Interference



Method /Peer Group CBC/CD/ PLT-I/PLT-H

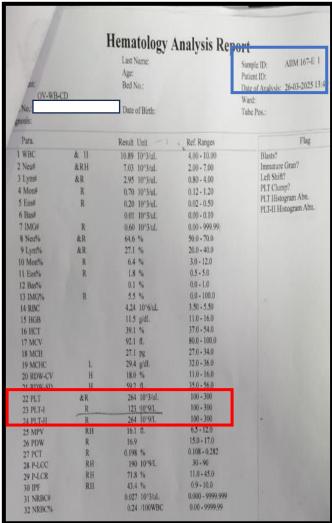
- ✓ Statistical procedure used in handling the data
- ✓ Grouping of the instrument or method is correct Peer Group

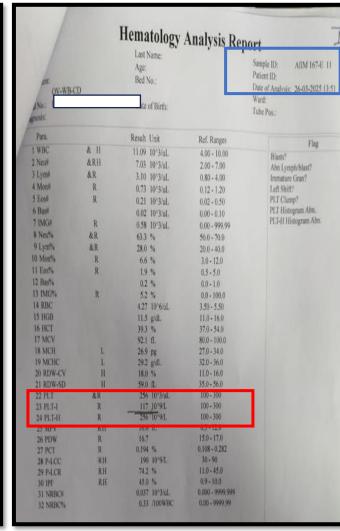


Background

Checked Original Test Results:

- Verified and Observed customer processed EQAS Samples in CD Mode in BC-720 is it correct mode to process EQAS Sample?
- In CD Mode PLT-I & PLT-H will be measured and default PLT results released is PLT-H.
- ➤ Is there any values difference for PLT-I & PLT-H for EQAS samples ?.
- AIIMS EQAP not defined peer group for PLT-H
 Wrong Peer Group Comparison ?.





Background

EQAS REPORT: 1

Date of Birth:

Result Unit

10.89 10/3/ul

7.03 10°3/uL

2.95 10°3/uL

0.70 10³/ul

0.20 10/3/ul

0.01 10°3/ul

29.4 g/dl

264 10°3/ul.

123 10/9/1

0.198 %

43.4 %

0.027 10°3/uL

0.24 /100WBC

OV-WB-CD

20 RDW-CV

31 NRBC# 32 NRBC% Hematology Analysis Report

Ref. Ranges

4.00 - 10.00

2.00 - 7.00

0.80 - 4.00

0.12 - 1.20

0.02 - 0.50

0.00 + 0.10

0.00 - 999.99

50.0 - 70.0

32.0 - 36.0

11.0 - 16.0

100 - 300

100 - 300

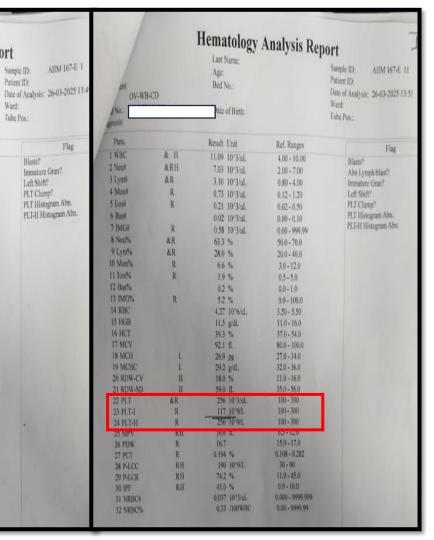
100 - 300

15.0 - 17.0

11.0 - 45.0

0.000 - 9999.999

EQAS REPORT: 2



AIMS EQAS SAMPLE -167: Report -1

PLT-I: 123 x10^3

PLT-H: 264 x10^3

PLT : 264 x10^3

AIMS EQAS SAMPLE -167: Report -2

PLT-I :117 x10^3

PLT-H: 256 x10^3

PLT : 256 x10^3

Peer Group Mean Data: 249 x10³

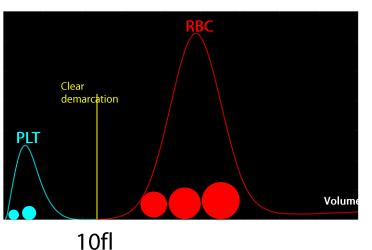
PLT-I : $123 + 117 = 240 \times 10^{3}$

 $PLT-H: 264 + 256 = 520 \times 10^{3}$

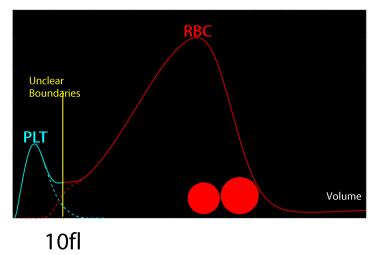
Observation: Customer reported PLT-H Instead of PLT-I. The peer group comparison data is with PLT-I.







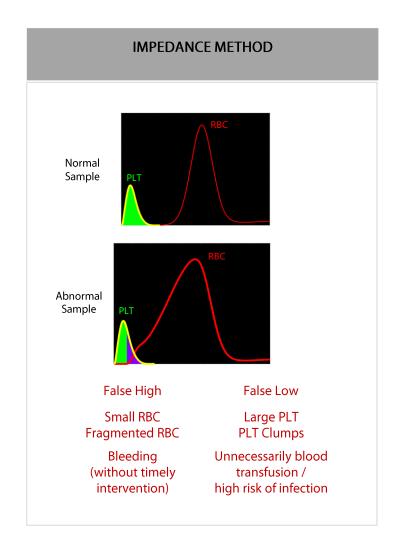
Interference sample

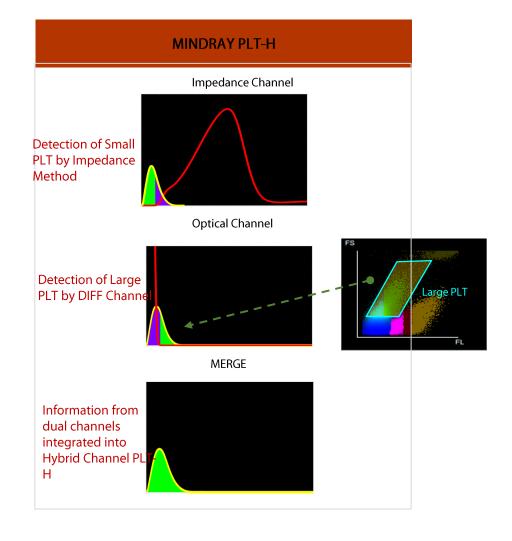


RBC/PLT volume distribution histogram

PLT-I: In the traditional impedance method, PLTs are subject to interferences that may lead to falsely high or false low results, the large PLTs are interfered by microcytic RBCs and fragments, but the small ones are not.

PLT-H: From the DIFF channel, the RBCs are dissolved by reagents, the PLT structure remains intact, and large PLTs are detected by the precise optical methodology. By combining the small PLTs from the conventional impedance method and, the large ones from the optical method, an accurate PLT count will be obtained.

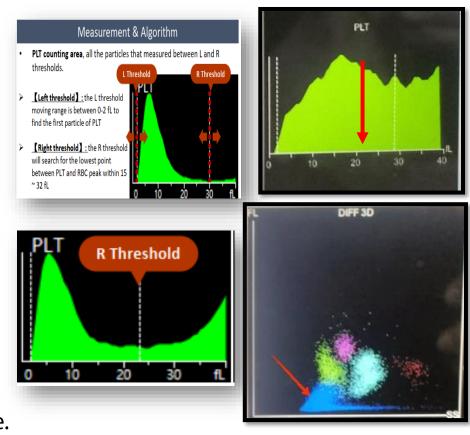




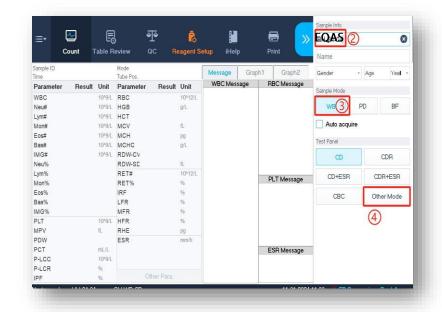
Why there is a difference between PLT-I and PLT-H in EQA Sample?

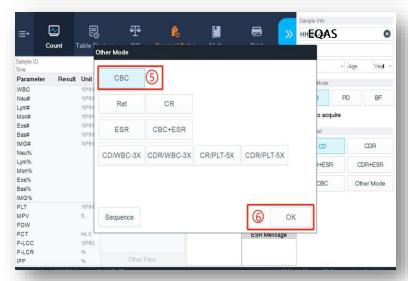
- > The most important property of the EQA sample is Commutability.
- A non-commutable EQA sample includes matrix related bias that occurs only in the EQA sample but not in authentic clinical patient Samples.
- Matrix relate bias is due to an unwanted distortion of the test result attributed to physical and chemical differences in the samples
- As EQAS is not true Blood sample itis Spiked / Artificially packed with cells,

 Tailored material, so SOP should be followed recommended by manufacture.



Reference: External Quality Assessment in Laboratory Medicine by Gunn Berit Berge Kristensen*1, Piet Meijer2





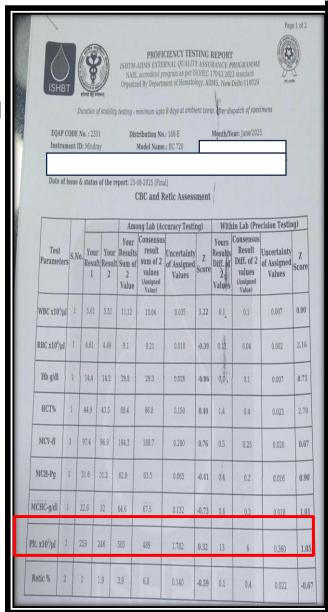
Proposed solutions for this Case:

- ✓ Always Run EQA sample in CBC Mode for AIIMS-EQA
- ✓ All parameters in EQAP Scops cover under CBC Mode
- ✓ In CBC Mode PLT-I & CD Mode PLT-I & PLT-H Default PLT-H released.
- ✓ Customer understood the problem and informed they will Run EOA in CBC Mode.

Tips: If there is no specified testing mode for other EQA projects, it is also possible to consider using quality control mode, as only PLT-I reports are used for PLT testing in quality control mode.

AIMS EQAS SAMPLE -168B - E: June/2025

- Latest result obtained for the Latest EQA sample (168B) had been found to be well within range.
- Performance of both Accuracy (Among Lab) and Precision (Within Lab) had been found satisfactory for PLT.
- Z score for PLT Indices 0.32



Test parameter	S.No.	Total participants covered in the current dist.	Total No. responded	% of Labs with Z Score 0-2		% of Labs with Z Score 2-3		% of Labs with Z Score >3	
- Instituteles				Among labs	Within lab	Among labs	Within lab	Among labs	Within
WBC x10 ³ /µl	1	368	367	81,47	82.63	3,54	5.45	14.990	11.72
RBC x10 ⁶ /µl	1	368	368	90.76	92.93	6.25	2.17	2.99	4.9
Hb g/dl	1	368	368	90.22	89.95	5.16	4.35	4.62	5.7
HCT%	1	368	367	85.83	89.37	9.26	5.18	4.91	5.45
MCV-fl	1	368	366	89.07	90.16	7.1	4.37	3.83	5.47
MCH-Pq	1	368	366	86.61	92.35	8.47	2.19	4.92	5.46
MCHC-g/dl	1	368	366	92.35	87.98	4.1	3.28	3.55	8.74
Plt. x10³/µl	1	368	368	88.04	92.66	4.35	3.53	7,61	3.81
eticCount%	2	368	315	95.56	91.75	4.13	2.86	0.31	5.39
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Comments

1). Among Lab (EQA): Results acceptable

2). Within Lab (IQA): Precision acceptable.

the accuracy of your results.

QA (Internal Quality Assurance): Your Performance of comparison of two consecutive measurement values within our lab to test the precision of your autoanalyzer.

Note-2: Z score among & within lab were calculated, as per to ISO/IEC 13528:2022 standard. Z score among lab

EQA)= (Your Result Sum of two values - Consensus Result sum of two values)/(Normalised IQR)

Z score within lab (IQA)= (Your Result Difference of two values - Consensus Result difference of two

values)/(Normalised IQR)

IQR = Quartile 3 - Quartile 1 of participant data, Normalised IQR = 0.7413 x IQR

vote-3: Z score 0 to ± 2 : Acceptable, Z score ± 2 to ± 3 : Warning Signal, Z score $> \pm 3$: Unacceptable (As per ISO/IEC 3528:2022 standard)

Note-4: Z score value between 0 to ± 2 are texted in green colour. Z score value between ± 2 to ± 3 are texted in green colour. Z score value $> \pm 3$ are texted in red colour.

iote-5: Homogeneity and stability testing of PT sample were done as per ISO 13528:2022 standard. To pass omogeneity test, between sample SD (Ss) should be smaller than the check value (0.3*SDPA). To pass the stability st, average difference in measurement values of first and last day sample (\$\overline{x}\overline{y}) should be smaller than the check line (0.3*SDPA)

ote-6: ISHTM-AIIMS-EQAP does not subcontract any task of its scheme

7: Participants are free to use methods/analyzer of their own choice.

te-8: Proficiency testing (PT) samples are sent quarterly to each participant.

te-9: All the necessary details regarding design and implementation of PT, are provided in the instruction sheet as

a 10. Panerte are kent confidential

Report authorized by,



Dr. Manoranjan Mahapatra (Prof. & Head)

PT Co-ordinator: ISHTM-AIIMS-EQAP

Department of Hematology, AIIMS, New Delhi

-----End Of Report-----

Background Ideas Solution

Summary

✓ EQA Outliers Should Lead to Corrective Actions :



"Corrective Actions": An action taken to correct a problem or deficiency

✓ Steps for Corrective Actions :



- ✓ PLT-H Results is more Accurate than PLT-I, Due to Matrix effect EQAS sample is not Compatible with PLT-H
- ✓ Guidance should be given to customer to Process EQAS in CBC mode to Avoid outliers.

THANK YOU

mindray迈瑞