

Laboratory, Department of Pathology, Care Hospital, Bareilly

RCA/ CAPA FORMAT

Reference NC/ Issue Reference to: EQAS – Hematology, AIIMS Delhi

Details of the NC raised:

- In EQAS of Hematology from AIIMS Delhi on report dated 11/05/2022 the Z Score for Accuracy of MCH-Pg >3 (4.00)

Investigation to determine root-cause:

- All inputs including Equipment calibration, reagents, controls, technical manpower, environmental controls like temperature, humidity and storage conditions including fridge temperature etc. was examined for any deficiencies and deviations.
- The Root Case Identified: MCH is a calculative parameter of Hb & RBC and since both of them were showing deviation above 2 SD (Within acceptable range) the MCH overall went beyond 3SD. The deviation of Hb and RBC were due to calibration deviation within acceptable parameters.

Implementation of corrective action:

- Equipment was recalibrated for the above parameters with known set of controls run 5 times.

Preventive Action:

- Routine calibration to be followed as per guidelines.

Prepared by Technical Incharge:

Mohd. Hasen Saif

Closed out by: Quality Manager

Chirya Shanker

Approved by Lab Director:

डॉ० मॉनिका गॉयल

M.B.B.S., DCP

(पैथोलॉजिस्ट)

REG NO- 08-5177



Dr. Monika Goel

Laboratory, Department of Pathology, Care Hospital, Bareilly

RCA/ CAPA FORMAT

Reference NC/ Issue Reference to: EQAS – Hematology, AIIMS Delhi

Details of the NC raised:

- In EQAS of Hematology from AIIMS Delhi on report dated 06/03/2022 the Z Score for Accuracy of RBC>3 (3.23) and MCV-fl>3 (-4.15)

Investigation to determine root-cause:

- All inputs including Equipment calibration, reagents, controls, technical manpower, environmental controls like temperature, humidity and storage conditions including fridge temperature etc. was examined for any deficiencies and deviations.
- The Root Cause Identified: RBC deviated because of clog detected in RBC chamber. Also as the McV is RBC dependent it is also showing deviation alongwith RBC.

Implementation of corrective action:

- Cleaning of RBC circuit was done followed by crosschecking the values by running a known set of internal control was done

Preventive Action:

- Ensuring timely cleaning and servicing as per recommendations as well as timely rinsing of the chamber as per manufacturers recommendations.

Prepared by Technical Incharge:

Mohd Hasleen Saifee

Closed out by: Quality Manager

Girja Shanker

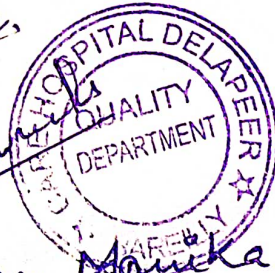
Approved by Lab Director:

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M.B.B.S., DCP

(पैथोलॉजिस्ट)

REG NO- 08-6177





PROFICIENCY TESTING REPORT
ISHTM-AIIMS EXTERNAL QUALITY ASSURANCE PROGRAMME
 NABL accredited program as per ISO/IEC 17043:2010 standard
 Organized By Department of Hematology, AIIMS, New Delhi-110029



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

EQAP CODE No. : 2834

Distribution No.: 155-G

Month/Year: March/2022

Instrument ID: ErmaPCE 210,S.N-29210

Name & Contact No. of PT Co-ordinator: Dr. Seema Tyagi (Prof.), Hematology, AIIMS, Delhi,
 Tel: 9013085730 , E-Mail : accuracy2000@gmail.com

Date of issue & status of the report: 11-05-2022[Final].

CBC and Retic Assessment

Test Parameters	S.No.	Among Lab (Accuracy Testing)						Within Lab (Precision Testing)			
		Your Result 1	Your Result 2	Your Results Sum of 2 Value	Consensus result sum of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score	Yours Results Diff. of 2 Values	Consensus Result Diff. of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score
WBC x10 ³ /µl	1	6.4	6.3	12.7	12.4	0.0660	0.23	0.1	0.11	0.0120	-0.06
RBC x10 ⁶ /µl	1	4.42	4.37	8.79	8.19	0.0100	2.42	0.05	0.03	0.0030	0.54
Hb g/dl	1	11.3	11.2	22.5	24.4	0.0300	-2.85	0.1	0.1	0.0080	0.00
HCT%	1	35.6	35.4	71	71.8	0.1490	-0.22	0.2	0.4	0.0280	-0.54
MCV-fl	1	81	80.5	161.5	176.3	0.3030	-2.01	0.5	0.4	0.0290	0.20
MCH-Pg	1	25.8	25.3	51.1	59.7	0.0880	-4.00	0.5	0.2	0.0180	1.35
MCHC-g/dl	1	31.9	31.4	63.3	67.4	0.1350	-1.09	0.5	0.3	0.0240	0.57
Plt. x10 ³ /µl	1	207	207	414	388	1.73	0.65	0	7	0.42	-1.18
Retic %	2	6	5	11	12.4	0.26	-0.21	1	0.4	0.03	1.35

P.S . Assesment

YOUR REPORT			CONSENSUS REPORT		
DLC%	3	Nrbcs= , Poly=55 L=05, E=02, Mono/Promono= , B1=05 P.M.=10, Mye=08, Meta=13, Other=2% band cells	Poly: 40 - 55, Myelo: 14 - 25, Meta: 7 - 16, Blast: 2-8, Lympho: 2-6 , Promyelo: 1-5 nRBC/Eos/Baso/Mono: 0 - 5		
RBC Morphology	3	Normocytic normochromic, mild poikilocytosis with schistocytes & target cells	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, hypochromia, Microcytosis; Mild: Macrocytosis, Poikilocytosis		
Diagnosis	3	Chronic myeloid leukemia	Chronic Myeloid Leukemia (Chronic Phase)		

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 155--G	Total No. responded	% of Labs with Z Score 0-2		% of Labs with Z Score 2-3		% of Labs with Z Score >3	
				Among labs	Within lab	Among labs	Within lab	Among labs	Within lab
WBC x10 ³ /µl	1	264	262	82.06	84.35	3.44	3.44	14.5	12.21
RBC x10 ⁶ /µl	1	264	264	90.15	88.26	4.92	5.3	4.93	6.44
Hb g/dl	1	264	264	85.98	89.39	7.95	4.17	6.07	6.44
HCT%	1	264	262	89.31	90.08	7.25	4.58	3.44	5.34
MCV-fl	1	264	262	89.69	91.98	8.02	2.29	2.29	5.73
MCH-Pg	1	264	262	89.69	90.46	6.11	4.58	4.2	4.96
MCHC-g/dl	1	264	262	94.27	89.69	4.2	4.58	1.53	5.73
Plt. x10 ³ /µl	1	264	261	87.74	88.51	7.66	4.21	4.6	7.28
ReticCount%	2	264	264	90.53	86.74	1.89	5.68	7.58	7.58
PS Assessment	3	264	250	Satisfactory :85.62%, Borderline Sat. :10.22%, Unsatisfactory :4.16%					

Comments:

1). Among Lab (EQA) : Results acceptable.

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

Note-1: EQA (External Quality Assurance) : Your Performance among various of participating labs in PT, to determine the accuracy of your results.

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

Note-2: Z score among & within lab were calculated, as per to ISO/IEC 13528:2015 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

Note-3: Z score 0 to ±2: Acceptable, Z score ±2 to ±3 :Warning Signal, Z score > ±3 : Unacceptable [As per ISO/IEC 13528:2015 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 orange colour. Z score value > ±3 are texted in red colour.

Note-5: Homogeneity and stability testing of PT sample were done as per ISO 13528:2015 standard. To pass homogeneity test, between sample SD (Ss) should be smaller than the check value (0.3*SDPA). To pass the stability test, average difference in measurement values of first and last day sample ($\bar{x}-\bar{y}$) should be smaller than the check value (0.3*SDPA).

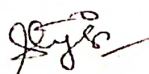
Note-6: ISHTM-AIIMS-EQAP does not subcontract any task of its scheme

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

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

Note-9: All the necessary details regarding design and implementation of PT, are provided in the instruction sheet as well as on programme's website www.ishtmaiimseqap.com.

Report authorized by,



Dr. Seema Tyagi (Prof.)

PT Co-ordinator: ISHTM-AIIMS-EQAP

Department of Hematology, AIIMS, New Delhi

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



PROFICIENCY TESTING REPORT
ISHTM-AIIMS EXTERNAL QUALITY ASSURANCE PROGRAMME
 NABL accredited program as per ISO/IEC 17043:2010 standard
 Organized By Department of Hematology, AIIMS, New Delhi-110029



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

EQAP CODE No. : 2834

Distribution No.: 154-G Month/Year: December/2021

Instrument ID: Erma PCE 210,S.No. 29210

Name & Contact No. of PT Co-ordinator: Dr. Seema Tyagi (Prof.), Hematology, AIIMS, Delhi,
 Tel: 9013085730 , E-Mail : accuracy2000@gmail.com

Date of issue & status of the report: 06-03-2022[Final].

CBC and Retic Assessment

Test Parameters	S.No.	Among Lab (Accuracy Testing)						Within Lab (Precision Testing)			
		Your Result 1	Your Result 2	Your Results Sum of 2 Value	Consensus result sum of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score	Yours Results Diff. of 2 Values	Consensus Result Diff. of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score
WBC x10 ³ /µl	1	5.3	5.2	10.5	11.49	0.0430	-1.15	0.1	0.1	0.0090	0.00
RBC x10 ⁶ /µl	1	4.88	4.57	9.45	8.66	0.0110	3.23	0.31	0.04	0.0030	6.07
Hb g/dl	1	12.8	12.7	25.5	25.5	0.0270	0.00	0.1	0.1	0.0090	0.00
HCT%	1	35.9	34.3	70.2	81.6	0.1940	-2.52	1.6	0.4	0.0290	3.24
MCV-fl	1	78.5	70.2	148.7	188.1	0.3850	-4.15	8.3	0.3	0.0290	17.99
MCH-Pg	1	27.7	26.2	53.9	59	0.0980	-2.55	1.5	0.3	0.0200	4.05
MCHC-g/dl	1	37.3	35.3	72.6	62.6	0.1560	2.75	2	0.2	0.0210	6.07
Plt. x10 ³ /µl	1	181	167	348	311	1.63	1.00	14	5	0.46	1.73
Retic %	2	7.5	6.5	14	13	0.27	0.17	1	0.5	0.03	0.84

P.S . Assesment

YOUR REPORT			CONSENSUS REPORT	
DLC%	3	Nrbcs=1.00 , Poly=57.00 L=1.00, E=5.00, Mono/Promono= , B1=3.00 P.M.=15.00, Mye=6.00, Meta=4.00, Other=0.00	Poly: 40 - 60, Myelo: 11 - 22, Meta: 6 - 14, Blast/nRBC: 1 - 15, Promyelo/Eos/Baso/Lympho/Mono: 0 - 5	
RBC Morphology	3	Normocytic normochromic with normoblast seen in smear	Predominantly: Microcytosis, Anisocytosis; Moderate: Hypochromia, Poikilocytosis; Mild: Normocytic/Normochromic, Macrocytosis, Tear drop cells	
Diagnosis	3	Chronic myeloid leukemia	Chronic Myeloid Leukemia (CML)	

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 154--G	Total No. responded	% of Labs with Z Score 0-2		% of Labs with Z Score 2-3		% of Labs with Z Score >3	
				Among labs	Within lab	Among labs	Within lab	Among labs	Within lab
WBC x10 ³ /µl	1	218	217	82.95	96.31	7.83	1.38	9.22	2.31
RBC x10 ⁶ /µl	1	218	218	89.45	92.66	6.42	3.21	4.13	4.13
Hb g/dl	1	218	218	93.12	93.12	5.05	4.13	1.83	2.75
HCT%	1	218	217	94.93	90.78	3.23	5.53	1.84	3.69
MCV-fl	1	218	217	97.24	93.09	1.84	2.76	0.92	4.15
MCH-Pg	1	218	217	91.71	94.93	6.45	2.76	1.84	2.31
MCHC-g/dl	1	218	217	94.47	88.94	4.15	6.91	1.38	4.15
Plt. x10 ³ /µl	1	218	217	92.63	92.17	4.61	4.61	2.76	3.22
ReticCount%	2	218	218	90.37	91.74	9.17	5.96	0.46	2.3
PS Assessment	3	218	206	Satisfactory :90.37%, Borderline Sat. :8.71%, Unsatisfactory :0.91%					

Comments:

- 1). Among Lab (EQA) : Results acceptable.
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Report authorized by,



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PT Co-ordinator: ISHTM-AIIMS-EQAP

Department of Hematology, AIIMS, New Delhi

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