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

PC-1002

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

EQAP CODE No. : 1975 **Distribution No.:** 157-E **Month/Year:** August/2022

Instrument ID: MINDRAY BC-6200

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: 22-10-2022[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	8.6	8.22	16.82	17.38	0.1220	**-0.18**	0.38	0.17	0.0110	**1.42**
RBC x10^6/µl	1	5.63	5.62	11.25	10.98	0.0110	**0.91**	0.01	0.04	0.0030	**-0.67**
Hb g/dl	1	10.8	10.8	21.6	21.1	0.0220	**0.84**	0	0.1	0.0070	**-1.35**
HCT%	1	43.1	42.9	86	71.3	0.1690	**3.21**	0.2	0.3	0.0230	**-0.27**
MCV-fl	1	76.6	76.2	152.8	129.15	0.2640	**3.17**	0.4	0.2	0.0120	**0.90**
MCH-Pg	1	19.2	19.1	38.3	38.5	0.0510	**-0.17**	0.1	0.1	0.0090	**0.00**
MCHC-g/dl	1	25.1	25	50.1	59.2	0.1610	**-2.05**	0.1	0.2	0.0130	**-0.45**
Plt. x10^3/µl	1	264	258	522	465	2.38	**0.86**	6	7	0.49	**-0.12**
Retic %	2	5	3	8	8.5	0.17	**-0.10**	2	0.4	0.02	**5.40**

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=4 , Poly=36 L=2, E=1, Mono/Promono=1 , B1=1 P.M.=1, Mye=38, Meta=19, Other=	Poly: 19 – 36, Myelo: 20 - 40, Meta: 9 – 20, Lympho: 2 – 6, Promyelo: 1 - 6, nRBC/ Baso/ Eos/ Mono /Blast: 0 – 5
RBC Morphology	3	Anisocytosis, Predominantly Normocytic Normochromic, microcytes, macrocytes and hypochromic cells seen.	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, hypochromia, Microcytosis; Mild: Macrocytosis, Poikilocytosis
Diagnosis	3	Chronic Myeloid Leukemia- Chronic Phase	Chronic Myeloid Leukemia (Chronic Phase)

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 157--E	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 $x10^3/\mu l$	1	313	311	85.85	89.07	10.29	4.18	3.86	6.75
RBC $x10^6/\mu l$	1	313	313	87.86	90.42	5.43	3.83	6.71	5.75
Hb g/dl	1	313	313	85.94	90.73	5.11	4.47	8.95	4.8
HCT%	1	313	310	92.26	89.03	4.52	4.52	3.22	6.45
MCV-fl	1	313	310	91.94	88.39	3.87	9.03	4.19	2.58
MCH-Pg	1	313	309	85.76	91.91	5.5	4.21	8.74	3.88
MCHC-g/dl	1	313	309	91.59	91.91	5.18	4.53	3.23	3.56
Plt. $x10^3/\mu l$	1	313	311	94.53	87.14	4.5	6.43	0.97	6.43
ReticCount%	2	313	288	97.92	93.4	1.39	1.04	0.69	5.56
PS Assessment	3	313	289	Satisfactory :74.77%, Borderline Sat. :9.58%, Unsatisfactory :15.65%					

Comments:

1). Among Lab (EQA) : CBC result for HCT & MCV unacceptable, please check calibration/human error.Remaining results acceptable.

2). Within Lab (IQA) : RETIC result is unacceptable, may be due to random/human error.

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.

Note 10: Reports are kept confidential.

Report authorized by,

Dr. Seema Tyagi (Prof.)
PT Co-ordinator: ISHTM-AIIMS-EQAP
Department of Hematology, AIIMS, New Delhi

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

	TELANGANA DIAGNOSTICS HUB, NIZAMABAD	Form: TD/QSP/08-EQCAR
	TITLE: EQAS CORRECTIVE ACTION FORM	Issue No. 01 Page 1 of 1

EQAS Details	
Analyte:	MCV - fL | HCT %.
Month:	AUG - 2022
Date Sample Tested:	05 - 09 - 2022

SPECIMEN HANDLING		
Were specimens received in an acceptable condition?	Yes ☑	No ☐
Were specimens stored according to the instructions on the result forms?	Yes ☑	No ☐
Were the samples hemolyzed?	Yes ☐	No ☑
Were samples tested within the time allowed for sample stability?	Yes ☑	No ☐
If applicable, were the samples reconstituted correctly? NA	Yes ☐	No ☐
Notes:		

CLERICAL ERRORS		
Were the results transcribed onto the result forms correctly?	Yes ☑	No ☐
Were the results transcribed from the result forms to the website correctly?	Yes ☑	No ☐
Were the results recorded on the correct result form?	Yes ☑	No ☐
Was the correct instrument/reagent/kit selected?	Yes ☑	No ☐
Were the results recorded in the correct units?	Yes ☑	No ☐
Were the results on your evaluation the same as the results you reported?	Yes ☑	No ☐
Notes:		

QUALITY CONTROL		
Were quality control materials within the acceptable range on the date of PT testing? (Verify the quality control acceptable range in use.)	Yes ☑	No ☐
Is there any indication of trending or shifting of the control results?	Yes ☐	No ☑
Notes:		

CALIBRATION		
Were there any problems with the most recent calibration?	Yes ☑	No ☐
When was the last calibration performed?	16-08-2022	
How often is a calibration performed?	Yearly	
When was the last calibration verification performed?	NA	
Notes:		

INSTRUMENT		
Were instrument problems noted the day the samples were tested?	Yes ☐	No ☑

PREPARED BY : LAB MANAGER : SIRISHA	APPROVED & ISSUED BY: LAB HEAD: Dr. NADIPALLY DIVYA
REVIEWED BY : LAB HEAD: DR . NADIPALLY DIVYA N. Divya	N. Divya

Has there been any recent maintenance on the analyzer?	Yes ☐	No ☑
Have you contacted your analyzer manufacturer for assistance?	Yes ☐	No ☑
Notes:		

REAGENTS		
Were the reagents stored properly?	Yes ☑	No ☐
Were the reagents expired or was the open vial stability exceeded?	Yes ☐	No ☑
Have there been any changes in reagent manufacturer or formulation?	Yes ☐	No ☑
Notes:		

TESTING PERSONNEL		
Date of last competency assessment for testing personnel 5-08-2022	Yes ☑	No ☐
Review assay procedure and proficiency test sample preparation instructions with testing personnel to ensure that instructions were followed	Yes ☑	No ☐
Review with testing personnel how samples were loaded to rule out misidentification or transposition of samples.	Yes ☑	No ☐
Notes:		

Corrective Action:
Random error - will check in next cycle.

Person Performing Investigation: Pramod. Date: 24-10-2022
Lab Director: Dr. N. Divya. Date: 24-10-2022

	TELANGANA DIAGNOSTICS HUB, NIZAMABAD		Form: TD/QSP/08-EQCAR
	TITLE	EQAS CORRECTIVE ACTION FORM	Issue No. 01 Page 1 of 1

INVESTIGATION SUMMARY: ROOT CAUSE

Pre-analytic Phase of Testing	Analytic Phase of Testing	Post-Analytic Phase of Testing
☐ PROBLEM WITH PT SAMPLE	☐ METHODOLOGICAL PROBLEM	☐ CLERICAL ERROR
☐ SAMPLE PROCESSING	☐ TECHNICAL PROBLEM	☐ REPORTING PROBLEM
☐ DATA ENTRY	☐ REAGENT PROBLEM	☐ NO EXPLANATION AFTER INVESTIGATION
☐ OTHER (SPECIFY):	☐ CALIBRATOR PROBLEM	OTHER (SPECIFY):
	☑ OTHER (SPECIFY): Random error	

PREVENTION

Preventive action proposed

NA

Preventive action Plan

NA

Responsibility

NA

Date 24-10-2022	Testing Personnel Pramod.
Date 24-10-2022	Department Technical In charge M. Lavanya

PREPARED BY : LAB MANAGER : SIRISHA	APPROVED & ISSUED BY: LAB HEAD: Dr. NADIPALLY DIVYA
REVIEWED BY : LAB HEAD: DR . NADIPALLY DIVYA N. Divya.	N. Divya.

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PC-1002

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

EQAP CODE No. : 1975 **Distribution No.:** 158-E **Month/Year:** December/2022

Instrument ID: MINDRAY BC-6200

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: 24-01-2023[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	8.02	7.93	15.95	15.7	0.0450	**0.21**	0.09	0.13	0.0080	**-0.39**
RBC x10^6/µl	1	3.56	3.54	7.1	6.92	0.0070	**0.97**	0.02	0.03	0.0020	**-0.27**
Hb g/dl	1	12.8	12.7	25.5	25.1	0.0210	**0.77**	0.1	0.1	0.0080	**0.00**
HCT%	1	42.7	42.7	85.4	78.3	0.1850	**1.33**	0	0.4	0.0250	**-1.35**
MCV-fl	1	120.4	120.1	240.5	225.75	0.5040	**1.03**	0.3	0.3	0.0230	**0.00**
MCH-Pg	1	35.9	35.7	71.6	72.6	0.0840	**-0.50**	0.2	0.3	0.0210	**-0.34**
MCHC-g/dl	1	29.9	29.7	59.6	63.75	0.1540	**-0.86**	0.2	0.3	0.0190	**-0.34**
Plt. x10^3/µl	1	211	208	419	459	1.62	**-1.00**	3	5	0.35	**-0.39**
Retic %	2	22.3	22	44.3	29	0.68	**0.72**	0.3	1	0.07	**-0.63**

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=1 , Poly=8 L=3, E=2, Mono/Promono=1 , B1=83 P.M.=1, Mye=1, Meta=1, Other=0	Blast: 65-87, Poly: 5-10, Lympho: 3-8, Myelo: 0-7, Mono: 1-10.5, nRBC/Promyelo/Meta/Eos: 0-5
RBC Morphology	3	NORMOCYTIC NORMOCHROMIC WITH MILD ANISOCYTOSIS	Predominantly: Normocytic/Normochromic; Moderate: Microcytosis, Hypochromia; Mild: Anisocytosis, Macrocytosis
Diagnosis	3	ACUTE LEUKEMIA	Acute Myeloid Leukemia (AML)

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 158--E	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 $x10^3/\mu l$	1	291	289	84.08	88.24	3.81	5.54	12.11	6.22
RBC $x10^6/\mu l$	1	291	291	88.32	93.47	7.56	2.41	4.12	4.12
Hb g/dl	1	291	291	87.97	90.38	4.12	6.53	7.91	3.09
HCT%	1	291	289	96.54	92.39	2.08	3.81	1.38	3.8
MCV-fl	1	291	288	97.92	95.14	1.39	2.08	0.69	2.78
MCH-Pg	1	291	288	87.15	87.5	8.33	7.29	4.52	5.21
MCHC-g/dl	1	291	288	96.88	86.46	2.43	6.25	0.69	7.29
Plt. $x10^3/\mu l$	1	291	289	89.97	92.39	7.27	2.42	2.76	5.19
ReticCount%	2	291	260	97.31	89.62	2.69	1.54	0	8.84
PS Assessment	3	291	264	Satisfactory :87.3%, Borderline Sat. :5.49%, Unsatisfactory :7.21%					

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.
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