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. : 1576

Instrument ID: MINDRAY BC 6200 **Distribution No.:** 157-D **Month/Year:** August/2022

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: 15-10-2022[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	3.02	2.95	5.97	6.13	0.0170	**-0.36**	0.07	0.07	0.0050	**0.00**
RBC x10^6/µl	1	4.32	4.21	8.53	9.36	0.0080	**-3.86**	0.11	0.04	0.0020	**1.89**
Hb g/dl	1	11.2	11.2	22.4	22.6	0.0200	**-0.39**	0	0.1	0.0070	**-1.35**
HCT%	1	36.9	36.3	73.2	78.1	0.1120	**-1.61**	0.6	0.3	0.0210	**1.01**
MCV-fl	1	86.3	85.6	171.9	166.6	0.2100	**0.88**	0.7	0.3	0.0200	**1.08**
MCH-Pg	1	26.6	25.9	52.5	48.2	0.0450	**3.63**	0.7	0.2	0.0110	**3.37**
MCHC-g/dl	1	30.8	30.3	61.1	57.7	0.0940	**1.27**	0.5	0.3	0.0160	**0.67**
Plt. x10^3/µl	1	108	108	216	231	0.95	**-0.59**	0	5	0.28	**-0.96**
Retic %	2										

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=0 , Poly=27 L=10, E=2, Mono/Promono=2 , B1=15 P.M.=18, Mye=11, Meta=15, Other=	Blast: 43-80, Poly: 4-12, Lympho: 4-10, Promyelo: 0-12.25, Myelo: 1-6.5, nRBC/Mono/Meta/Eos: 0-5
RBC Morphology	3	normocytic normpchromic, microcytes	Predominantly: Normocytic/Normochromic; Moderate: Microcytosis, Hypochromia; Mild: Anisocytosis, Macrocytosis
Diagnosis	3	Acute Promyelocytic Leukemia	Acute Myeloid Leukemia (AML)

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 157--D	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	354	349	82.81	92.26	3.72	3.44	13.47	4.3
RBC $x10^6/\mu l$	1	354	354	87.85	88.42	6.21	5.08	5.94	6.5
Hb g/dl	1	354	354	85.31	90.68	5.93	3.95	8.76	5.37
HCT%	1	354	349	89.11	91.12	6.3	4.58	4.59	4.3
MCV-fl	1	354	349	91.12	93.41	5.73	2.58	3.15	4.01
MCH-Pg	1	354	349	85.67	93.98	8.31	2.29	6.02	3.73
MCHC-g/dl	1	354	349	89.68	91.4	5.44	2.87	4.88	5.73
Plt. $x10^3/\mu l$	1	354	349	88.54	88.83	6.02	6.88	5.44	4.29
ReticCount%	2	354	232	89.22	95.26	9.05	9.91	1.73	-5.17
PS Assessment	3	354	338	Satisfactory :94.64%, Borderline Sat. :3.95%, Unsatisfactory :1.41%					

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.

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

EQAS Details	AIIMS, Pathology
Analyte:	RBC
Month:	August 2022
Date Sample Tested:	18/08/22

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?	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?		
How often is a calibration performed?		
When was the last calibration verification performed?		
Notes:		

INSTRUMENT		
Were instrument problems noted the day the samples were tested?	Yes ☐	No ☑
Has there been any recent maintenance on the analyzer?	Yes ☑	No ☐

PREPARED & REVIEWED BY : CONSULTANT PATHOLOGIST: Dr. R. Madhavi	APPROVED & ISSUED BY: LAB HEAD: Dr. R. Madhavi
Madhavi	Madhavi

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	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:

It is a Random error

Person Performing Investigation: Mounika Date: 16/10/22

Lab Director: Dr. R. Madhavi Date: 16/10/22

TELANGANA DIAGNOSTICS		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 ☐ SAMPLE PROCESSING ☐ DATA ENTRY ☐ OTHER (SPECIFY): _____	☐ METHODOLOGICAL PROBLEM ☐ TECHNICAL PROBLEM ☐ REAGENT PROBLEM ☐ CALIBRATOR PROBLEM ☐ OTHER (SPECIFY): _____	☐ CLERICAL ERROR ☐ REPORTING PROBLEM ☐ NO EXPLANATION AFTER INVESTIGATION OTHER (SPECIFY): _____

PREVENTION

Preventive action proposed

we will monitor Performance of RBC Parameter closely.

Preventive action Plan

we will monitor Performance of RBC Parameter in next cycle of EQAS

Responsibility

-

Date	16/10/22	Testing Personnel	Mounika
Date	16/10/22	Department Technical In charge	Dr. R. Madhavi

PREPARED & REVIEWED BY : CONSULTANT PATHOLOGIST: Dr. R. Madhavi	APPROVED & ISSUED BY: LAB HEAD: Dr. R. Madhavi
Madhavi	Madhavi

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

EQAS Details	AIIMS, Pathology
Analyte:	MCH
Month:	August 2022
Date Sample Tested:	18/08/22

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?	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?		
How often is a calibration performed?		
When was the last calibration verification performed?		
Notes:		

INSTRUMENT		
Were instrument problems noted the day the samples were tested?	Yes ☐	No ☑
Has there been any recent maintenance on the analyzer?	Yes ☑	No ☐

PREPARED & REVIEWED BY : CONSULTANT PATHOLOGIST: Dr. R. Madhavi	APPROVED & ISSUED BY: LAB HEAD: Dr. R. Madhavi
Madhavi	Madhavi

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	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:

It is a Random Error.

Person Performing Investigation: Mounika Date: 16/10/22

Lab Director: Dr. R. Madhavi Date: 16/10/22

	TELANGANA DIAGNOSTICS	**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 ☐ SAMPLE PROCESSING ☐ DATA ENTRY ☐ OTHER (SPECIFY): _____	☐ METHODOLOGICAL PROBLEM ☐ TECHNICAL PROBLEM ☐ REAGENT PROBLEM ☐ CALIBRATOR PROBLEM ☐ OTHER (SPECIFY): _____	☐ CLERICAL ERROR ☐ REPORTING PROBLEM ☐ NO EXPLANATION AFTER INVESTIGATION OTHER (SPECIFY): _____

PREVENTION

Preventive action proposed

We will monitor performance of MCH Parameter closely.

Preventive action Plan

We will monitor Performance of MCH Parameter in next cycle of EQAS.

Responsibility

Date	16/10/22	Testing Personnel	Mounika
Date	16/10/22	Department Technical In charge	Dr. R. Madhavi

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