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. : 1979 **Distribution No.:** 157-E **Month/Year:** August/2022

Instrument ID: 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	7.79	7.68	15.47	17.38	0.1220	**-0.61**	0.11	0.17	0.0110	**-0.40**
RBC x10^6/µl	1	5.36	5.35	10.71	10.98	0.0110	**-0.88**	0.01	0.04	0.0030	**-0.67**
Hb g/dl	1	10.3	10.2	20.5	21.1	0.0220	**-1.01**	0.1	0.1	0.0070	**0.00**
HCT%	1	44.4	44.2	88.6	71.3	0.1690	**3.78**	0.2	0.3	0.0230	**-0.27**
MCV-fl	1	82.8	82.5	165.3	129.15	0.2640	**4.85**	0.3	0.2	0.0120	**0.45**
MCH-Pg	1	19.1	19.1	38.2	38.5	0.0510	**-0.25**	0	0.1	0.0090	**-0.79**
MCHC-g/dl	1	231	230	461	59.2	0.1610	**90.34**	1	0.2	0.0130	**3.60**
Plt. x10^3/µl	1	234	231	465	465	2.38	**0.00**	3	7	0.49	**-0.49**
Retic %	2	1.8		1.8							

P.S . Assesment

YOUR REPORT			CONSENSUS REPORT
DLC%	3	Nrbcs= , Poly=12 L=11, E=1, Mono/Promono=0 , B1=07 P.M.=06, Mye=16, Meta=24, Other=BAND FORMS -18	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	Normocytic hypochromic RBCs admixed with microcytic hypochromic,nRBCs seen (3/100) Anisocytosis 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 $x10^3$/µl	1	313	311	85.85	89.07	10.29	4.18	3.86	6.75
RBC $x10^6$/µl	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. $x10^3$/µl	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 & MCHC unacceptable, please check calibration/human error.Remaining results acceptable.

2). Within Lab (IQA) : MCHC & RETIC result is unacceptable, please check precision/human error.Remaining 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:	HCT
Month:	AUGUST
Date Sample Tested:	08-09-2022

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?	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 PATHLOGIST:DR.B.JYOTHI	APPROVED & ISSUED BY: LAB HEAD: DR.B.JYOTHI
B. Jyothi	B. Jyothi

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: G. Sateesh kumar Date: 16/10/2022

Lab Director: Dr. B. Jyothi Date: 16/10/2022

PREPARED & REVIEWED BY : CONSULTANT PATHLOGIST: DR.B.JYOTHI	APPROVED & ISSUED BY: LAB HEAD: DR.B.JYOTHI
B. Jyothi	B. Jyothi

	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 HCT Parameter closely

Preventive action Plan

we will moniter Performance of HCT Parameter in next cycle of EQAS

Responsibility

Date 16/10/2022	Testing Personnel G. Sateesh Kumar
Date 16/10/2022	Department Technical In charge Dr. B. Jyothi

PREPARED & REVIEWED BY : CONSULTANT PATHLOGIST: DR.B.JYOTHI	APPROVED & ISSUED BY: LAB HEAD: DR.B.JYOTHI
B. Jyothi	B Jyothi

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

EQAS Details	AIIMS PATHOLOGY
Analyte:	MCHC
Month:	AUGUST
Date Sample Tested:	08-09-2022

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?	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 ☐

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B. Jyothi	B. Jyothi

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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: G. Sateesh Kumar Date: 16/10/22

Lab Director: Dr. B. Jyothi Date: 16/10/22

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	TELANGANA DIAGNOSTICS	Form: TD/QSP/08-EQCAR
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PREVENTION

Preventive action proposed

we will monitor performance of MCHC Parameter closely

Preventive action Plan

we will monitor Performance of MCHC Parameter in next cycle of Eqas

Responsibility

Date	16/10/22	Testing Personnel	G. Satesh Kumar
Date	16/10/22	Department Technical In charge	Dr-B.Jyothi

PREPARED & REVIEWED BY : CONSULTANT PATHLOGIST:DR.B.JYOTHI	APPROVED & ISSUED BY: LAB HEAD: DR.B.JYOTHI
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	TELANGANA DIAGNOSTICS	Form: TD/QSP/08-EQCAR
	TITLE: EQAS CORRECTIVE ACTION FORM	Issue No. 01 Page 1 of 1

EQAS Details	AIIMS PATHOLOGY
Analyte:	MCV
Month:	AUGUST
Date Sample Tested:	08-09-2022

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?	Yes ☐	No ☐
Notes:		

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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		
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Notes:		

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Has there been any recent maintenance on the analyzer?	Yes ☑	No ☐

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Have there been any changes in reagent manufacturer or formulation?	Yes ☐	No ☑
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Notes:		

Corrective Action:

It is a random error

Person Performing Investigation: G. Sateesh Kumar Date: 16/10/2022

Lab Director: Dr. B. Jyothi Date: 16/10/2022

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PREVENTION

Preventive action proposed

We will monitor Performance of MCV Parameter closely.

Preventive action Plan

We will monitor performance of MCV Parameter in next cycle of EQAS

Responsibility

Date	16/10/2024	Testing Personnel	G. Sateesh Kumar
Date		Department Technical In charge	Dr. B. Jyothi

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