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. : 4777 **Distribution No.:** 158-L **Month/Year:** January/2023

Instrument ID: yumizen 550

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: 23-02-2023[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	1.18	1.17	2.35	9.2	0.0280	-10.15	0.01	0.1	0.0060	-0.81
RBC x10^6/µl	1	4.77	4.73	9.5	9.42	0.0130	0.23	0.04	0.05	0.0030	-0.22
Hb g/dl	1	13.8	13.6	27.4	26.9	0.0280	0.75	0.2	0.1	0.0080	0.67
HCT%	1	40	39.6	79.6	85	0.2400	-0.69	0.4	0.4	0.0240	0.00
MCV-fl	1	83.9	83.8	167.7	183.2	0.4090	-1.16	0.1	0.2	0.0180	-0.34
MCH-Pg	1	28.9	28.9	57.8	57.2	0.0640	0.35	0	0.2	0.0160	-0.90
MCHC-g/dl	1	34.4	34.4	68.8	62.8	0.1560	1.05	0	0.3	0.0210	-1.01
Plt. x10^3/µl	1	221	216	437	452	1.51	-0.34	5	6	0.37	-0.17
Retic %	2	20.5	19.8	40.3	20.5	0.37	1.78	0.7	0.7	0.05	0.00

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=2 , Poly=43 L=21, E=, Mono/Promono= , Bl= P.M.=01, Mye=10, Meta=25, Other=	Poly: 28 - 51, Myelo: 12 - 22, Meta: 10- 20, Lympho: 3- 10, Eosino: 1-4, Promyelo: 2-8, nRBC/Blast/Baso/Mono: 0 - 5
RBC Morphology	3	Normocytic Normochromic	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, hypochromia, Microcytosis; Mild: Macrocytosis, Poikilocytosis
Diagnosis	3		Chronic Myeloid Leukemia (Chronic Phase)

Reviewed
25 Feb 2023

Reviewed
25/Feb/23

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 158--L	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	338	337	83.09	93.47	4.15	3.56	12.76	2.97
RBC $x10^6/\mu l$	1	338	338	88.17	88.76	6.51	4.44	5.32	6.8
Hb g/dl	1	338	338	86.98	84.32	5.62	6.21	7.4	9.47
HCT%	1	338	336	97.62	90.77	1.79	3.57	0.59	5.66
MCV-fl	1	338	337	99.11	85.76	0.89	3.86	0	10.38
MCH-Pg	1	338	337	91.69	89.91	4.45	5.34	3.86	4.75
MCHC-g/dl	1	338	337	98.52	88.43	0.89	5.64	0.59	5.93
Plt. $x10^3/\mu l$	1	338	337	95.55	88.72	3.56	5.93	0.89	5.35
ReticCount%	2	338	217	97.7	92.17	1.84	3.23	0.46	4.60
PS Assessment	3	338	212	Satisfactory :93.14%, Borderline Sat. :3.43%, Unsatisfactory :3.43%					

Comments:

1). Among Lab (EQA) : CBC result for WBC unacceptable, may be due to random/human error.PS Diagnosis not reported, remaining 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----------

TATA 1mg	TATA 1mg Labs	
	TATA 1mg Technologies Private Limited	
	Form Name	Proficiency Testing - Action Needed Form
	Form No.	Gen / FR / 59
	Issue Date & Version No.	01-Oct-2021 V1

Section 1 - Initiation of ANF (to be filled by the person who raising the ANF)

PT/EQAS Agency ☐ CAP ☐ AIIMS ☐ BIORAD ☐ Other

Survey name & distribution ID: **ISHTM-AIIMS EQAP** **Distribution No.: 158-L**
Date on agency report: 23-02-2023

ANF No: DDN/MAR/23/08	Issued by: Prashant Singh	Issue Date: 16-03-2023	Due date: 25-03-2023

Department: Haematology

ANALYTE or EXAMINATION: **WBC** $x10^3$ /µl

Sample ID	Result submitted	PT targets	PT acceptable range	Problem/Performance
Sample No - 158-L	1.18/1.17 $x10^3$ /µl	9.2 $x10^3$ /µl	NA	-10.15

Comment /Observations: (e.g. trend, previously missed within last 12 months, lab in regulatory jeopardy for this analyte?)

Section 2 - Investigation of Non Conformance- Checklist

Sl	ANF-CHECKLIST	Yes	No	N/A
1	Specimen temperature check, as per kit instructions	✓		
2	Specimen storage condition check, as per kit instructions	✓		
3	Specimen physical condition check	✓		
4	Sample integrity up to arrival in lab: any shipping, delay or other sample problems?		✓	
5	Sample integrity in-house: any problems with sample handling in the lab?		✓	
6	Were there any instrument problem?			
7	Were there any method problem?		✓	
8	Were there any faulty reagent/QC and Calibrator?		✓	
9	Were there QC trends / problems at time of assay?		✓	
10	Was Peer group data checked, if required		✓	
11	Were there any Calibration (Intercept/slope) problems at time of assay?		✓	
12	Was water quality checked?			✓
13	Did any technical errors occur due to pipetting error		✓	
14	Did any technical errors occur due to sample mix-up		✓	
15	Did any technical errors occur due to incorrect process, other than reconstitution, dilution or calculation errors,		✓	

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16	Did any technical errors occur due to misinterpretations		✓	
17	Was the instrument checked for daily. Weekly. Monthly, semiannually and Annual maintenance	✓		
18	Was there a lab clerical error? (e.g. error in unit conversion needed for survey only, transcription error onto result form, wrong method details submitted, Factor removal)		✓	
19	Was there a clerical error by the PT / EQA agency?		✓	
20	Were there Patient data trends / problems at time of assay?		✓	
21	Were there any gaps / issues in training or competency assessment?		✓	
22	Was the sample condition appropriate at time of retesting (mention temperature...)		✓	
23	Has sample been re-tested / re-examined?		✓	
24	Has the lab perform Interlaboratory Comparison	✓		

Questions 4-22 give details for any Yes answers

All the required maintenance was done timely as per the scheduled.

Question 23/24: if answer is yes, give results of repeat testing

Sample ID	Original result	Repeat value/ Lab Result	PT Targets/ Referral Lab Result	PT/ILC Acceptable Range	Status (Acceptable/Not acceptable)
NA	NA	NA	NA	NA	NA

Section 3 Root cause (Refer to Non-conformance error Reason)

Why do you think the non-conformance / error occurred? Use this area to explain your findings.

Same issue has been observed PAN India with WBC where the EQAS sample was performed on Horiba H550 instrument.

Assessment of the impact of root cause on patient results (Patient results may be affected before, during or after the PT event). Describe how the conclusion of impact was made and any corrective actions made to the patient result(s); "If No" - Explain why there was no patient impact?

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There is no patient impact as the ILC result for a sample which had similar WBC Count was sent and the results are concordant.
Describe any previous proficiency testing issues with this test in the last cycle:
Same issue was observed with the previous EQAS result of WBC.

Section 4: Department - Conclusion & Corrective / Preventive Action

What corrective action have you carried out?
The pre analytical,analytical and post analytical assessment has been done, There are no issue observed.ILC has
been done with one patient sample to rule out any patient impact.The ILC result is satisfactory.
Also the daily QC is being monitored regularly.
Preventive action put into place?
The issue has been escalated to the Central QA team.As per the Central QA team CBC will be enrolled with
Metropolis EQAS.The first cycle for Metropolis EQAS is expected in April 23. We will closely monitor the next
Metropolis EQAS cycle for any outliers.
Due date for closure of proposed corrective and preventive action: NA

Person investigated **Department Manager** **Lab Director**

Signature with Date: _____ _____ _____

Note: After signatures please hand over the form along with supporting documents to QA.

Date when ANF received to QA along with supporting documents: _____ **by:** _____

MC - 5424

Name	: Miss. ILC MANJU GOEL	Client Name	: PROFICIENCY TESTING
Age/Gender	: 65 Y 0 M 0 D /Female DOB:	Registration Date	: 20-Mar-23 06:58 PM
Patient ID	: DDN23922	Collection Date	: 20/Mar/2023 07:01PM
Barcode ID/Order ID	: B1799188 /	Sample Receive Date	: 21/Mar/2023 08:33AM
Referred By	: SELF	Report Status	: Final Report
Sample Type	: Whole Blood-EDTA	Report Date	: 21/Mar/2023 12:03PM

HAEMATOLOGY

Test Name	Result	Unit	Bio. Ref. Interval	Method
Complete Blood Count				
Hemoglobin	12.9	g/dL	12.0 - 15.0	Cyanide Free SLS
RBC	4.57	10^6/cu.mm	3.8-4.8	Impedance
HCT	39.1	%	36-46	Calculated
MCV	85.6	fL	83 - 101	RBC pulse measurement
MCH	28.4	pg	27 - 32	Calculated
MCHC	33.1	g/dL	31.5 - 34.5	Calculated
RDW-CV	**20.4**	%	11.6-14	Calculated
Total Leucocyte Count	8.19	10^3/µL	4 - 10	Impedance
Differential Leucocyte Count				
Neutrophils	62.3	%	40-80	Flowcytometery DHHS/ Microscopy
Lymphocytes	27.4	%	20-40	Flowcytometery DHHS/ Microscopy
Monocytes	7.6	%	2-10	Flowcytometery DHHS/ Microscopy
Eosinophils	2.5	%	1-6	Flowcytometery DHHS/ Microscopy
Basophils	0.2	%	0-2	Impedance / Microscopy
Absolute Leucocyte Count				
Absolute Neutrophil Count	5.1	10^3/µL	2-7	Calculated
Absolute Lymphocyte Count	2.24	10^3/µL	1-3	Calculated
Absolute Monocyte Count	0.62	10^3/µL	0.2-1	Calculated
Absolute Eosinophil Count	0.2	10^3/µI	0.02-0.5	Calculated
Absolute Basophil Count	0.02	10^3/µL	0.02-0.1	Calculated
Platelet Count	295	10^3/µL	150-410	Impedance /Microscopy
MPV	10.2	fL	6.5 - 12	Calculated
PDW	**19**	fL	9-17	Calculated

Comment:

- As per the recommendation of International council for Standardization in Hematology, the differential leucocyte counts

Dr. Reema Agrawal
MBBS, MD (Pathology)
Consultant Pathologist
Reg No: 56096

This test has Been Performed at **TATA 1MG OKHLA**

PO No :PO1132507903-620

Name	: Ms.MANJU GOEL	Client Name	: TATA 1MG DEHRADUN
Age/Gender	: 65/Female DOB:	Registration Date	: 20-Mar-23 11:08 AM
Patient ID	: DDN23846	Collection Date	: 20/Mar/2023 07:03AM
Barcode ID/Order ID	: D1799188 / 6892562	Sample Receive Date	: 20/Mar/2023 11:28AM
Referred By	: Dr.	Report Status	: Final Report
Sample Type	: Whole Blood-EDTA	Report Date	: 20/Mar/2023 12:15PM

HAEMATOLOGY

GOOD HEALTH GOLD PACKAGE

Test Name	Result	Unit	Bio. Ref. Interval	Method
Complete Blood Count				
Hemoglobin	13.8	g/dL	12.0 - 15.0	Spectrophometry
RBC	4.61	10^6/cu.mm	3.8 - 4.8	Electrical Impedence
HCT	39.4	%	36 - 46	Pulse Height Average
MCV	85.3	fl	83 - 101	Calculated
MCH	30.0	pg	27 - 32	Calculated
MCHC	**35.1**	g/dL	31.5 - 34.5	Calculated
RDW-CV	**18.2**	%	11.6-14	Calculated
Total Leucocyte Count	8.99	10^3/µl	4 - 10	DHSS/Microscopy
Differential Leucocyte Count				
Neutrophils	70.0	%	40 - 80	DHSS/Microscopy
Lymphocytes	25.0	%	20 - 40	DHSS/Microscopy
Monocytes	2.0	%	2 -10	DHSS/Microscopy
Eosinophils	3.0	%	1 - 6	DHSS/Microscopy
Basophils	0.0	%	0 - 2	DHSS/Microscopy
Absolute Leucocyte Count				
Absolute Neutrophil Count	6.29	10^3/µl	2-7	Calculated
Absolute Lymphocyte Count	2.25	10^3/µl	1-3	Calculated
Absolute Monocyte Count	**0.18**	10^3/µl	0.2-1	Calculated
Absolute Eosinophil Count	0.27	10^3/µl	0.02-0.5	Calculated
Absolute Basophil Count	**0**	10^3/µl	0.02-0.1	Calculated
Platelet Count	264	10^3/µl	150 - 410	Electrical Impedence/Microscopy
MPV	10.5	fl	6.5 - 12	Calculated
PDW	**19**	fL	9 - 17	Calculated

Comment:

- As per the recommendation of International council for Standardization in Hematology, the differential leucocyte counts are additionally being reported as absolute numbers of each cell in per unit volume of blood.