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. : 4347 **Distribution No.:** 163-K **Month/Year:** April/2024

Instrument ID: HORIBA MEDICAL **Model Name.:** YUMIZEN H550 **Serial No.:** 211YADH04052

Name & Contact No. of PT Co-ordinator: Dr. Manoranjan Mahapatra (Prof. & Head), Hematology, AIIMS, Delhi, Tel: 9013085730 , E-Mail : info@ishtmaiimseqap.com

Date of issue & status of the report: 19-06-2024[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	5.37	5.31	10.68	8.55	0.033	**2.54**	0.06	0.1	0.006	**-0.45**
RBC x10^6/µl	1	4.67	4.62	9.29	9.1	0.010	**0.78**	0.05	0.04	0.003	**0.19**
Hb g/dl	1	13.6	13.6	27.2	25.5	0.030	**2.08**	0	0.1	0.007	**-1.35**
HCT%	1	56.9	56.2	113.1	79.2	0.170	**7.79**	0.7	0.4	0.023	**0.81**
MCV-fl	1	121.8	121.7	243.5	174	0.314	**8.47**	0.1	0.3	0.022	**-0.54**
MCH-Pg	1	29.5	29.5	59	56.2	0.067	**1.73**	0	0.2	0.016	**-0.90**
MCHC-g/dl	1	24.8	23.2	48	64.35	0.161	**-3.89**	1.6	0.3	0.019	**4.38**
Plt. x10^3/µl	1	211	204	415	179.5	1.782	**4.81**	7	5	0.297	**0.45**
Retic %	2	10	9	19	16	0.260	**0.42**	1	0.5	0.036	**0.84**

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=00 , Poly=10 L=89, E=01, Mono/Promono=00 , B1=00 P.M.=00, Mye=00, Meta=00, Other=Many Smudged cells seen. Prolymphocytes.	Lymp: 77-88, Poly: 8-14.25, mono: 1-3, nRBC/Blast/Myelo/Meta/Eosino: 0-5
RBC Morphology	3	Normocytic Normochromic	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, Mild: Microcytic
Diagnosis	3	Chronic Lymphoproliferative Disorder CLL.	Chronic Lymphoproliferative Disorder/CLL

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 163--K	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	303	303	79.21	89.44	5.61	5.28	15.18	5.28
RBC $x10^6$/µl	1	303	303	89.44	90.76	5.28	3.96	5.28	5.28
Hb g/dl	1	303	303	90.1	91.42	5.61	3.96	4.29	4.62
HCT%	1	303	302	93.05	89.4	4.97	5.3	1.98	5.3
MCV-fl	1	303	302	92.05	85.1	5.3	7.28	2.65	7.62
MCH-Pg	1	303	302	87.09	92.38	6.95	4.64	5.96	2.98
MCHC-g/dl	1	303	302	93.05	93.38	3.64	3.31	3.31	3.31
Plt. $x10^3$/µl	1	303	302	93.71	91.06	3.64	5.63	2.65	3.31
ReticCount%	2	303	251	95.22	86.85	3.19	7.17	1.59	5.98
PS Assessment	3	303	249	Satisfactory :92.74%, Borderline Sat. :3.30%, Unsatisfactory :3.96%					

*Comments:

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

2). Within Lab (IQA) : Difference in the CBC measurement values for *MCHC* 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. Manoranjan Mahapatra (Prof. & Head)
PT Co-ordinator: ISHTM-AIIMS-EQAP
Department of Hematology, AIIMS, New Delhi

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

GAUTAM LABDHI DIAGNOSTIC CENTER

	NON- CONFORMANCE/ Corrective Action & Preventive Action Report	

Details of Non-Conformance: -
Haematology EQAS of April 2024 2 score of MCHC (-3.89), HCT (7.79), MCV (8.47), Platelet (4.81) count was out.

Root Cause: -
Human error - Mixing of EQAS sample was not properly mixed.

Corrective Action :- review all aspects of the test performance. Review the internal quality control results at the time the EQA sample were measured.

Preventive Action :- (1) Training given to technician about sample mixing & processing.
(2) We will Run EQA sample of Hematology 4 times in two days of span & then submit.

Follow up :- Wait for next cycle Result.

Technical Manager :- Mrs. Rohini Gaikwad.

Sign: - Rgaikwad

Date: - 21/06/24

Effectiveness of Corrective Action Taken by – Mrs. Rohini Gaikwad.

Technical Manager/ Quality Manager:- Dr. Sushil Agarwal.

Sign: - Agarwal

Date: -