DLS DIAGNOSTIC LABORATORY SERVICES

CORRECTIVE AND PERMANENT ACTION REPORT

Management Review by	Dr. Suvarna Jawale		
Department	**Complaint Date / Time:**	**Revision Date(s)**	**Location:**
Laboratory	23/01/2023	24/01/2023	lab

Root Cause Analysis

CBC result for MCH unacceptable in PT repoert & may be due to random/human error- MCH is calculeted as per Methodology for Applied Parameters

Corrective And Preventive Actions [CAPA]

N0.	Action Item	Date issued	Date Due	Date Completed	
1	training provided to technician to avoied human error Calculeted & checked	24/01/2023		24/01/2023	Report within range

Administrator Sign

DLS DIAGNOSTIC LABORATORY SERVICES

Authorised Signatory

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. : 2398 **Distribution No.:** 158-F **Month/Year:** December/2022

Instrument ID: ERBA H-360, 3 PART (K10012116054

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: 23-01-2023[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	9.7	9.53	19.23	18.2	0.0730	**0.49**	0.17	0.12	0.0090	**0.61**
RBC x10^6/µl	1	4.81	4.77	9.58	9.11	0.0100	**1.92**	0.04	0.04	0.0030	**0.00**
Hb g/dl	1	12.5	12.4	24.9	25.8	0.0220	**-1.73**	0.1	0.1	0.0080	**0.00**
HCT%	1	45	44.9	89.9	84.35	0.2260	**0.93**	0.1	0.4	0.0260	**-0.81**
MCV-fl	1	94.3	93.4	187.7	185.4	0.4410	**0.18**	0.9	0.2	0.0210	**2.36**
MCH-Pg	1	26.1	26	52.1	56.4	0.0550	**-3.22**	0.1	0.2	0.0140	**-0.45**
MCHC-g/dl	1	27.8	27.7	55.5	60.7	0.1560	**-1.11**	0.1	0.2	0.0160	**-0.45**
Plt. x10^3/µl	1	206	191	397	373	1.71	**0.52**	15	5	0.32	**1.93**
Retic %	2	15	13	28	27	0.63	**0.06**	2	1	0.06	**0.79**

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=08 , Poly=48 L=05, E=03, Mono/Promono= , B1=01 P.M.=01, Mye=18, Meta=24, Other=	Poly: 49 – 67, Myelo: 10 - 19, Meta: 6– 14, Lympho: 2– 6, Eosino: 0-2, Promyelo: 1-5, nRBC/Blast/Baso/Mono: 0 – 5
RBC Morphology	3	ANISOPOIKILOCYTOSIS ++, MICROCYTIC +, HYPOCHCROMIC+, POLYCHROMATIC RBCS , NRBCS SEEN	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, hypochromia, Microcytosis; Mild: Macrocytosis, Poikilocytosis
Diagnosis	3	S/O CHRONIC MYELOID LEUKEMIA	Chronic Myeloid Leukemia (Chronic Phase)

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 158--F	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	296	295	87.46	88.81	5.42	5.08	7.12	6.11
RBC $x10^6$/µl	1	296	296	83.78	92.23	9.46	3.38	6.76	4.39
Hb g/dl	1	296	296	82.77	89.53	8.45	6.08	8.78	4.39
HCT%	1	296	294	95.92	94.22	3.06	2.04	1.02	3.74
MCV-fl	1	296	294	97.62	93.2	1.7	2.04	0.68	4.76
MCH-Pg	1	296	294	85.03	91.16	7.14	3.4	7.83	5.44
MCHC-g/dl	1	296	294	97.28	92.86	1.36	3.74	1.36	3.4
Plt. $x10^3$/µl	1	296	294	94.22	91.84	4.76	4.42	1.02	3.74
ReticCount%	2	296	265	92.83	93.58	4.53	2.64	2.64	3.78
PS Assessment	3	296	265	Satisfactory :92.21%, Borderline Sat. :3.05%, Unsatisfactory :4.74%					

*Comments:

1). Among Lab (EQA) : CBC result for MCH unacceptable, may be due to random/human error

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----------