CORRECTIVE AND PERMANENT ACTION REPORT

Management Review by	Outlines Of The Parameters In Pathology, Microbiology & Biochemistry		
Department	**Date / Time:**	**Revision**	**Location:**
CCL	20/4/2022		CCL

Root Cause Analysis

Training of all concern staff

Calibration Of all equipment

Corrective And Preventive Actions [CAPA]

N0.	Action Item	Date issued	Date Completed	List Similar Products or Processes Affected
1	Training of all concern staff	20/4/2022	24/4/2022	
2	Calibration Of all equipment	21/4/2022	23/4/2022	
3				

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. : 3569 **Distribution No.:** 154-J **Month/Year:** January/2022

Instrument ID: Beckman DxH 500(AZ080377)

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: 16-03-2022[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	6.92	6.66	13.58	14.9	0.0430	**-1.38**	0.26	0.11	0.0110	**1.56**
RBC x10^6/µl	1	3.45	3.41	6.86	6.82	0.0080	**0.21**	0.04	0.03	0.0030	**0.27**
Hb g/dl	1	11.18	11.13	22.31	21.8	0.0240	**0.86**	0.05	0.1	0.0080	**-0.67**
HCT%	1	35.8	35.4	71.2	68.6	0.1510	**0.78**	0.4	0.3	0.0270	**0.34**
MCV-fl	1	103.9	103.8	207.7	200.6	0.3570	**0.81**	0.1	0.5	0.0370	**-0.60**
MCH-Pg	1	32.6	32.4	65	64.1	0.0800	**0.51**	0.2	0.2	0.0160	**0.00**
MCHC-g/dl	1	31.4	31.2	62.6	63.6	0.1440	**-0.31**	0.2	0.3	0.0220	**-0.27**
Plt. x10^3/µl	1	232	229	461	418	1.39	**1.38**	3	6	0.39	**-0.58**
Retic %	2	2.8	1.8	4.6	6.6	0.17	**-0.45**	1	0.3	0.02	**2.36**

P.S . Assesment

	YOUR REPORT		CONSENSUS REPORT
DLC%	3	Nrbcs=2.00 , Poly=51.00 L=5.00, E=6.00, Mono/Promono=30.00 , B1=4.00 P.M.=1.00, Mye=1.00, Meta=1.00, Other=	Poly: 45 - 58 , Myelo: 8 - 21, Meta: 6 - 13; Lympho/Promyelo: 1 - 10; Blast/nRBC/Eos/Baso/Mono: 0 - 5
RBC Morphology	3	Normocytic Normochromic, Mild Hypochromasia, Polychromasia +	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, Microcytosis, Hypochromia; Mild: Macrocytosis, Poikilocytosis
Diagnosis	3	Chronic Myeloproliferative disorder with Monocytosis	Chronic Myeloid Leukemia

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 154--J	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	237	237	86.92	85.65	4.64	1.69	8.44	12.66
RBC $x10^6/\mu l$	1	237	237	91.14	91.56	4.22	4.22	4.64	4.22
Hb g/dl	1	237	237	92.83	89.87	3.8	3.8	3.37	6.33
HCT%	1	237	237	90.3	84.81	8.44	7.59	1.26	7.6
MCV-fl	1	237	236	94.92	94.92	3.81	2.97	1.27	2.11
MCH-Pg	1	237	237	89.03	88.19	7.17	6.75	3.8	5.06
MCHC-g/dl	1	237	237	90.72	89.45	8.44	5.06	0.84	5.49
Plt. $x10^3/\mu l$	1	237	237	89.03	91.56	7.59	4.22	3.38	4.22
ReticCount%	2	237	232	96.12	83.19	1.29	10.78	2.59	6.03
PS Assessment	3	237	217	Satisfactory :90.99%, Borderline Sat. :7.17%, Unsatisfactory :1.84%					

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----------

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. : 3569 **Distribution No.:** 155-J **Month/Year:** March/2022

Instrument ID: Beckman Coulter DxH500 AZ080377

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: 31-05-2022[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	52.69	52.5	105.19	10.56	0.0580	**67.36**	0.19	0.1	0.0100	**0.87**
RBC x10^6/µl	1	4.5	4.5	9	9.37	0.0140	**-1.02**	0	0.05	0.0040	**-0.96**
Hb g/dl	1	12.63	12.56	25.19	28	0.0370	**-3.45**	0.07	0.1	0.0100	**-0.20**
HCT%	1	43	42.7	85.7	84.1	0.1710	**0.39**	0.3	0.5	0.0310	**-0.54**
MCV-fl	1	95.6	94.9	190.5	179.8	0.2720	**1.64**	0.7	0.3	0.0310	**0.77**
MCH-Pg	1	28.1	28.1	56.2	59.55	0.1010	**-1.46**	0	0.3	0.0200	**-1.01**
MCHC-g/dl	1	29.6	29.4	59	66.5	0.1520	**-2.16**	0.2	0.3	0.0230	**-0.34**
Plt. x10^3/µl	1	215	207	422	286	2.24	**2.70**	8	8	0.55	**0.00**
Retic %	2	6.5	5.8	12.3	8	0.15	**1.15**	0.7	0.4	0.03	**0.81**

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs= , Poly=4 L=8, E=, Mono/Promono= , B1=88 P.M.=, Mye=, Meta=, Other=Giant platelets seen	Blast: 60-85, Poly: 2-6, Lympho: 6-21, nRBC/mono/Eosino/Myelo/Meta/promyelo: 0-1
RBC Morphology	3	Normocytic Normochromic, few Macrocytes seen	Predominantly: Normocytic/ Normochromic, Moderate: Anisocytosis, Microcytic
Diagnosis	3	Acute Leukemia(lymphoblastic)	Acute Leukemia (AL)

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 155--J	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	252	250	87.2	81.6	2	3.6	10.8	14.8
RBC $x10^6/\mu l$	1	252	252	90.48	87.7	4.37	3.97	5.15	8.33
Hb g/dl	1	252	252	85.71	89.68	5.95	5.16	8.34	5.16
HCT%	1	252	250	90.4	88.8	5.2	4	4.4	7.2
MCV-fl	1	252	249	91.97	92.77	5.22	2.81	2.81	4.42
MCH-Pg	1	252	250	89.6	88.8	5.2	2.4	5.2	8.8
MCHC-g/dl	1	252	250	87.6	86	7.2	7.6	5.2	6.4
Plt. $x10^3/\mu l$	1	252	248	84.68	90.73	6.45	4.44	8.87	4.83
ReticCount%	2	252	230	92.61	94.78	4.35	0.87	3.04	4.35
PS Assessment	3	252	236	Satisfactory :94.82%, Borderline Sat. :3.58%, Unsatisfactory :1.59%					

Comments:

1). Among Lab (EQA) : CBC result for WBC & HB unacceptable, please check calibration/human error.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.

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Report authorized by,

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PT Co-ordinator: ISHTM-AIIMS-EQAP
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PROFICIENCY TESTING REPORT

ISHTM-AIIMS EXTERNAL QUALITY ASSURANCE PROGRAMME

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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. : 3569 **Distribution No.:** 156-J **Month/Year:** June/2022

Instrument ID: Beckman Coulter DxH500 AZ080377

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: 29-08-2022[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	9.11	8.64	17.75	10.6	0.0820	3.71	0.47	0.12	0.0110	2.62
RBC x10^6/µl	1	4.31	4.24	8.55	8.84	0.0120	-1.09	0.07	0.05	0.0030	0.39
Hb g/dl	1	11.09	10.9	21.99	25.4	0.0320	-4.60	0.19	0.1	0.0100	0.61
HCT%	1	40.3	39	79.3	80.55	0.2100	-0.25	1.3	0.4	0.0340	1.73
MCV-fl	1	93.6	92	185.6	181.8	0.3220	0.49	1.6	0.3	0.0260	2.92
MCH-Pg	1	25.7	25.7	51.4	57.4	0.0800	-3.11	0	0.3	0.0200	-1.01
MCHC-g/dl	1	27.9	27.5	55.4	62.75	0.1690	-1.84	0.4	0.4	0.0240	0.00
Plt. x10^3/µl	1	228	226	454	402.5	2.29	0.96	2	6	0.43	-0.60
Retic %	2	2.5	2	4.5	5.6	0.16	-0.27	0.5	0.3	0.02	0.90

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=0 , Poly=6 L=6, E=2, Mono/Promono=2 , B1=52 P.M.=27, Mye=3, Meta=2, Other=Myeloblast with Auer rod	Blast: 24-67, Poly: 5-18, Lympho: 6-15, mono:2-15 , Myelo:0-7 , Meta: 0-7, promyelo: 0-6, Eosino:0-1
RBC Morphology	3	Normocytic Normochromic with few microcytic hypochromic cells with few macrocytes with mild anisopoikiocytosis	Predominantly: Normocytic/ Normochromic, Moderate: Anisocytosis, Microcytic
Diagnosis	3	Acute Myeloid Leukemia AML M3	Acute Leukemia (AL)

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 156--J	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	249	246	85.77	89.84	5.69	3.66	8.54	6.5
RBC $x10^6$/µl	1	249	249	87.95	86.35	4.82	6.43	7.23	7.22
Hb g/dl	1	249	249	86.35	83.53	3.61	5.62	10.04	10.85
HCT%	1	249	246	89.84	89.84	5.28	4.47	4.88	5.69
MCV-fl	1	249	246	89.43	93.5	5.28	2.03	5.29	4.47
MCH-Pg	1	249	246	87.8	88.21	5.69	3.66	6.51	8.13
MCHC-g/dl	1	249	246	91.06	89.02	4.88	5.28	4.06	5.7
Plt. $x10^3$/µl	1	249	246	92.68	91.06	4.88	4.88	2.44	4.06
ReticCount%	2	249	222	92.79	81.53	4.5	11.26	2.71	7.21
PS Assessment	3	249	231	Satisfactory :85.95%, Borderline Sat. :0.803%, Unsatisfactory :13.25%					

*Comments:

1). Among Lab (EQA) : CBC result for WBC, HB & MCH unacceptable, please check calibration/human error.Remaining results acceptable.

2). Within Lab (IQA) : Precision acceptable.

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IQR = Quartile 3 - Quartile 1 of participant data, Normalised IQR = 0.7413 x IQR

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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).

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