8. Immediate Action Taken, if any: We perform ILC study from our and CCH Varanasi lab and value found ok.

9. Summary of re-assayed results:

Sr No.	Analyte	Previous Results/ ILC Result of Lab 1	Re-assayed Results/ ILC Result of Lab 2	Acceptability Limits/ Obtained CV & Acceptable Criteria of ILC
1	Lanka (Hariba Yumize MSSo)	TLC- 16.3	TLC- 16.2	Accepted
2	Mahmoorganj (Hariba Jamize MSSo)			

10. Comment on Re-Assayed Results: Check the Preventive maintenance of analyzer. and QC of re-assayed date and than Re-run ILC sample, Value found ok.

11. Preventive Action to prevent recurrence: check PM record and it's daily maintenance with QC acceptance.

12. Documents Attached: ILC study of both lab report. QC. of same date when ILC sample Process.

13. Conclusion:

a. Clerical Error
b. Methodology Error ✓
c. Methodology Error
d. Technical Problem
e. Problem with EQAS material
f. Others (please Specify)

Corrective Action Taken By:

Corrective Action Reviewed By: Amita

Corrective Action Approved By: OK Ratn 20.09.21

CONTROLLED COPY
AUTH
QA FUNCTION

Path Kind Labs	PATHKIND DIAGNOSTICS PVT LTD	ISSUE DATE: 10-03-2018	AMENDEMENT DATE:	B31/82 A-9-B,RASHMI NAGAR, BHOJUBIR, NEAR BHU EMERGENCY GATE, LANKA, VARANASI, UTTAR PRADESH - 221005
	CAPA LOG FOR EQAS FAILURE	ISSUE NO: 01	AMENDEMENT NO:	

1. Date of Corrective Action Taken: 25/09/2021
2. Name of the Survey: TLC
3. Details of Samples: TLC
4. EQAS Sample Run Date: 17/8/2021
5. Outlier Results: TLC 2.69
6. EQAS Trends of last 2 cycles (if applicable): Not applicable
7. Root Cause Analysis:

Sr No.	RCA	Acceptable	Unacceptable
1	IQC Status	✓	
2	Preventive Maintenance Status	✓	
3	Calibration Status	✓	
4	Reagent Status	✓	
5	Clerical Error	✓	
6	Technical Problem	✓	
7	Problem with EQAS Samples	✓	
Any Other (Please Specify): No Comment			

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

NABL Certificate No. PC - 1002

Duration of stability testing - minimum upto 8 days at ambient temp. after dispatch of specimens

EQAP CODE No. : 1432 **Distribution No.:** 153-D **Month/Year:** August/2021

Instrument ID: horiba yumizen h550 902YAXH02141

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: 13-09-2021[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	1.74	0.95	2.69	5.5	0.0230	**-4.81**	0.79	0.08	0.0050	**10.64**
RBC x10^6/µl	1	3.64	3.53	7.17	7.54	0.0070	**-2.00**	0.11	0.03	0.0020	**2.16**
Hb g/dl	1	11.8	11.7	23.5	23.8	0.0200	**-0.58**	0.1	0.1	0.0070	**0.00**
HCT%	1	35.4	34.6	70	74.3	0.1290	**-1.18**	0.8	0.3	0.0230	**1.35**
MCV-fl	1	97.8	97.3	195.1	196.55	0.2900	**-0.16**	0.5	0.3	0.0250	**0.47**
MCH-Pg	1	33.3	32.1	65.4	63.1	0.0300	**1.50**	1.2	0.2	0.0160	**4.50**
MCHC-g/dl	1	34.1	33.3	67.4	64.15	0.1170	**1.02**	0.8	0.2	0.0170	**2.70**
Plt. x10^3/µl	1	91	88	179	222	1.09	**-1.35**	3	4	0.28	**-0.19**
Retic %	2	0.2	0.16	0.36	1.2	0.03	**-1.04**	0.04	0.1	0.01	**-0.81**

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=3.00 , Poly=45.00 L=5.00, E=1.00, Mono/Promono=1.00 , B1=4.00 P.M.=3.00, Mye=23.00, Meta=17.00, Other=0.00	Poly: 40 – 60, Myelo: 10 - 25, Meta: 5 – 20, Promyelo: 1-10, nRBC/Lympho/Blast/Eos/Baso/Mono: 0 – 5
RBC Morphology	3	Anisocytosis mild hypochromia predominantly normocytic	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, hypochromia, Microcytosis; Mild: Macrocytosis, Poikilocytosis
Diagnosis	3	Normocytic anemia with chronic myloidd 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. 153--D	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	316	314	84.71	87.9	3.5	1.59	11.79	10.51
RBC $x10^6$/µl	1	316	316	93.04	90.51	3.16	3.8	3.8	5.69
Hb g/dl	1	316	316	87.66	91.14	6.65	3.8	5.69	5.06
HCT%	1	316	314	95.22	90.13	2.23	3.5	2.55	6.37
MCV-fl	1	316	314	96.5	92.68	2.23	3.18	1.27	4.14
MCH-Pg	1	316	314	88.85	91.72	7.96	3.5	3.19	4.78
MCHC-g/dl	1	316	314	94.59	88.22	3.5	3.18	1.91	8.6
Plt. $x10^3$/µl	1	316	314	93.31	90.45	4.46	4.14	2.23	5.41
ReticCount%	2	316	316	81.33	78.16	3.8	6.01	14.87	15.83
PS Assessment	3	316	295	Satisfactory :98.65%, Borderline Sat. :1.35%, Unsatisfactory :0%					

*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.

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

NABL Certificate No. PC - 1002

Duration of stability testing - minimum upto 8 days at ambient temp. after dispatch of specimens

EQAP CODE No. : 1432 **Distribution No.:** 154-D **Month/Year:** November/2021

Instrument ID: 902YAXH02141

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: 22-02-2022[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	2.69	1.58	4.27	7.26	0.0600	**-1.62**	1.11	0.1	0.0090	**8.01**
RBC x10^6/µl	1	3.74	3.68	7.42	7.36	0.0070	**0.32**	0.06	0.04	0.0030	**0.45**
Hb g/dl	1	11.5	11	22.5	21.2	0.0210	**2.19**	0.5	0.1	0.0080	**2.70**
HCT%	1	32	31.1	63.1	64.1	0.1070	**-0.33**	0.9	0.3	0.0250	**1.30**
MCV-fl	1	85.7	84.5	170.2	173.95	0.2260	**-0.63**	1.2	0.3	0.0240	**2.02**
MCH-Pg	1	30.8	29.8	60.6	57.5	0.0590	**1.99**	1	0.3	0.0190	**2.36**
MCHC-g/dl	1	36	35.2	71.2	66.1	0.1060	**1.76**	0.8	0.3	0.0220	**1.35**
Plt. x10^3/µl	1	129	122	251	269	0.95	**-0.67**	7	4	0.28	**0.58**
Retic %	2	2.6	2.2	4.8	4.45	0.10	**0.12**	0.4	0.2	0.01	**0.90**

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=1.00 , Poly=3.00 L=18.00, E=0.00, Mono/Promono=1.00 , B1=78.00 P.M.=0.00, Mye=0.00, Meta=0.00, Other=	Blast: 60-85, Poly: 2-6, Lympho: 6-21, nRBC/mono/Eosino/Myelo/Meta: 0-1
RBC Morphology	3	Aniso-poikilocytosis, moderate hypochromia, Dimorphic RBCs	Predominantly: Normocytic/ Normochromic, Moderate: Anisocytosis, Microcytic
Diagnosis	3	Acute Leukemia with Dimorphic Anemia with Thrombocytopenia	Acute Leukemia (AL)

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 154--D	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	318	311	79.74	85.53	5.14	5.47	15.12	9
RBC $x10^6$/µl	1	318	318	88.05	88.05	5.03	4.72	6.92	7.23
Hb g/dl	1	318	318	87.11	87.74	5.03	5.66	7.86	6.6
HCT%	1	318	312	91.35	89.74	3.85	5.45	4.8	4.81
MCV-fl	1	318	312	91.67	90.38	4.49	5.13	3.84	4.49
MCH-Pg	1	318	312	90.06	89.42	5.45	4.17	4.49	6.41
MCHC-g/dl	1	318	312	90.38	88.46	6.09	6.41	3.53	5.13
Plt. $x10^3$/µl	1	318	312	91.03	95.83	4.81	3.21	4.16	0.96
ReticCount%	2	318	318	95.28	89.62	2.2	2.2	2.52	8.18
PS Assessment	3	318	297	Satisfactory :94.36%, Borderline Sat. :5.32%, Unsatisfactory :0.31%					

*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.
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Report authorized by,

Dr. Seema Tyagi (Prof.)
PT Co-ordinator: ISHTM-AIIMS-EQAP
Department of Hematology, AIIMS, New Delhi

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