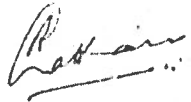



CONTROLLED COPY

AUTH: 

QA FUNCTION

	PATHKIND DIAGNOSTICS PVT LTD	ISSUE DATE: 20-07-2019	AMENDMENT DATE:	C/O SHARDA NARAYAN HOSPITAL, GHAZIPUR TIRAHA, SAHADATPURA MAU, UTTAR PRADESH- 275101
	CAPA LOG FOR EQAS FAILURE	ISSUE NO: 01	AMENDMENT NO:	

1. Date of Corrective Action Taken: 7/6/23
2. Name of the Survey: ISHTM - AIIMS EXTERNAL Quality Assurance programme
3. Details of Samples: 159-K
4. EQAS Sample Run Date: 14/04/23
5. Outlier Results: No
6. EQAS Trends of last 2 cycles (if applicable):
No - Acceptable
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	No -	
6	Technical Problem	✓	
7	Problem with EQAS Samples	✓	
Any Other (Please Specify):			


DOC NO.: P041/GEN/019	CAPA LOG FOR EQAS FAILURE	Page 01 of 02
ISSUED BY: DR ASHOK RATTAN		

2

CONTROLLED COPY

AUTH: *[Signature]*

QA FUNCTION

	PATHKIND DIAGNOSTICS PVT LTD CAPA LOG FOR EQAS FAILURE	ISSUE DATE: 20-07-2019	AMENDMENT DATE:	C/O SHARDA NARAYAN HOSPITAL, GHAZIPUR TIRAHA, SAHADATPURA MAU, UTTAR PRADESH- 275101
		ISSUE NO: 01	AMENDMENT NO:	

8. Immediate Action Taken, if any:
IOc reviewed for Hb and found ok. checked instrument PM and cal status and 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
	<i>—</i>	<i>—</i>	<i>—</i>	<i>—</i>

10. Comment on Re-Assayed Results:

Sample cannot be re-assayed as result came after offay 1 month. As Accuracy is acceptable also the repeats results have no different it could be random error.

11. Preventive Action to prevent recurrence:

last 2 cycles result of Hb was Acceptable hence same will be monitored for next cycle

12. Documents Attached:

IOc report attached.

13. Conclusion:

- a. Clerical Error
- c. Random Error
- g. Problem with EQAS material

- b. Methodology Error
- d. Technical Problem
- f. Others (please Specify)
Random Error

Corrective Action Taken By:

Kishant Chandel

Corrective Action Reviewed By:

Dr. Davish Ahluwalia

Corrective Action Approved By:

[Signature]

DOC NO.: P041/GEN/019	CAPA LOG FOR EQAS FAILURE	Page 02 of 02
ISSUED BY: DR ASHOK RATTAN		



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



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

EQAP CODE No. : 4317

Distribution No.: 159-K

Month/Year: April/2023

Instrument ID: 705ESOH11486

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: 01-06-2023[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	5.9	5.9	11.8	10.41	0.067	0.97	0	0.1	0.010	-0.79
RBC x10 ⁶ /µl	1	3.51	3.5	7.01	7.07	0.010	-0.26	0.01	0.04	0.003	-0.67
Hb g/dl	1	11.4	11.4	22.8	23.5	0.031	-1.05	0	0.1	0.008	-4.50
HCT%	1	33.5	33.3	66.8	71.9	0.160	-1.30	0.2	0.4	0.028	-0.45
MCV-fl	1	95	95	190	203	0.412	-1.21	0	0.4	0.030	-0.90
MCH-Pg	1	32.5	32.4	64.9	66.5	0.119	-0.51	0.1	0.3	0.021	-0.67
MCHC-g/dl	1	34.1	34	68.1	65.4	0.156	0.67	0.1	0.3	0.023	-0.54
Plt. x10 ³ /µl	1	187	186	373	362	2.487	0.19	1	5	0.368	-0.77
Retic %	2	13	12.2	25.2	29	0.590	-0.26	0.8	1	0.067	-0.18

P.S . Assesment

YOUR REPORT			CONSENSUS REPORT
DLC%	3	Nrbcs= , Poly=08 L=81, E=01, Mono/Promono=02 , B1=08 P.M.=, Mye=, Meta=, Other=	Lympho: 60-83, Blast: 0-18, Poly: 4-13, Mono: 1-5, Eos: 1-2, nRBC//Baso/Myelo/Meta/ Promyelo: 0-5
RBC Morphology	3	Mild Anisocytosis predominantly normocytic normochromic	Predominantly: Normocytic/ Normochromic, Moderate: Anisocytosis, Microcytic
Diagnosis	3	Normocytic normochromic blood picture with relative lymphocytosis, with thrombocytopenia. Reactive lymphocytes seen. Differential diagnosis -: 1 - Rule out viral infection (P Dengue). 2 - Sub leukemic leukemia. Adv:- Bone marrow study to rule-out leuka	Acute Leukemia (AL)

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 159--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	265	261	73.95	86.21	7.28	4.98	18.77	8.81
RBC x10 ⁶ /µl	1	265	265	83.77	88.68	9.43	5.28	6.8	6.04
Hb g/dl	1	265	265	87.55	85.66	6.79	7.55	5.66	6.79
HCT%	1	265	261	90.8	91.57	4.21	4.6	4.99	3.83
MCV-fl	1	265	261	93.87	94.64	3.83	3.07	2.3	2.29
MCH-Pg	1	265	261	94.64	88.12	2.3	7.66	3.06	4.22
MCHC-g/dl	1	265	261	93.1	91.19	4.21	4.21	2.69	4.6
Plt. x10 ³ /µl	1	265	261	86.97	92.34	10.34	4.21	2.69	3.45
ReticCount%	2	265	221	96.38	89.14	3.17	4.98	0.45	5.88
PS Assessment	3	265	200	Satisfactory :83.35%, Borderline Sat. :9.46%, Unsatisfactory :7.19%					

***Comments:**

1). Among Lab (EQA) : Results acceptable.

2). Within Lab (IQA) : Difference in the CBC measurement values for *HB* 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. Seema Tyagi (Prof.)

PT Co-ordinator: ISHTM-AIIMS-EQAP

Department of Hematology, AIIMS, New Delhi

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

PATIENT RESULT REPORT

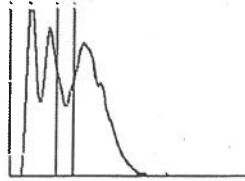
SID : 1/159K
PID :
Name :
Firstname :
Type : Man
Department :
Local :
Complete: 14/04/2023 16:33:
45
Operator : labtech

RESULT

Analyser Alarms T⁰
Analysis Alarms SCH, G1,
G2, L1, M2, Qct1, XB

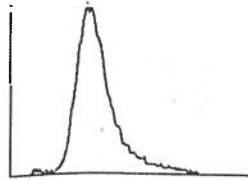
WBC	5.9		$10^3/mm^3$
LYM%	41.3		%
MON%	13.5	H	%
GRA%	45.2	L	%
LYM#	2.40		$10^3/mm^3$
MON#	0.70		$10^3/mm^3$
GRA#	2.80		$10^3/mm^3$

WBC



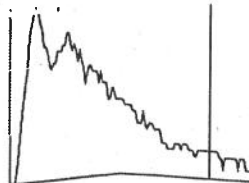
RBC	3.50	L	$10^6/mm^3$
HGB	11.4	L	g/dl
HCT	33.3	L	%
MCV	95		μm^3
MCH	32.5	H	pg
MCHC	34.1	H	g/dl
RDW-CV	14.7		%
RDW-SD	50	H	μm^3

RBC



PLT	186	*	$10^3/mm^3$
MPV	10.2	*H	μm^3
PCT	0.189	*	%
PDW	17.0	*	%

PLT



Handwritten signature
14/4/23

PATIENT RESULT REPORT

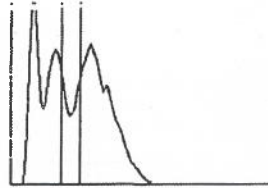
SID : 1/159K
PID :
Name :
Firstname :
Type : Man
Department :
Local :
Complete: 14/04/2023 16:35:
36
Operator : labtech

RESULT

Analyser Alarms T^o
Analysis Alarms SCH, G1,
G2, L1, M2, Qct1, XB

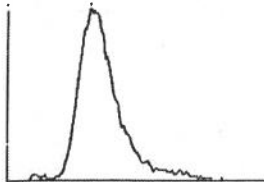
WBC	5.9		$10^3/\text{mm}^3$
LYM%	41.5		%
MON%	13.8	H	%
GRA%	44.7	L	%
LYM#	2.40		$10^3/\text{mm}^3$
MON#	0.80	H	$10^3/\text{mm}^3$
GRA#	2.70		$10^3/\text{mm}^3$

WBC



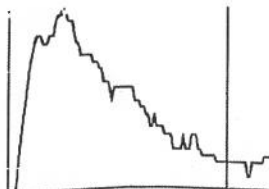
RBC	3.51	L	$10^6/\text{mm}^3$
HGB	11.4	L	g/dl
HCT	33.5	L	%
MCV	95		μm^3
MCH	32.4	H	pg
MCHC	34.0	H	g/dl
RDW-CV	15.4	H	%
RDW-SD	52	H	μm^3

RBC



PLT	187	*	$10^3/\text{mm}^3$
MPV	10.6	*H	μm^3
PCT	0.197	*	%
PDW	20.8	*H	%

PLT



Kom
14/4/23

: 14/04/2023 05:55:22
er : labtech

QC RESULT REPORT

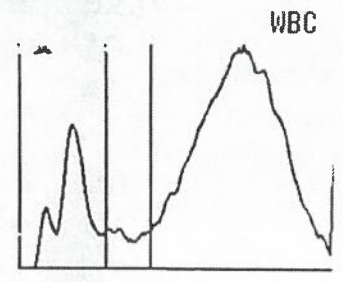
PID : MX440H
Name : MX440

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20
Operator : labtech

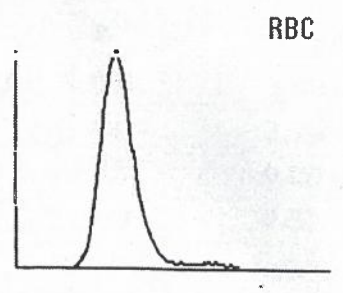
RESULT

Analyser Alarms
Analysis Alarms

WBC	22.0	$10^3/mm^3$
LYM%	16.3	%
MON%	5.3	%
GRA%	78.4	%
LYM#	3.50	$10^3/mm^3$
MON#	1.10	$10^3/mm^3$
GRA#	17.40	$10^3/mm^3$



RBC	5.64	$10^6/mm^3$
HGB	18.5	g/dl
HCT	50.6	%
MCV	90	μm^3
MCH	32.9	pg
MCHC	36.7	g/dl
RDW-CV	12.6	%



labtech
14/4/23

PLT	540	$10^3/mm^3$
MPV	8.1	μm^3

PLT