



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. : 4355 **Distribution No.:** 156-L Month/Year: July/2022

Instrument ID: YUMIZEN H550

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: 27-09-2022[Final].

CBC and Retic Assessment

				Amo	Among Lab (Accuracy Testing)			Within Lab (Precision Testing)				
Test Parameters	S.No.	Your Result 1		Your Results Sum of 2 Value	Consensus result sum of 2 values (Assigned Value)	Uncertainty		Results	Consensus Result Diff. of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score	
WBC x10³/μl	1	6.1	4.75	10.85	12.18	0.0990	-0.45	1.35	0.15	0.0120	7.36	
RBC x10 ⁶ /μl	1	4.4	4.36	8.76	8.69	0.0140	0.18	0.04	0.05	0.0040	-0.15	
Hb g/dl	1	12.5	12.5	25	24.8	0.0290	0.25	0	0.1	0.0100	-0.45	
НСТ%	1	39.5	39.3	78.8	79.6	0.2150	-0.14	0.2	0.4	0.0290	-0.34	
MCV-fl	1	90.1	89.7	179.8	183.3	0.3570	-0.35	0.4	0.4	0.0270	0.00	
МСН-Рд	1	28.7	28.5	57.2	57.3	0.0800	-0.05	0.2	0.3	0.0200	-0.34	
MCHC-g/dl	1	31.9	31.7	63.6	62.4	0.1610	0.28	0.2	0.3	0.0230	-0.27	
Plt. x10³/μl	1	190	187	377	348	1.70	0.65	3	7	0.47	-0.45	
Retic %	2											

P.S. Assesment

		YOUR REPORT	CONSENSUS REPORT				
DLC%	3		Poly: 32 - 50, Myelo: 14 - 28, Meta: 10 - 18, Promyelo: 2-8, Lympho: 2-7, nRBC//Blast/Eos/Baso/Mono: 0 - 5				
RBC Morphology	3		Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, hypochromia, Microcytosis; Mild: Macrocytosis, Poikilocytosis				
Diagnosis	. ≺	CHRONIC MYELOID LEUKAEMIA (CHRONIC PHASE)	Chronic Myeloid Leukemia (Chronic Phase)				

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test never eters	S.No.	Total participants covered in the current dist. 156L	Total No. responded	% of Labs with Z Score 0-2		% of Labs with Z Score 2-3		% of Labs with Z Score >3	
Test parameters				Among labs	Within lab	Among labs	Within lab	Among labs	Within lab
WBC x10³/μl	1	318	306	<mark>9</mark> 2.16	82.35	5.56	5.88	2.28	11.77
RBC x10 ⁶ /μl	1	318	318	87.11	83.65	5.35	4.4	7.54	11.95
Hb g/dl	1	318	318	87.74	84.91	3.14	5.35	9.12	9.74
HCT%	1	318	3 <mark>07</mark>	92.18	89.25	4.56	5.21	3.26	5.54
MCV-fl	1	318	307	91.21	91.86	5.54	3.58	3.25	4.56
MCH-Pg	1	318	307	89.25	<mark>8</mark> 5.67	4.89	3.58	5.86	10.75
MCHC-g/dl	1	318	307	90.88	86.97	5.86	5.21	3.26	7.82
Plt. x10³/μl	1	318	307	91.86	92.18	5.86	2.61	2.28	5.21
ReticCount%	2	318	218	91.28	83.94	3.67	13.3	5.05	2.76
PS Assessment	3	318	216	Satisfactory	:93.4%, Bor	derline Sat.	:2.83%, Uns	satisfactory	:3.77%

*Comments:

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

2). Within Lab (IQA): Difference in the CBC measurement values for WBC 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 $> \pm 3$: 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 $> \pm 3$ 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-----

Title	PT/ EQAS EVALUATION RECORD
Document Number	FRM.QCM.03
Version	01
Amendment No	01
Effective Date	01.09.2022



Date of Investigation: 29/09/2022

PT/EQAS Set Identification: ISHTM - #11 MS	(156-L)
Date of PT/EQAS: 10 10 10 10 10 10 10 10 10 10 10 10 10	
Acceptable/ Unacceptable Results _ 🚶 3.6	
Acceptable Result Range:	
Previous Trends/ Unacceptable Results from this Analyte/ Test:	- No
Classification of Problems: (Please tick) Clerical: Transcription error (may be pre- or post-analytical factors)	A began part underted
☐ Wrong method has been registered for analysis or meth	od change not updated.
Details of Investigation:	
Methodological ☐ Instrument function checks (e.g., temperatures, blank read	lings, pressures) not performed as necessary, or
results not within acceptable range.	
☐ Scheduled instrument maintenance not performed appropr	ately.
☐ Incorrect instrument calibration.	
□ Standards or reagents improperly reconstituted and sto	red, or inadvertently used beyond expiration date.
□ Instrument probes misaligned.	
□ Problem with instrument data processing functions. The I	aboratory may need to contact the manufacturer to
evaluate such problems.	
☐ Problem in manufacture of reagents / standards, or with	n instrument settings specified by manufacturer
□ Carry-over from previous specimen.	

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Title	PT/ EQAS EVALUATION RECORD
Document Number	FRM.QCM.03
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	Automatic pipettor not calibrated to acceptable precision and accuracy.				
	Imprecision from result being close to detection limit of method.				
	QC material not run within expiration date, or improperly stored.				
	QC material not run at relevant analyte concentration.				
	Result not within reportable range (linearity) for instrument / reagent system.				
	Obstruction of instrument tubing / orifice by clot or protein.				
	Incorrect incubation times.				
De	etails of Investigation:				
_					
Te	echnical				
	EQA material improperly reconstituted.				
	Testing delayed after reconstitution of EQA material (with problem from evaporation or deterioration).				
	Sample not placed in proper order on instrument.				
	Result released despite unacceptable QC data.				
	QC data within acceptable limits but showed trend suggestive of problem with the assay.				
	Inappropriate quality control limits / rules. If the acceptable QC range is too wide, the probability increases that				
	a result will fall within the acceptable QC range yet exceed acceptable limits for EQA.				
	Manual pipetting / diluting performed inaccurately, at an incorrect temperature or with incorrect diluent.				
Г	In addition to above discipline specific errors may also occur				
	Details of Investigation:				
F	Problem with PT/EQAS Material				
	Matrix effects: The performance of some instrument / method combinations may be affected by the matrix of				
	the PT/EQAS sample. This can be overcome to some extent by assessing participants in peer groups – to be done				
	by the PT/EQAS provider.				

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□ Non-homogenous test material due to variability infill volumes, inadequate mixing, or inconsistent heating of
lyophilized specimens.
□ Non-viable samples for microbiology PT/EQAS program.
☐ Haemolysis on an immune-haemtology program samples.
Details of Investigation:
ANY .
Problem with PT/EQAS Evaluation
□ Peer group not appropriate.
□ Inappropriate target value: Target values developed from participant consensus can be inappropriate from
non-homogeneous testing material or lingering ("masked") outliers. However, occasional inappropriate target
values occur in every PT program. Inappropriate evaluation interval: An evaluation interval may be
inappropriately narrow e.g. if ± 2 standard deviation units are used with an extremely precise method;
the acceptable range may be much narrower than needed for clinical usefulness.
□ Incorrect data entry by PT provider.
Details of Investigation:
Nil
No Explanation: Attributed to Random Error
Any Others (explain)
Summary of Investigation:
No any Specific deviations noted in 190

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Was patient data affected? & Corrective action taken if Patient data was affected.

NO

Corrective/ Preventive action taken to prevent Reoccurrence

Performance monti monitored closly in next sample

Conclusions

Darred on into Labonatory Comparision Study and Dal Partormance Suspeted random error.

Schorup saini

Quality Manager/ Team Leader

Date: 24.12.2022

Lab Head

2

Date: 21.12.2022

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NON AVAILABILITY OF EQAP MATERIAL 🏠





me

dr.biplabkumarbiswas@yahoo.in

Show less

To



EQAP accuracy2000@gmail.com



me Md Ehtesham mdehtesham@lupindia...



Kanchan Amar Mundhe kanchanmund...



Manisha Khanna manishakhanna@lup...



HLM JeevanSuraksha hlmjsh@lupindi...

23 Dec 2022 at 7:33 pm

RESPECTED SIR/ MADAM.

I AM DR BIPLAB BISWAS, LAB HEAD, LUPIN DIAGNOSTICS & HLM JEEBAN SURAKSHA HOSPITAL, BANKURA, WEST BENGAL. WE HAVEN'T RECEIVED THE EQAP MATERIAL OF FOURTH QUARTER (OCT - DEC '22 TILL NOW.

REGARDS DR BIPLAB BISWAS 9775689990











More



Objective:

Inter Laboratory comparison study conducted because AIMMS EQAS sample of period October-December-2022 is not received. As a part of preventive action ILC study performed with two patient samples.

Reference Laboratory- Lupin Diagnostics, NRL Date of study conducted- 24.12.2022

Sr No	Parameters	NRL	JSH	%Diff	Reference range	%Clinical Correlation
1	RBC	5.68	5.68	0.00	3.8-6	100
2	НВ	15.8	16	-1.25	11.5-17	100
3	PCV	50.2	48.5	3.51	35-52	100
4	MCV	88.3	85.3	3.52	76-100	100
5	НСН	27.7	28.2	-1.77	27-34	100
6	НСНС	31.4	33	-4.85	32-35	0
7	RDWCV	15.3	14.1	8.51	11.0-17	100
8	RDWSD	50.4	47.9	5.22	37-49	75
9	PLT	316	281	12.46	150-400	100
10	PCT	0.38	0.34	11.76	0.15-0.40	100
11	MPV	11.9	12.1	-1.65	8.0-11	75
12	PDW	23.2	22	5.45	11.0-22	75
13	PLCC	162	143	13.29	44-140	100
14	PLCR	51.4	50.8	1.18	18-50	100
15	WBC	7.11	7.23	-1.66	3.5-10	100
16	NEUT	3.54	3.58	-1.12	1.6-7	100
17	LYMP	2.76	2.63	4.94	1.0-3	100
18	MONO	0.49	0.56	-12.50	0.2-0.8	100
19	EOS	0.24	0.3	-20.00	0.0-0.50	100
20	BASO	0.04	0.07	-42.86	0.0-0.15	100
21	LIC	0.04	0.09	-55.56	0.0-0.10	75
22	NEUT%	49.8	50.3	-0.99	40-73	75
23	LYM%	39.1	36.8	6.25	15-45	75
24	MONO%	7	7.8	-10.26	4.0-12	100
25	EOS%	3.5	4.2	-16.67	0.5-7	100
26	BASO%	0.6	0.9	-33.33	0.0-2.0	100
27	LIC%	0.6	1.2	-50.00	0.0-1.0	75
	14				Average	89.81

Sr No	Parameters	NRL	JSH	%Diff	Reference range	%Clinical Correlation
1	RBC	5.15	5.24	-1.72	3.8-6	100
2	НВ	15.3	15.3	0.00	11.5-17	100
3	PCV	46.7	46	1.52	35-52	100
4	MCV	90.6	87.8	3.19	76-100	100
5	HCH	29.8	29.2	2.05	27-34	100
6	HCHC	32.9	· 33.2	-0.90	32-35	75
7	RDWCV	15.7	15.2	3.29	11.0-17	100
8	RDWSD	51.2	52.1	-1.73	37-49	100
9	PLT	165	170	-2.94	150-400	100
10	PCT	0.13	0.13	0.00	0.15-0.40	100
11	MPV	8	7.9	1.27	8.0-11	100
12	PDW	11.5	10.6	8.49	11.0-22	25
13	PLCC	31	28	10.71	44-140	100

Lupin Diagnostics ,Jeeban Suraksha (HLM)	_
Inter laboratory comparison study report of Complete Blood count	



14	PLCR	18.9	16.7	13.17	18-50	50
15	WBC	6.43	6.32	1.74	3.5-10	100
16	NEUT	4.39	4.18	5.02	1.6-7	100
17	LYMP	1.36	1.38	-1.45	1.0-3	100
18	MONO	0.49	0.57	-14.04	0.2-0.8	100
19	EOS	0.15	0.13	15.38	0.0-0.50	100
20	BASO	0.03	0.05	-40.00	0.0-0.15	100
21	LIC	0.01	0.01	0.00	0.0-0.10	100
22	NEUT%	68.4	66.5	2.86	40-73	100
23	LYM%	21.2	21.8	-2.75	15-45	100
24	MONO%	7.7	9	-14.44	4.0-12	100
25	EOS%	2.3	2	15.00	0.5-7	100
26	BASO%	0.4	0.7	-42.86	0.0-2.0	100
27	LIC%	0.2	0.2	0.00	0.01.0	100
						94.44

Observations-

- √ >80% Clinical correlation noted in both samples.
- \checkmark High % Difference noted due to statistical limitations.

Conclusion:

Based on obtained result recovery Inter laboratory comparison study successfully passed for CBC test parameter.

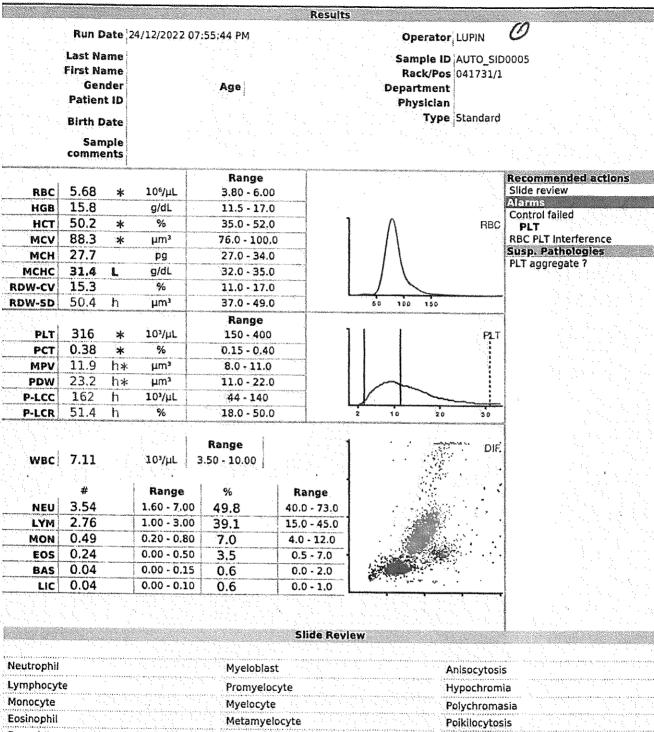
Scramp Somi Documented By (Mr Swarup Saini)

Approved by (Dr Biplab K.)

Results Run Date 24/12/2022 08:09:38 PM Operator JSH **Last Name** Sample ID JITENDRA VALID First Name Rack/Pos Department Gender Age Physician Patient ID Type Standard Birth Date Sample comments Recommended actions Range Slide review 5.68 106/µL REC 3.80 - 6.00 Alemis 16.0 g/dL 11.5 - 17.0 HGB Control falled RBC Control solution expired 48.5 % 35.0 - 52.0 HCT 76.0 - 100.0 85.3 μm_3 MCV LYM Interference 27.0 - 34.0 28.2 MCH pg Susp. Pathologies 32.0 - 35.0 g/dL MCHC 33.0 Macroplatelets PLT aggregate or NRBC ? 11.0 - 17.0 RDW-CV 14.1 % 158 RDW-SD um³ 37.0 - 49.0 Range 103/μL 150 - 400 281 PLY 0.15 - 0.40 0.34 PCT % 8.0 - 11.0 12.1 µm³ MPV H 22.0 um³ 11.0 - 22.0 PDW * 103/µL 44 - 140 143 h P-LCC 18.0 - 50.0 50.8 h % P-LCR Range DIF 7.23 103/μL 3.50 - 10.00WBC % # Range Range 1.60 - 7.00 40.0 - 73.0 3.58 50.3 NEU 15.0 - 45.0 2.63 1.00 - 3.00 LYM 36.8 4.0 - 12.0 MON 0.56 0.20 - 0.807.8 0.30 0.00 - 0.504.2 0.5 - 7.0EOS ¥ 0.07 0.00 - 0.15 0.9 0.0 - 2.0 BAS 0.00 - 0.101.2 0.0 - 1.0 0.09 h× LIC

Slide Review

Neutrophil			Myeloblast		Anisocytosis
Lymphocyte			Promyelocyte		Hypochromia
Monocyte			Myelocyte	٠.,	Polychromasia
Eosinophil			Metamyelocyte		Poikilocytosis
Basophil			Blast		Microcytosis
Atypical Lymphocyte		17%	Target Cell		Macrocytosis
Other	*. *		Sickle Cell	•	Platelet Clumps
Reviewed on		by	Signa	itur	€:



Neutrophil	Myeloblast		Anisocytosis	ericania esta de esta de la constancia e	plication of contrast and children black
Lymphocyte	Promyelocyte	4.4	Hypochromia	The state of the s	
Monocyte	Myelocyte	And the second s	Polychromasia		
Eosinophil	Metamyelocyte	n gant yang ang tang ang ang ang ang ang ang ang ang ang	Poikilocytosis	The second secon	
Basophil	Blast	Service and the service of the servi	Microcytosis	garjanga germatrikan Kangangan	Angert (and the second
Atypical Lymphocyte	Target Celi	egeneral general som begre var begre verken er den er stage beståre en det er stage og det en general er stage Det er	Macrocytosis	julius garinesti san	And the court of the section of the
Other	Sickle Cell		Platelet Clumps	. Straissingly	Enfirst instantion
Reviewed on	by	Signat	ure:		The second of the second of

Results Operator JSH Run Date 24/12/2022 08:13:01 PM Sample ID RUSHIKESHVALID **Last Name** Rack/Pos First Name Department Gender Age Patient ID Physician Type Standard Birth Date Sample comments Range Control failed 3.80 - 6.00 5.24 106/µL RBC Control solution expired 11.5 - 17.0 HGB 15.3 g/dL RBC 46.0 % 35.0 - 52.0 HCT µm³ 76.0 - 100.0 87.8 MCV 27.0 - 34.0 29.2 MCH pg 32.0 - 35.0 g/dL MCHC 33.2 11.0 - 17.0 RDW-CV 15.2 % µm³ 37.0 - 49.0 52.1 h RDW-SD Range PLT 103/µL 150 - 400 170 PLT 0.15 - 0.40 0.13 % PCT 8.0 - 11.0 7.9 µm³ MPV 10.6 μm^3 11.0 - 22.0 PDW 103/µL 44 - 140 28 P-LCC 20 30 18.0 - 50.0 % P-LCR 16.7 Range DIF 6.32 103/µL 3.50 - 10.00 WBC # % Range Range 1.60 - 7.00 40.0 - 73.0 4.18 66.5 WEU 15.0 - 45.0 1.00 - 3.00 1.38 21.8 LYM 4.0 - 12.0 0.20 - 0.80 0.57 9.0 MON 0.5 - 7.0 0.00 - 0.50 2.0 EOS 0.13 0.00 - 0.15 0.0 - 2.00.05 0.7 BAS 0.00 - 0.10 0.0 - 1.0 0.01 0.2 LIC

Slide Review

Neutrophil		Myeloblast	Anisocytosis
Lymphocyte		Promyelocyte	Hypochromia
Monocyte		Myelocyte	Polychromasia
Eosinophil		Metamyelocyte	Poikilocytosis
Basophil		Blast	Microcytosis
Atypical Lymphocyte		Target Cell	Macrocytosis
Other		Sickle Cell	Platelet Clumps
Reviewed on	b	/Sign	ature :

Results Run Date 24/12/2022 07:58:02 PM **Operator** LUPIN **Last Name** Sample ID AUTO SID0006 First Name Rack/Pos 041731/2 Gender Age Department Patient ID Physician Type Standard **Birth Date** Sample comments Range Alarms 5.15 RBC 106/µL 3.80 - 6.00 Control failed HGB 15.3 q/dL 11.5 - 17.0 46.7 % HCT 35.0 - 52.0 RBC MCV 90.6 μm³ 76.0 - 100.0 29.8 MCH pg 27.0 - 34.0 MCHC 32.9 g/dL 32.0 - 35.0 RDW-CV 15,7 % 11.0 - 17.0 μm³ RDW-SD 51.2 37.0 - 49.0 160 150 Range PLT 165 103/μL 150 - 400 PLT PCT 0.13 % 0.15 - 0.40 MPV 8.0 μm³ 8.0 - 11.0 μm³ PDW 11.5 11.0 - 22.0 P-LCC 31 103/µL 44 - 140 18.9 P-LCR % 18.0 - 50.0 10 20 30 Range DIF 10³/μL WBC 6.43 3.50 - 10.00 Range % Range NEU 4.39 1.60 - 7.00 68.4 40.0 - 73.0 1.00 - 3.00 LYM 1.36 21.2 15.0 - 45.0 MON 0.49 0.20 - 0.80 7.7 4.0 - 12.0 0.15 EO5 0.00 - 0.50 2.3 0.5 - 7.0 BAS 0.03 0.00 - 0.15 0.4 0.0 - 2.0 LIC 0.01 0.00 - 0.10 0.2 0.0 - 1.0Slide Review Neutrophil Myeloblast Anisocytosis Lymphocyte Promyelocyte Hypochromia Monocyte Myelocyte Polychromasia Eosinophil Metamyelocyte **Poikilocytosis** Basophil Blast Microcytosis Atypical Lymphocyte Target Cell Macrocytosis

Other

Reviewed on

Sickle Cell

Platelet Clumps

Signature: