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. : 3919 **Distribution No.:** 161-K **Month/Year:** October/2023

Instrument ID: HORIBA **Model Name.:** YUMIZEN H550 **Serial No.:** 207YAXH03883

Name & Contact No. of PT Co-ordinator: Dr. Manoranjan Mahapatra (Prof. & Head), Hematology, AIIMS, Delhi, Tel: 9013085730 , E-Mail : accuracy2000@gmail.com

Date of issue & status of the report: 29-01-2024[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	2.86	0.54	3.4	7.7	0.043	**-4.14**	2.32	0.1	0.006	**24.96**
RBC x10^6/µl	1	4.71	4.69	9.4	9.43	0.010	**-0.11**	0.02	0.05	0.003	**-0.58**
Hb g/dl	1	14.2	14.2	28.4	28.4	0.030	**0.00**	0	0.1	0.008	**-0.67**
HCT%	1	43.9	43.6	87.5	86.05	0.190	**0.30**	0.3	0.5	0.028	**-0.45**
MCV-fl	1	93.2	92.2	185.4	183	0.333	**0.28**	1	0.2	0.023	**2.70**
MCH-Pg	1	30.4	30.2	60.6	60.2	0.070	**0.25**	0.2	0.2	0.017	**0.00**
MCHC-g/dl	1	32.7	32.4	65.1	66	0.145	**-0.25**	0.3	0.3	0.020	**0.00**
Plt. x10^3/µl	1	106	98	204	255.5	2.060	**-1.00**	8	5	0.396	**0.51**
Retic %	2	1.9	0.5	2.4	15	0.317	**-1.43**	1.4	0.4	0.027	**1.69**

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=00 , Poly=77 L=17, E=01, Mono/Promono=05 , B1=00 P.M.=00, Mye=00, Meta=00, Other=00	Poly: 73-80 , Lympho: 15-22 , Mono: 2-4, Eosino: 1-2 , Blast/Promyelo/Myelo/Meta: 0-5
RBC Morphology	3	ANISOPOIKILOCYTOSIS (+), NORMOCYTIC TO MACROCYTIC RBC. TEAR DROP CELLS AND TARGET CELLS NOTED. POLYCHROMATOPHILS SEEN.	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, Poikilocytosis , Target cells , tear drop cells
Diagnosis	3	00	Sickle cell-Beta Thalassemia

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 161--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	272	269	84.01	89.96	3.35	4.83	12.64	5.21
RBC x10^6/µl	1	272	272	83.46	94.49	6.25	1.84	10.29	3.67
Hb g/dl	1	272	272	88.24	89.71	6.62	3.68	5.14	6.61
HCT%	1	272	268	92.54	93.28	4.48	3.73	2.98	2.99
MCV-fl	1	272	268	93.28	88.43	4.85	7.46	1.87	4.11
MCH-Pg	1	272	268	87.69	92.54	7.84	4.48	4.47	2.98
MCHC-g/dl	1	272	268	91.42	91.04	5.97	4.85	2.61	4.11
Plt. x10^3/µl	1	272	268	92.91	88.81	5.97	6.34	1.12	4.85
ReticCount%	2	272	224	94.64	89.73	3.57	7.14	1.79	3.13
PS Assessment	3	272	208	Satisfactory :88.98%, Borderline Sat. :3.30%, Unsatisfactory :7.72%					

***Comments:**

1). Among Lab (EQA) : CBC result for WBC unacceptable, may be due to random/human error.PS Diagnosis not reported, remaining 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 > ±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. Manoranjan Mahapatra (Prof. & Head)
PT Co-ordinator: ISHTM-AIIMS-EQAP
Department of Hematology, AIIMS, New Delhi

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

Patient Information		Specimen Information		Client/Doctor Information	
Name	: Mrs.ANJU NATANI	Visit ID	: LNNG442	Client Code	: PUP2937
Age/Gender	: 60 Y 0 M 0 D /Female	Collected	: 16/Feb/2024 07:48	Client Name	: PUP SHRI JI DIAGNOSTICS
MobileNo	:	Received	: 16/Feb/2024 12:39	Client Add.	: MATA MANDIR
UHID	: LDAA01567941	Reported	: 16/Feb/2024 15:26	Client No.	: 9340658151
Address	:	IP/OP/Barcode	:	Ref Doctor	: Dr.SELF
		Report Status	: Final Report		

Test Name	Result	Bio. Ref. Range	Unit	Method
Complete Blood Count (CBC) , *WHOLE BLOOD EDTA*				
Hemoglobin (Hb)	**11.3**	12-15	g/dL	Spectrophotometry
Red Blood Cell (RBC) Count	**3.48**	3.8-4.8	Million/cu.mm	Impedence
Packed Cell Volume (PCV) / Hematocrit	**34.7**	36-46	%	Calculated
Mean Corpuscular Volume (MCV)	99.8	83-101	fL	Calculated
Mean Corpuscular Hemoglobin (MCH)	**32.6**	27-32	pg	Calculated
Mean Corpuscular Hb Concentration (MCHC)	32.6	31.5-34.5	g/dL	Calculated
Red Cell Distribution Width (RDW)	13.6	11.6-14	%	Calculated
Total Leucocyte Count (TLC)	5,800	4000-10000	Cells/cu.mm	Impedence
Differential Leucocyte Count (DLC)				
Neutrophils	60.0	40-80	%	Impedence & FCM
Lymphocytes	34.0	20-40	%	Impedence & FCM
Monocytes	4.0	2-10	%	Impedence & FCM
Eosinophils	2.0	1-6	%	Impedence & FCM
Basophils	0.0	<1-2	%	Impedence & FCM
Absolute Leucocyte Count				
Neutrophils	3,480	2000-7000	Cells/cu.mm	Calculated
Lymphocytes	1,972	1000-3000	Cells/cu.mm	Calculated
Monocytes	232	200-1000	Cells/cu.mm	Calculated
Eosinophils	116	20-500	Cells/cu.mm	Calculated
Platelet Count	207,000	150000-410000	per cu.mm	Impedence
Mean Platelet Volume (MPV)	**14.1**	7.4-12.0	fL	Impedence

***** End Of Report *****

Dr. Priyanka Saxena
MD (Pathologist)
Consultant Pathologist

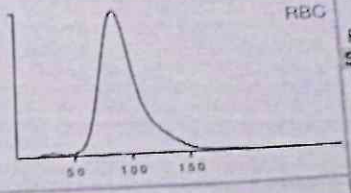
SIN No:HA00651318

NRBC DLC JLC

Results

Run Date	02/17/2024 10:41:53 AM	Operator	LUPIN
Last Name		Sample ID	HA00651318
First Name		Rack/Pos	
Gender		Department	
Age		Physician	
Patient ID		Type	Standard
Birth Date			
Sample comments			

				Range
RBC	3.49	L	$10^6/\mu L$	3.80 - 6.00
HGB	11.3	l	g/dL	11.5 - 17.0
HCT	33.9	l	%	35.0 - 52.0
MCV	97.1		μm^3	76.0 - 100.0
MCH	32.3		pg	27.0 - 34.0
MCHC	33.3		g/dL	32.0 - 35.0
RDW-CV	13.7		%	11.0 - 17.0
RDW-SD	55.4	H	μm^3	37.0 - 49.0

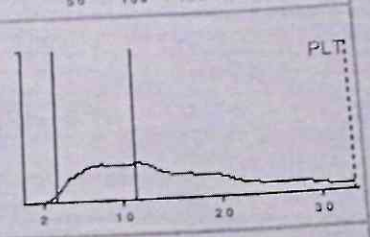


Recommended actions
Slide review

Alarms
Control solution expired
PLT
RBC PLT Interference

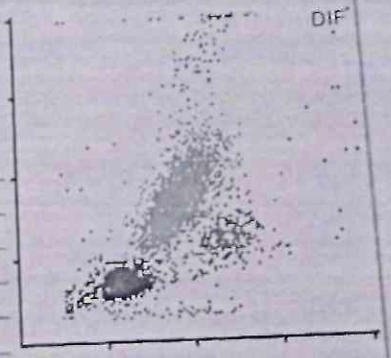
Susp. Pathologies
Macroplatelets
PLT aggregate ?
Malaria P. vivax ?

				Range
PLT	235	*	$10^3/\mu L$	150 - 400
PCT	0.32	*	%	0.15 - 0.40
MPV	13.6	H*	μm^3	8.0 - 11.0
PDW	33.8	H*	μm^3	11.0 - 22.0
P-LCC	138		$10^3/\mu L$	44 - 140
P-LCR	58.7	h	%	18.0 - 50.0



WBC	5.48	$10^3/\mu L$	3.50 - 10.00

	#	Range	%	Range
NEU	3.11	1.60 - 7.00	57.0	40.0 - 73.0
LYM	1.81	1.00 - 3.00	33.2	15.0 - 45.0
MON	0.40	0.20 - 0.80	7.3	4.0 - 12.0
EOS	0.11	0.00 - 0.50	2.0	0.5 - 7.0
BAS	0.03	0.00 - 0.15	0.5	0.0 - 2.0
LIC	0.02	0.00 - 0.10	0.3	0.0 - 1.0



Slide Review

utrophil	Myeloblast	Anisocytosis
mphocyte	Promyelocyte	Hypochromia
nocyte	Myelocyte	Polychromasia
inophil	Metamyelocyte	Poikilocytosis
ophil	Blast	Microcytosis
ical Lymphocyte	Target Cell	Macrocytosis
r	Sickle Cell	Platelet Clumps

wed on _____ by _____ Signature :

2024 10:43:28 AM **Printed by :** LUPIN S/N 207YAXH03863

Lupin Diagnostics , (DL Bhopal)	LUPIN DIAGNOSTICS Good health starts here
Inter laboratory comparison study report of Complete Blood count	

Reference Laboratory- Lupin Diagnostics, NRL
Date of study conducted- 17.02.2024

Sr No	Parameters	Sample-1			
		Mrs. Anju Natani			Reference range
		NRL	DL Bhopal	%Diff	
1	RBC	3.49	3.48	0.29	3.8-6
2	HB	11.3	11.3	0.00	11.5-17
3	PCV	33.9	34.7	-2.33	35-52
4	MCV	97.1	99.8	-2.74	76-100
5	MCH	32.3	32.6	-0.92	27-34
6	MCHC	33.3	32.6	2.12	32-35
7	RDWCV	13.7	13.6	0.73	11.0-17
8	RDWSD	55.4	52.9	4.62	37-49
9	PLT	235	207	12.67	150-400
10	PCT	0.32	0.29	9.84	0.15-0.40
11	MPV	13.6	14.1	-3.61	8.0-11
12	PDW	33.8	36.1	-6.58	11.0-22
13	PLCC	138	131	5.20	44-140
14	PLCR	58.7	63.3	-7.54	18-50
15	WBC	5.48	5.8	-5.67	3.5-10
16	NEUT	3.11	3.37	-8.02	1.6-7
17	LYMP	1.81	1.99	-9.47	1.0-3
18	MONO	0.4	0.22	58.06	0.2-0.8
19	EOS	0.11	0.15	-30.77	0.0-0.50
20	BASO	0.03	0.0	200.0	0.0-0.15
21	LIC	0.02	0.02	0.00	0.0-0.10
22	NEUT%	57	57.7	-1.22	40-73
23	LYM%	33.2	33.9	-2.09	15-45
24	MONO%	7.3	3.8	63.06	4.0-12
25	EOS%	2	2.5	-22.22	0.5-7
26	BASO%	0.5	0.0	200.0	0.0-2.0
27	LIC	0.3	0.3	0.00	0.0-0.10

Observations-
- ✓ >80% Clinical correlation noted in samples.
- ✓ High % Difference noted due to statistical limitations.

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

Documented By
(Mr. Manish Patel)

Approved by
(Dr. Priyanka S)

Date of Investigation: 17/02/24

PT/EQAS Set Identification:	AIIMS EQAS 161-K
Date of PT/EQAS:	Oct-2023
Acceptable/ Unacceptable Results	TWBC
Acceptable Result Range:	± 7.7 – ±0.006

Previous Trends/ Unacceptable Results from this Analyte/ Test:

No

Classification of Problems: (Please tick)

Clerical:

- ☐ Transcription error (may be pre- or post-analytical factors)
- ☐ Wrong method has been registered for analysis or method change not updated.

Details of Investigation: No

Methodological

- ☐ Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range.
- ☐ Scheduled instrument maintenance not performed appropriately.
- ☐ Incorrect instrument calibration.
- ☐ Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date.
- ☐ Instrument probes misaligned.
- ☐ Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems.
- ☐ Problem in manufacture of reagents / standards, or with instrument settings specified by manufacturer
- ☐ Carry-over from previous specimen.
- ☐ 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.

Details of Investigation: NO

Technical

- ☐ 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.
- ☐ Calculation error or result reported using too few significant digits.
- ☐ Secondary specimen tubes incorrectly labeled.
- ☐ In addition to above discipline specific errors may also occur

Details of Investigation: NO

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.
- ☐ 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:

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: NO

✓ No Explanation: Attributed to Random Error

Any Others (explain)

Summary of Investigation:

NO any deviation in IQC performance. NO any issue with respect to reggent, analyser, previous EQAS performance within a acceptable range.

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

NO

Corrective/ Preventive action taken to prevent Reoccurrence

performance any TWBC parameters closely monitor in next sample.

Conclusions Based on above findings concluded unacceptable performance due to transitional dry sample performance monitor closely in next cycle.
Quality Manager/ Team Leader Manish Date: 17/02/24
Lab Head Jayanthi Date: 17/02/24