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. : 3529 **Distribution No.:** 162-J **Month/Year:** January/2024

Instrument ID: HORIBA **Model Name.:** YUMIZEN H550 **Serial No.:** 909YAXH02625

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: 21-03-2024[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	1.69	1.53	3.22	10.41	0.030	-10.21	0.16	0.1	0.006	0.62
RBC x10^6/µl	1	4.88	4.79	9.67	9.51	0.011	0.55	0.09	0.05	0.003	0.90
Hb g/dl	1	12.7	12.7	25.4	24.79	0.022	1.19	0	0.1	0.008	-0.71
HCT%	1	39.2	38.2	77.4	78.9	0.207	-0.24	1	0.4	0.028	1.35
MCV-fl	1	80.2	79.9	160.1	168.4	0.394	-0.67	0.3	0.3	0.021	0.00
MCH-Pg	1	26.4	26	52.4	51.9	0.065	0.30	0.4	0.3	0.015	0.45
MCHC-g/dl	1	33.1	32.4	65.5	62	0.166	0.69	0.7	0.3	0.020	1.66
Plt. x10^3/µl	1	205	198	403	421	2.119	-0.36	7	7	0.417	0.00
Retic %	2	18	14	32	22.55	0.336	1.06	4	0.7	0.057	2.78

P.S . Assesment

YOUR REPORT			CONSENSUS REPORT
DLC%	3	Nrbcs=1 , Poly=76 L=05, E=2, Mono/Promono=01 , B1=02 P.M.=05, Mye=02, Meta=05, Other=Nil	Poly: 65.25 - 78, Lympho: 5- 9, Myelo: 3 - 8, Meta: 2.75 - 6, Eosino: 2-6, Mono: 1-2, Promyelo: 0.5-3, Blast/Baso: 0-5
RBC Morphology	3	NORMOCYTIC NORMOCHROMIC RBCs ADMIXED WITH FEW MICROCYTIC MILD TO MODERATE HYPOCHROMIC RBCs	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, Mild: Poikilocytosis, Polychromatophilic, Macrocytes, Tear drop cells
Diagnosis	3	Differential Diagnosis-1) CML- CHRONIC PHASE or 2) Myeloid Leukemoid Reaction	Chronic Myeloid Leukemia (Chronic Phase)

Patient Information		Specimen Information		Client / Doctor Information	
Name	: Mrs.JAYSHRI MAROTI PHAD	Visit ID	: LGRG15469	Client Code	: HLM0010
Age/Gender	: 35 Y 0 M 0 D /Female	Collected	: 22/Mar/2024 12:58	Client Name	: HLM LATUR FERTILITY PRIVATE LIMITED
MobileNo	: 7507900871	Received	: 22/Mar/2024 12:59	Client Add.	: LATUR
UHID	: LDAA01697830	Reported	: 22/Mar/2024 14:02	Client No.	:
Address	:	IP/OP/Barcode	: R.1249080	Ref Doctor	: Dr.K B Barmade
		Report Status	: Final Report		

Test Name	Result	Bio. Ref. Range	Unit	Method
Complete Blood Count (CBC) , *WHOLE BLOOD EDTA*				
Hemoglobin (Hb)	**9.9**	12-15	g/dL	Spectrophotometry
Red Blood Cell (RBC) Count	4.59	3.8-4.8	Million/cu.mm	Impedance
Packed Cell Volume (PCV) / Hematocrit	**30.1**	36-46	%	Calculated
Mean Corpuscular Volume (MCV)	**65.6**	83-101	fL	Calculated
Mean Corpuscular Hemoglobin (MCH)	**21.5**	27-32	pg	Calculated
Mean Corpuscular Hb Concentration (MCHC)	32.8	31.5-34.5	g/dL	Calculated
Red Cell Distribution Width (RDW)	**16.2**	11.6-14	%	Calculated
Total Leucocyte Count (TLC)	8,030	4000-10000	Cells/cu.mm	Impedance
Differential Leucocyte Count (DLC)				
Neutrophils	50.0	40-80	%	Impedance & FCM
Lymphocytes	40.0	20-40	%	Impedance & FCM
Monocytes	6.0	2-10	%	Impedance & FCM
Eosinophils	4.0	1-6	%	Impedance & FCM
Basophils	0.0	0-2	%	Impedance & FCM
Absolute Leucocyte Count				
Neutrophils	4,015	2000-7000	Cells/cu.mm	Calculated
Lymphocytes	**3,212**	1000-3000	Cells/cu.mm	Calculated
Monocytes	482	200-1000	Cells/cu.mm	Calculated
Eosinophils	321	20-500	Cells/cu.mm	Calculated
Platelet Count	347,000	150000-410000	per cu.mm	Impedance
Mean Platelet Volume (MPV)	8.4	7.4-12.0	fL	Impedance

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

SIN No:HA00704519

This test has been performed at Lupin Diagnostics Laboratory, HLM LATUR FERTILITY PRIVATE LIMITED Barmade Hospital Old Adarsh Colony Ausa Road,LATUR,LATUR , 413512

Patient Information		Specimen Information		Client / Doctor Information	
Name	: Mrs.JAYSHRI MAROTI PHAD	Visit ID	: LGRG15469	Client Code	: HLM0010
Age/Gender	: 35 Y 0 M 0 D /Female	Collected	: 22/Mar/2024 12:58	Client Name	: HLM LATUR FERTILITY PRIVATE LIMITED
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Address	:	IP/OP/Barcode	: R.1249080	Ref Doctor	: Dr.K B Barmade
		Report Status	: Final Report		

Test Name	Result	Bio. Ref. Range	Unit	Method

Dr. Sharayu Patil
MD Pathologist

SIN No:HA00704519

This test has been performed at Lupin Diagnostics Laboratory, HLM LATUR FERTILITY PRIVATE LIMITED Barmade Hospital Old Adarsh Colony Ausa Road,LATUR,LATUR , 413512

Patient Information		Specimen Information		Client / Doctor Information	
Name	: Mrs.JAYSHRI MAROTI PHAD	Visit ID	: LGRG15473	Client Code	: HLM0010
Age/Gender	: 35 Y 0 M 0 D /Female	Collected	: 22/Mar/2024 14:18	Client Name	: HLM LATUR FERTILITY PRIVATE LIMITED
MobileNo	: 7507900871	Received	: 23/Mar/2024 09:09	Client Add.	: LATUR
UHID	: LDAA01697830	Reported	: 23/Mar/2024 12:13	Client No.	:
Address	:	IP/OP/Barcode	:	Ref Doctor	: Dr.K B Barmade
		Report Status	: Final Report		

Test Name	Result	Bio. Ref. Range	Unit	Method
Complete Blood Count (CBC) , *WHOLE BLOOD EDTA*				
Hemoglobin (Hb)	**9.7**	12-15	g/dL	Spectrophotometry
Red Blood Cell (RBC) Count	4.44	3.8-4.8	Million/cu.mm	Impedance
Packed Cell Volume (PCV) / Hematocrit	**30.7**	36-46	%	Calculated
Mean Corpuscular Volume (MCV)	**69.3**	83-101	fL	Calculated
Mean Corpuscular Hemoglobin (MCH)	**21.8**	27-32	pg	Calculated
Mean Corpuscular Hb Concentration (MCHC)	31.5	31.5-34.5	g/dL	Calculated
Red Cell Distribution Width (RDW)	**15.8**	11.6-14	%	Calculated
Total Leucocyte Count (TLC)	7,210	4000-10000	Cells/cu.mm	Impedance
Differential Leucocyte Count (DLC)				
Neutrophils	51.2	40-80	%	Impedance & FCM
Lymphocytes	**40.7**	20-40	%	Impedance & FCM
Monocytes	5.9	2-10	%	Impedance & FCM
Eosinophils	1.7	1-6	%	Impedance & FCM
Basophils	0.5	0-2	%	Impedance & FCM
Absolute Leucocyte Count				
Neutrophils	3,692	2000-7000	Cells/cu.mm	Calculated
Lymphocytes	2,934	1000-3000	Cells/cu.mm	Calculated
Monocytes	425	200-1000	Cells/cu.mm	Calculated
Eosinophils	123	20-500	Cells/cu.mm	Calculated
Basophils	36	0-100	Cells/cu.mm	Calculated
Platelet Count	359,000	150000-410000	per cu.mm	Impedance
Mean Platelet Volume (MPV)	8.8	7.4-12.0	fL	Impedance
Peripheral blood smear examination (PS)				

RBC: Microcytic Hypochromia mild to moderate

WBC: Within normal limits

Platelets: Adequate.

SIN No:HA00704750

MC-5498

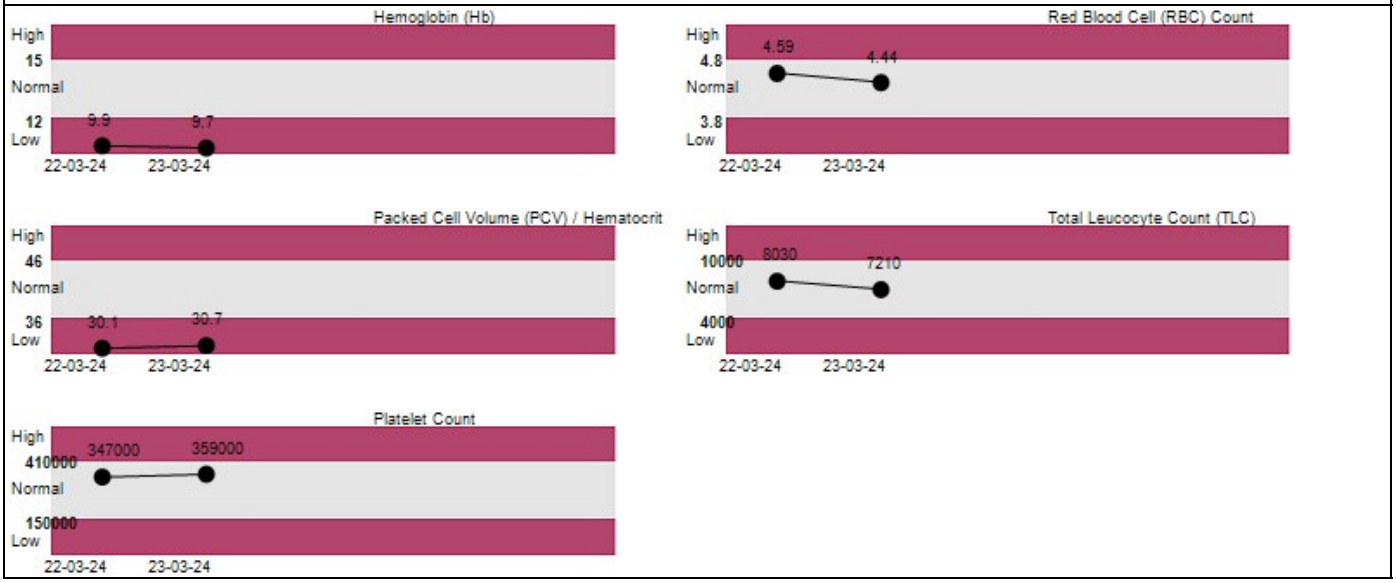
This test has been performed at Lupin Diagnostics Laboratory, NRL MUMBAI National Reference Laboratory, Plot No.C-533, MIDC, TTC Industrial Area, Pawane,Turbhe,NAVI MUMBAI , 400705

Patient Information		Specimen Information		Client / Doctor Information	
Name	: Mrs.JAYSHRI MAROTI PHAD	Visit ID	: LGRG15473	Client Code	: HLM0010
Age/Gender	: 35 Y 0 M 0 D /Female	Collected	: 22/Mar/2024 14:18	Client Name	: HLM LATUR FERTILITY PRIVATE LIMITED
MobileNo	: 7507900871	Received	: 23/Mar/2024 09:09	Client Add.	: LATUR
UHID	: LDAA01697830	Reported	: 23/Mar/2024 12:13	Client No.	:
Address	:	IP/OP/Barcode	:	Ref Doctor	: Dr.K B Barmade
		Report Status	: Final Report		

Test Name	Result	Bio. Ref. Range	Unit	Method

Impression: suggestive of microcytic anemia.

Advise: 1) Sr. Iron profile 2) Kindly Correlate Clinically.



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

Dr. Manoj Sawadkar
Consultant - MD Path

SIN No:HA00704750

MC-5498

This test has been performed at Lupin Diagnostics Laboratory, NRL MUMBAI National Reference Laboratory, Plot No.C-533, MIDC, TTC Industrial Area, Pawane,Turbhe,NAVI MUMBAI , 400705

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

Reference Laboratory- Lupin Diagnostics, NRL
Date of study conducted- 23.03.2024

Sr No	Parameters	Sample-1			
		Mrs. Jayashri Phad			Reference range
		NRL	HLM Latur	%Diff	
1	RBC	4.44	4.59	-3.32	3.8-6
2	HB	9.7	9.9	-2.04	11.5-17
3	PCV	30.7	30.1	1.97	35-52
4	MCV	69.3	65.6	5.49	76-100
5	MCH	21.8	21.5	1.39	27-34
6	MCHC	31.5	32.8	-4.04	32-35
7	RDWCV	15.8	16.2	-2.50	11.0-17
8	RDWSD	42.8	37	14.54	37-49
9	PLT	359	347	3.40	150-400
10	PCT	0.32	0.29	9.84	0.15-0.40
11	MPV	8.8	8.4	4.65	8.0-11
12	PDW	14.7	13.6	7.77	11.0-22
13	PLCC	88	82	7.06	44-140
14	PLCR	24.6	23.5	4.57	18-50
15	WBC	7.21	8.03	-10.76	3.5-10
16	NEUT	3.7	4.06	-9.28	1.6-7
17	LYMP	3	3.26	-8.31	1.0-3
18	MONO	0.35	0.41	-15.79	0.2-0.8
19	EOS	0.12	0.18	-40.00	0.0-0.50
20	BASO	0.03	0.08	-90.91	0.0-0.15
21	LIC	0.01	0.04	-120.00	0.0-0.10
22	NEUT%	51.2	50.8	0.78	40-73
23	LYM%	41.7	40.8	2.18	15-45
24	MONO%	4.9	5.1	-4.00	4.0-12
25	EOS%	1.7	2.3	-30.00	0.5-7
26	BASO%	0.5	1	-66.67	0.0-2.0
27	LIC	0.2	0.5	-85.71	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.

Mustakim 23/03/24
Documented By
(Mr. Mustakim shaikh)

Sharayu 23/03/24
Approved by
(Dr. Sharayu P)

Title	PT/ EQAS EVALUATION RECORD
Document Number	FRM.QCM.03
Version	02
Amendment No	00
Effective Date	02.06.2023

LUPIN DIAGNOSTICS
Good health starts here

Date of Investigation: 27/03/2024

PT/EQAS Set Identification: AIIMS Hematology (January-2024)
Date of PT/EQAS: 19/01/2024
Acceptable/ Unacceptable Results WBC
Acceptable Result Range:
Previous Trends/ Unacceptable Results from this Analyte/ Test: Yes, WBC unacceptable performance in last sample also

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: None

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:

None

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:

None.

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: Due to transition of sample, WBC cell degenerated

which leads to low count identification in horiba analyzer. (also low count noted due to detection method ie flowcytometry)

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:

None

No Explanation: Attributed to Random Error

Any Others (explain)

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Summary of Investigation:

- No any specific issue noted wef. analyzer, reagents, Calibration performance found within range.
- Due to method of detection WBC cells found low and leads to unacceptable performance.

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

No

Corrective/ Preventive action taken to prevent Reoccurrence

performance when verify with PLE study and found to within satisfactory range. Also laboratory decided to shift in offer of EQAS program to check performance closely.

Conclusions

Based on finding concluding UB: unacceptable Performa due to d.method of detection i.e afflowcytometry.

Quality Manager/ Team Leader Mukherjee Date: 27/03/2024

Lab Head Sharayu Date: 27/3/24