# HEMATOLOGY

## PEER GROUP REPORT

### HORIBA INSTRUMENTS- H550/H1500

**Cycle-13/2024**

**Round -02**

**Lab Code: 3299**

**Date: 30/04/2024**

**Complete Blood Count (CBC)**

| Parameters | Instrument Group | No.of Participants | Robust Mean | Robust Standard deviation (SD) | Uncertainty of Assign Values | Range (± 2 SD) | Your Value | Z Score |
|---|---|---|---|---|---|---|---|---|
| Hb gm/dl | Horiba-H550/H1500 | 37 | 11.3 | 0.4 | 0.08 | 10.5-12.0 | 11.3 | 0.0 |
| WBC × $10^3$/µl. | Horiba-H550/H1500 | 37 | 8.8 | 1.8 | 0.37 | 5.3-12.3 | 10.0 | 0.7 |
| RBC × $10^6$/µl. | Horiba-H550/H1500 | 37 | 4.0 | 0.1 | 0.02 | 3.8-4.2 | 4.13 | 1.3 |
| Hct% | Horiba-H550/H1500 | 37 | 33.4 | 1.1 | 0.23 | 31.1-35.6 | 34.6 | 1.1 |
| MCV fl. | Horiba-H550/H1500 | 37 | 83.8 | 2.3 | 0.47 | 79.2-88.4 | 83.8 | 0.0 |
| MCH pg. | Horiba-H550/H1500 | 37 | 28.2 | 0.7 | 0.14 | 26.7-29.6 | 27.3 | -1.3 |
| MCHC gm/dl | Horiba-H550/H1500 | 37 | 33.8 | 1.5 | 0.31 | 30.8-36.7 | 32.5 | -0.9 |
| Platelet × $10^3$/µl. | Horiba-H550/H1500 | 37 | 255.8 | 18.8 | 3.86 | 218.3-293.3 | 255 | 0.0 |

**Interpretation of Z Score:**

| Z Score Value(+/-) | [Z] ≤ 2.0 | 2.0< [Z] < 3.0 | [Z] ≥ 3.0 |
|---|---|---|---|
| Interpretation | Satisfactory Performance No signal | Questionable Warning Signal | Unsatisfactory Performance action Signal |

| Legends | (*) Excluded From Group Mean | {.} Not Reported | (#)Late Result Submission | ($)Reported in other Unit |
|---|---|---|---|---|

Chief Coordinator

Dr. Sanjay Mehrotra

Programme Director

Dr.Bandana Mehrotra

Checked By:

Prepared By: SSK

**End of Report**

Doc. No.: ASS / FR / 06H / R 01 / Dt.: 20.02.2024

HORIBA
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Okhla Industrial Estate Phase III,
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https://www.horiba.com
CIN : U73100DL2006PTC153202

24th March 2023

# To Whom so ever it may concern

## Subject: Proficiency Testing

Dear Sir / Madam,

We would like to inform that performance of HORIBA Yumizen 500/550 has been successfully validated on different Proficiency testing programs, including Bio-Rad (EQAS), Randox (RIQAS) and Metropolis (MHL) programs.

However, we had received few concerns specially with non-correlation of WBC counts from customers enrolled with AIIMS proficiency testing. In Initial investigation we had observed that there are limited Peer group data for HORIBA Yumizen 500/550 which might be reasons for difference in correlation. However, our technical team is working on the same and any development would be shared shortly.

Thank you for your continued trust in HORIBA Medical products & let us know should you need any additional information.

HORIBA INDIA PVT. LTD. NEW DELHI

Thanking with Regards

Jitendra Pandit
Product Manager

# 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

PC-1002

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

**EQAP CODE No. :** 3529 **Distribution No.:** 160-J **Month/Year:** June/2023

**Instrument ID:** 909YAXH02625 **Model Name.:** **Serial No.:**

**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:** 16-08-2023[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 x$10^3$/µl | 1 | 2.63 | 2.55 | 5.18 | 11.17 | 0.067 | -3.41 | 0.08 | 0.1 | 0.008 | -0.17 |
| RBC x$10^6$/µl | 1 | 4.76 | 4.68 | 9.44 | 9.59 | 0.012 | -0.49 | 0.08 | 0.05 | 0.003 | 0.58 |
| Hb g/dl | 1 | 14.7 | 14.6 | 29.3 | 30.25 | 0.037 | -1.07 | 0.1 | 0.1 | 0.009 | 0.00 |
| HCT% | 1 | 46.1 | 45.6 | 91.7 | 91.75 | 0.234 | -0.01 | 0.5 | 0.5 | 0.028 | 0.00 |
| MCV-fl | 1 | 97.3 | 97 | 194.3 | 191 | 0.384 | 0.30 | 0.3 | 0.3 | 0.024 | 0.00 |
| MCH-Pg | 1 | 31.1 | 30.8 | 61.9 | 63.2 | 0.084 | -0.62 | 0.3 | 0.3 | 0.019 | 0.00 |
| MCHC-g/dl | 1 | 32 | 31.8 | 63.8 | 65.4 | 0.176 | -0.34 | 0.2 | 0.3 | 0.021 | -0.34 |
| Plt. x$10^3$/µl | 1 | 100 | 99 | 199 | 302 | 2.388 | -1.42 | 1 | 5 | 0.388 | -0.62 |
| Retic % | 2 | 2.8 | 2.5 | 5.3 | 13.1 | 0.279 | -1.10 | 0.3 | 0.5 | 0.038 | -0.34 |

**P.S . Assesment**

| | | YOUR REPORT | CONSENSUS REPORT |
|---|---|---|---|
| DLC% | 3 | Nrbcs=03 , Poly=16 L=9, E=01, Mono/Promono=04 , B1=42 P.M.=06, Mye=10, Meta=08, Other= | Blast: 36-65, Poly: 8-19, Lympho: 8-21, Myelo: 0-9, Mono: 2-7, nRBC/Promyelo/Meta/Eos: 0-5 |
| RBC Morphology | 3 | Microcytic RBCs with Mild to Moderate Hypochromia | Predominantly: Normocytic/Normochromic; Moderate: Microcytosis, Hypochromia; Mild: Anisocytosis |
| Diagnosis | 3 | Differential Diagnoses- 1) CML (Blast Phase) or 2) AML | Acute Myeloid Leukemia (AML) |

## COMBINED DATA VALUES OF TOTAL PARTICIPANTS

| Test parameters | S.No. | Total participants covered in the current dist. 160--J | 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 $x10^3/\mu l$ | 1 | 287 | 282 | 87.59 | 81.91 | 5.67 | 7.45 | 6.74 | 10.64 |
| RBC $x10^6/\mu l$ | 1 | 287 | 287 | 87.8 | 89.55 | 6.27 | 3.83 | 5.93 | 6.62 |
| Hb g/dl | 1 | 287 | 287 | 85.37 | 85.02 | 6.27 | 4.18 | 8.36 | 10.8 |
| HCT% | 1 | 287 | 283 | 89.4 | 89.75 | 6.71 | 3.53 | 3.89 | 6.72 |
| MCV-fl | 1 | 287 | 283 | 92.58 | 93.29 | 4.95 | 2.83 | 2.47 | 3.88 |
| MCH-Pg | 1 | 287 | 283 | 89.05 | 90.46 | 3.89 | 3.89 | 7.06 | 5.65 |
| MCHC-g/dl | 1 | 287 | 282 | 91.84 | 87.59 | 5.32 | 4.96 | 2.84 | 7.45 |
| Plt. $x10^3/\mu l$ | 1 | 287 | 282 | 95.74 | 89.01 | 3.55 | 5.67 | 0.71 | 5.32 |
| ReticCount% | 2 | 287 | 234 | 92.74 | 85.04 | 5.13 | 10.68 | 2.13 | 4.28 |
| PS Assessment | 3 | 287 | 241 | Satisfactory :93.04%, Borderline Sat. :1.04%, Unsatisfactory :5.92% | | | | | |

***Comments:**

**1). Among Lab (EQA) : CBC result for *WBC* unacceptable, may be due to random/human error**

**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.

**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----------

LUPIN DIAGNOSTICS
Good health starts here

Date of Investigation: 17/8/23

| | |
|---|---|
| PT/EQAS Set Identification: | June / 2023 160 – J |
| Date of PT/EQAS: | June 2023 |
| Acceptable/ Unacceptable Results | All acceptable except WBC – 25um → -34 |
| Acceptable Result Range: | < 2 25um. |

Previous Trends/ Unacceptable Results from this Analyte/ Test:

Previous trend of WBC only

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:

Transcription error & method reviewed

No discrepancy found

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: Methodological attributes reviewed No discrepancy found

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: Technical attributes reviewed - no discrepancy found

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: Matrix effect can be attributed to this marginal outlier

Problem with PT/EQAS Evaluation

- [x] 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: Reviewed Evaluation & suggestion from Horiba team → limited peer group results in the outlies

No Explanation: Attributed to Random Error

Any Others (explain) —.

Summary of Investigation:

Limited peergroup & non-comparison of data with peer group is resulting in outlier in WBC ZScore.

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

No. IQC of the run day reviewed & found satisfactory

Corrective/ Preventive action taken to prevent Reoccurrence

For correlation studies done by main lab with satellite lab & results were acceptable.

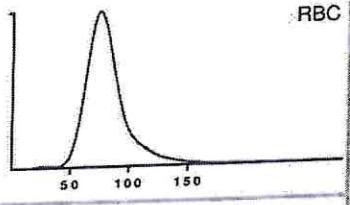
| |
|---|
| Conclusions<br>ILC studies between main lab & satellite lab indicates no issue with WBC analysis & as suggested by the manufacturer limited Peer group results in outlier in Z score of WBC |
| Quality Manager/ Team Leader Mustakim Date: 17/8/23 |
| Lab Head Dattatraya Date: 17/8/23 |

NRL – Sample

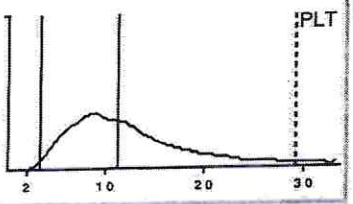
## Results

| | | | |
|---|---|---|---|
| **Run Date** | 03/04/2023 05:28:52 PM | **Operator** | LUPIN |
| **Last Name** | | **Sample ID** | PRIYA |
| **First Name** | | **Rack/Pos** | |
| **Gender** | | **Department** | |
| **Age** | | **Physician** | |
| **Patient ID** | | **Type** | Standard |
| **Birth Date** | | | |
| **Sample comments** | | | |

| | | | | Range |
|---|---|---|---|---|
| **RBC** | 4.76 | | $10^6/\mu L$ | 3.80 - 6.00 |
| **HGB** | 13.0 | | g/dL | 11.5 - 17.0 |
| **HCT** | 38.6 | | % | 35.0 - 52.0 |
| **MCV** | 81.0 | | $\mu m^3$ | 76.0 - 100.0 |
| **MCH** | 27.3 | | pg | 27.0 - 34.0 |
| **MCHC** | 33.7 | | g/dL | 32.0 - 35.0 |
| **RDW-CV** | 15.3 | | % | 11.0 - 17.0 |
| **RDW-SD** | 47.9 | | $\mu m^3$ | 37.0 - 49.0 |

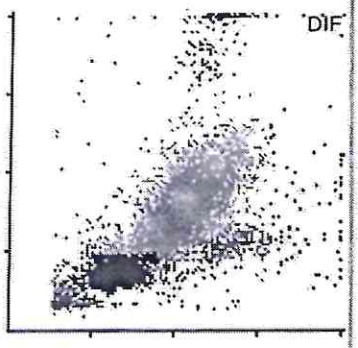



| | | | | Range |
|---|---|---|---|---|
| **PLT** | 290 | * | $10^3/\mu L$ | 150 - 400 |
| **PCT** | 0.33 | * | % | 0.15 - 0.40 |
| **MPV** | 11.2 | h* | $\mu m^3$ | 8.0 - 11.0 |
| **PDW** | 20.3 | * | $\mu m^3$ | 11.0 - 22.0 |
| **P-LCC** | 133 | | $10^3/\mu L$ | 44 - 140 |
| **P-LCR** | 45.9 | | % | 18.0 - 50.0 |




| | | | | Range |
|---|---|---|---|---|
| **WBC** | 10.30 | h* | $10^3/\mu L$ | 3.50 - 10.00 |

| | # | | Range | % | | Range |
|---|---|---|---|---|---|---|
| **NEU** | 6.59 | * | 1.60 - 7.00 | 64.9 | * | 40.0 - 73.0 |
| **LYM** | 2.83 | * | 1.00 - 3.00 | 27.8 | * | 15.0 - 45.0 |
| **MON** | 0.41 | * | 0.20 - 0.80 | 4.0 | * | 4.0 - 12.0 |
| **EOS** | 0.29 | * | 0.00 - 0.50 | 2.8 | * | 0.5 - 7.0 |
| **BAS** | 0.05 | * | 0.00 - 0.15 | 0.5 | * | 0.0 - 2.0 |
| **LIC** | 0.13 | h* | 0.00 - 0.10 | 1.3 | h* | 0.0 - 1.0 |




**Recommended actions**
Slide review

**Alarms**
**WBC**
LYM Interference

**Susp. Pathologies**
PLT aggregate or NRBC ?
Left shift

## 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 _____ by _____ Signature :

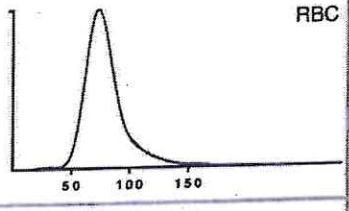
NRL sample - 2

144 hrs

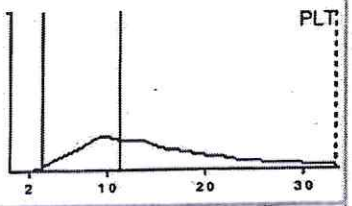
## Results

| | | | |
|---|---|---|---|
| **Run Date** | 03/04/2023 05:37:15 PM | **Operator** | LUPIN |
| **Last Name** | | **Sample ID** | DANISH |
| **First Name** | | **Rack/Pos** | |
| **Gender** | **Age** | **Department** | |
| **Patient ID** | | **Physician** | |
| **Birth Date** | | **Type** | Standard |
| **Sample comments** | | | |

| | | | | Range |
|---|---|---|---|---|
| **RBC** | 5.45 | | $10^6/\mu L$ | 3.80 - 6.00 |
| **HGB** | 14.4 | | g/dL | 11.5 - 17.0 |
| **HCT** | 43.2 | | % | 35.0 - 52.0 |
| **MCV** | 79.3 | | $\mu m^3$ | 76.0 - 100.0 |
| **MCH** | 26.5 | l | pg | 27.0 - 34.0 |
| **MCHC** | 33.4 | | g/dL | 32.0 - 35.0 |
| **RDW-CV** | 15.0 | | % | 11.0 - 17.0 |
| **RDW-SD** | 46.2 | | $\mu m^3$ | 37.0 - 49.0 |

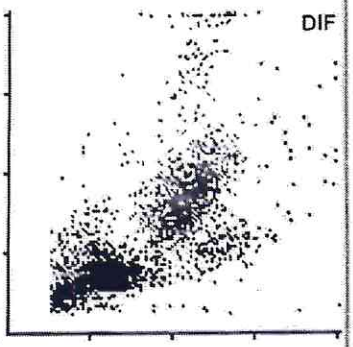



| | | | | Range |
|---|---|---|---|---|
| **PLT** | 212 | * | $10^3/\mu L$ | 150 - 400 |
| **PCT** | 0.29 | * | % | 0.15 - 0.40 |
| **MPV** | 13.6 | H* | $\mu m^3$ | 8.0 - 11.0 |
| **PDW** | 27.2 | H* | $\mu m^3$ | 11.0 - 22.0 |
| **P-LCC** | 129 | | $10^3/\mu L$ | 44 - 140 |
| **P-LCR** | 60.8 | h | % | 18.0 - 50.0 |




| | | | | Range |
|---|---|---|---|---|
| **WBC** | 4.09 | * | $10^3/\mu L$ | 3.50 - 10.00 |

| | # | | Range | % | | Range |
|---|---|---|---|---|---|---|
| **NEU** | 1.43 | L* | 1.60 - 7.00 | 35.3 | l* | 40.0 - 73.0 |
| **LYM** | 2.16 | * | 1.00 - 3.00 | 53.5 | h* | 15.0 - 45.0 |
| **MON** | 0.27 | * | 0.20 - 0.80 | 6.8 | * | 4.0 - 12.0 |
| **EOS** | 0.13 | * | 0.00 - 0.50 | 3.2 | * | 0.5 - 7.0 |
| **BAS** | 0.05 | * | 0.00 - 0.15 | 1.2 | * | 0.0 - 2.0 |
| **LIC** | 0.05 | * | 0.00 - 0.10 | 1.1 | h* | 0.0 - 1.0 |




**Recommended actions**

Slide review

**Alarms**

**WBC**

Background Noise

LYM Interference

**PLT**

RBC PLT Interference

**Susp. Pathologies**

Macroplatelets

PLT aggregate or NRBC ?

Neutropenia

## 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 _____ by _____ Signature :

Andheri Sample - 1

## Results

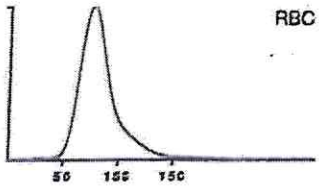
**Run Date** 03/05/2023 04:07:10 PM

**Last Name**
**First Name**
**Gender**
**Patient ID**
**Birth Date**
**Sample comments**

**Age**

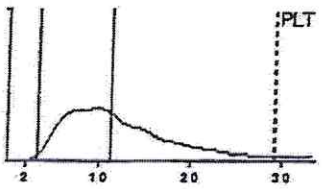
**Operator** LUPIN
**Sample ID** PS VALI DAY-6
**Rack/Pos**
**Department**
**Physician**
**Type** Standard

| | | | | Range |
|---|---|---|---|---|
| **RBC** | 4.63 | | $10^6$/µL | 3.80 - 6.00 |
| **HGB** | 12.9 | | g/dL | 11.5 - 17.0 |
| **HCT** | 39.6 | | % | 35.0 - 52.0 |
| **MCV** | 85.4 | | µm³ | 76.0 - 100.0 |
| **MCH** | 27.9 | | pg | 27.0 - 34.0 |
| **MCHC** | 32.6 | | g/dL | 32.0 - 35.0 |
| **RDW-CV** | 15.5 | | % | 11.0 - 17.0 |
| **RDW-SD** | 50.4 | h | µm³ | 37.0 - 49.0 |



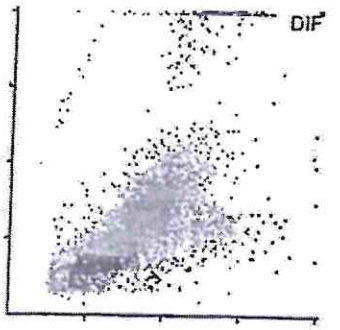

**Recommended actions**
Slide review
**Alarms**
Control failed
**WBC**
Background Noise
LYM Interference
Abnormal Differentiation
**Susp. Pathologies**
PLT aggregate or NRBC ?

| | | | | Range |
|---|---|---|---|---|
| **PLT** | 267 | * | $10^3$/µL | 150 - 400 |
| **PCT** | 0.31 | * | % | 0.15 - 0.40 |
| **MPV** | 11.6 | h* | µm³ | 8.0 - 11.0 |
| **PDW** | 21.6 | * | µm³ | 11.0 - 22.0 |
| **P-LCC** | 122 | | $10^3$/µL | 44 - 140 |
| **P-LCR** | 45.7 | | % | 18.0 - 50.0 |




| | | | | Range |
|---|---|---|---|---|
| **WBC** | 9.53 | * | $10^3$/µL | 3.50 - 10.00 |

| | # | | Range | % | | Range |
|---|---|---|---|---|---|---|
| **NEU** | 6.27 | * | 1.60 - 7.00 | 66.1 | * | 40.0 - 73.0 |
| **LYM** | 2.25 | * | 1.00 - 3.00 | 23.8 | * | 15.0 - 45.0 |
| **MON** | 0.57 | * | 0.20 - 0.80 | 6.1 | * | 4.0 - 12.0 |
| **EOS** | 0.32 | * | 0.00 - 0.50 | 3.4 | * | 0.5 - 7.0 |
| **BAS** | 0.06 | * | 0.00 - 0.15 | 0.6 | * | 0.0 - 2.0 |
| **LIC** | 0.06 | * | 0.00 - 0.10 | 0.7 | * | 0.0 - 1.0 |




## 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 _____ by _____ Signature :

Another Sample - 2

## Results

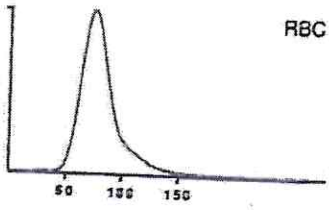
**Run Date** 03/05/2023 04:17:12 PM

**Operator** LUPIN

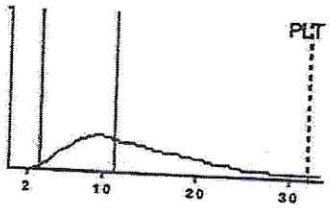
**Last Name**
**First Name**
**Gender** **Age**
**Patient ID**
**Birth Date**
**Sample comments**

**Sample ID** DS VALI DAY-6
**Rack/Pos**
**Department**
**Physician**
**Type** Standard

| | | | | Range |
|---|---|---|---|---|
| **RBC** | 5.30 | | $10^6/\mu L$ | 3.80 - 6.00 |
| **HGB** | 14.4 | | g/dL | 11.5 - 17.0 |
| **HCT** | 44.6 | | % | 35.0 - 52.0 |
| **MCV** | 84.1 | | $\mu m^3$ | 76.0 - 100.0 |
| **MCH** | 27.1 | | pg | 27.0 - 34.0 |
| **MCHC** | 32.2 | | g/dL | 32.0 - 35.0 |
| **RDW-CV** | 15.3 | | % | 11.0 - 17.0 |
| **RDW-SD** | 49.6 | h | $\mu m^3$ | 37.0 - 49.0 |

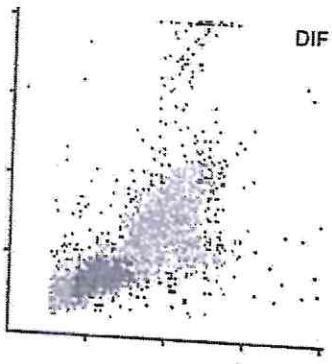



| | | | | Range |
|---|---|---|---|---|
| **PLT** | 208 | * | $10^3/\mu L$ | 150 - 400 |
| **PCT** | 0.28 | * | % | 0.15 - 0.40 |
| **MPV** | 13.4 | H* | $\mu m^3$ | 8.0 - 11.0 |
| **PDW** | 26.0 | H* | $\mu m^3$ | 11.0 - 22.0 |
| **P-LCC** | 121 | | $10^3/\mu L$ | 44 - 140 |
| **P-LCR** | 58.0 | h | % | 18.0 - 50.0 |




| | | | | Range |
|---|---|---|---|---|
| **WBC** | 4.32 | * | $10^3/\mu L$ | 3.50 - 10.00 |

| | # | | Range | % | | Range |
|---|---|---|---|---|---|---|
| **NEU** | 1.69 | * | 1.60 - 7.00 | 39.4 | l* | 40.0 - 73.0 |
| **LYM** | 2.18 | * | 1.00 - 3.00 | 50.7 | h* | 15.0 - 45.0 |
| **MON** | 0.22 | * | 0.20 - 0.80 | 5.0 | * | 4.0 - 12.0 |
| **EOS** | 0.12 | * | 0.00 - 0.50 | 2.7 | * | 0.5 - 7.0 |
| **BAS** | 0.09 | * | 0.00 - 0.15 | 2.2 | h* | 0.0 - 2.0 |
| **LIC** | 0.02 | * | 0.00 - 0.10 | 0.4 | * | 0.0 - 1.0 |




**Recommended actions**
Slide review

**Alarms**
Control failed
**WBC**
LYM Interference
Abnormal Differentiation
**PLT**
RBC PLT Interference
**Susp. Pathologies**
Macroplatelets
PLT aggregate or NRBC ?

## Slide Review

Neutrophil
Lymphocyte
Monocyte
Eosinophil
Basophil
Atypical Lymphocyte
Other

Myeloblast
Promyelocyte
Myelocyte
Metamyelocyte
Blast
Target Cell
Sickle Cell

Anisocytosis
Hypochromia
Polychromasia
Poikilocytosis
Microcytosis
Macrocytosis
Platelet Clumps

Reviewed on _____ by _____ Signature :

| | |
|---|---|
| **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: 25/11/2024

| |
|---|
| PT/EQAS Set Identification: AIIMS Hematology (Sample - OCT-2023) |
| Date of PT/EQAS: 19/10/2023 |
| Acceptable/ Unacceptable Results WBC |
| Acceptable Result Range: 12.77 . ±0.038 |
| Previous Trends/ Unacceptable Results from this Analyte/ Test: WBC outlier noted 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 det WBC method of detection i.e Hdwcyto mer zy

| 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

WBC cell count found low.
WBC cell degeneration leads to low count.

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)

Summary of Investigation:
WBC unacceptable performance noted in Horiba analyser due to method of detection ie Flowcytometry.
Low count of WBC found due to degenerated of WBC cells.

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

No

Corrective/ Preventive action taken to prevent Reoccurrence
As a part of corrective action performance verify with ILC study with referral laboratory and performance found satisfactory.

Conclusions

Due to degeration of WBC cell in EQAS sample leads to unacceptable performance.

Quality Manager/ Team Leader Mr. Mustkin Date: 25/01/2024

Lab Head Sharayu Date: 25/1/24

# 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.:** 161-J **Month/Year:** October/2023

**Instrument ID:** 909YAXH02625 **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:** 10-01-2024[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 x$10^3$/µl | 1 | 4.38 | 4.2 | 8.58 | 12.77 | 0.038 | -4.71 | 0.18 | 0.1 | 0.010 | 0.72 |
| RBC x$10^6$/µl | 1 | 4.55 | 4.19 | 8.74 | 8.72 | 0.011 | 0.07 | 0.36 | 0.05 | 0.003 | 6.97 |
| Hb g/dl | 1 | 10.9 | 10.9 | 21.8 | 22 | 0.024 | -0.34 | 0 | 0.1 | 0.008 | -1.35 |
| HCT% | 1 | 37.4 | 35.6 | 73 | 69.8 | 0.156 | 0.81 | 1.8 | 0.4 | 0.027 | 3.15 |
| MCV-fl | 1 | 85 | 82.2 | 167.2 | 160 | 0.272 | 1.14 | 2.8 | 0.3 | 0.025 | 5.62 |
| MCH-Pg | 1 | 26.1 | 23.9 | 50 | 50.45 | 0.063 | -0.32 | 2.2 | 0.2 | 0.016 | 8.99 |
| MCHC-g/dl | 1 | 30.7 | 29.1 | 59.8 | 63.3 | 0.146 | -0.94 | 1.6 | 0.3 | 0.022 | 3.51 |
| Plt. x$10^3$/µl | 1 | 209 | 182 | 391 | 397 | 1.557 | -0.16 | 27 | 7 | 0.440 | 3.37 |
| Retic % | 2 | 30 | 25 | 55 | 31 | 0.570 | 1.65 | 5 | 1 | 0.066 | 3.60 |

## P.S . Assesment

| YOUR REPORT | | | CONSENSUS REPORT |
|---|---|---|---|
| DLC% | 3 | Nrbcs=2 , Poly=57 L=3, E=2, Mono/Promono=1 , B1=9 P.M.=9, Mye=10, Meta=5, Other= | Poly: 43 - 56, Myelo: 14 - 28, Meta: 8- 16, Promyelo: 2-6, Lympho: 2- 5, Blast: 1-3, Eosino: 1-2, Mono: 1-2, nRBC/, Baso: 0-5 |
| RBC Morphology | 3 | NORMOCYTIC NORMOCHROMIC | Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, Hypochromic, Mild: Poikilocytosis |
| Diagnosis | 3 | CHRONIC MYELOID LEUKEMIA-CHRONIC PHASE | Chronic Myeloid Leukemia (Chronic Phase) |

# 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 x$10^3$/µl | 1 | 1.69 | 1.53 | 3.22 | 10.41 | 0.030 | -10.21 | 0.16 | 0.1 | 0.006 | 0.62 |
| RBC x$10^6$/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. x$10^3$/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 |
| 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 |
|---|---|---|---|---|

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

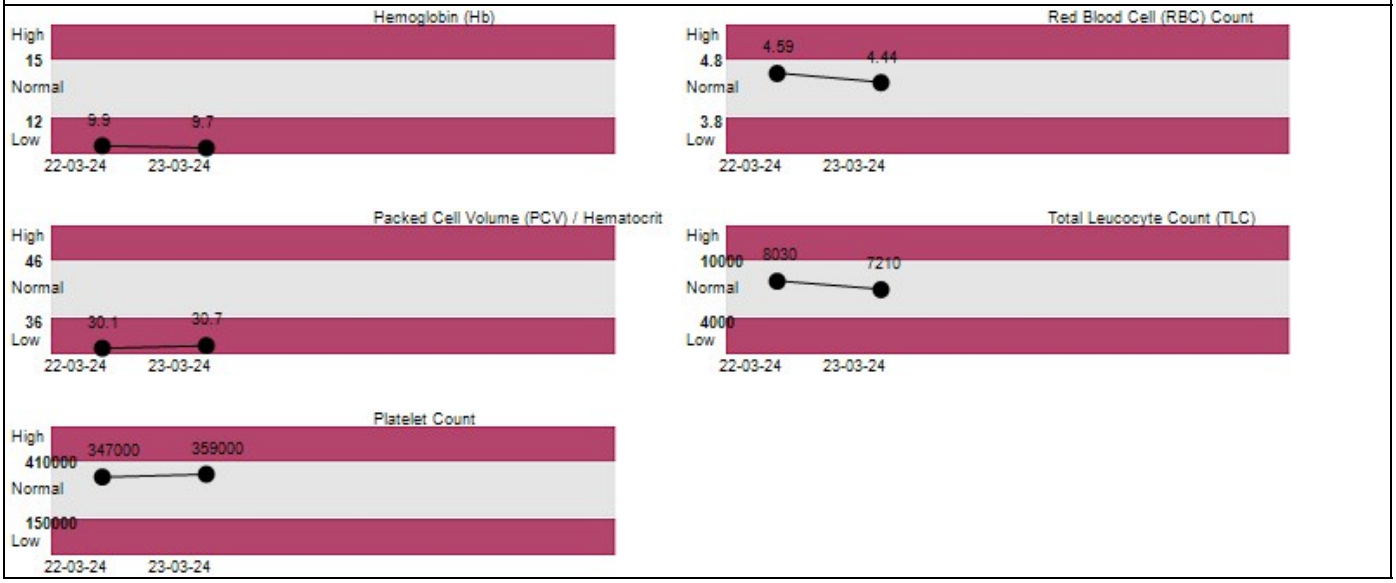
**This test has been performed at Lupin Diagnostics Laboratory, NRL MUMBAI National Reference Laboratory, Plot No.C-533, MIDC, TTC Industrial Area, Pawane,Turbhe,NAVI MUMBAI , 400705**

| 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)

—

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