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. : 4364 **Distribution No.:** 157-L **Month/Year:** October/2022

Instrument ID: 109YAXH03499

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: 17-11-2022[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	8.36	7.38	15.74	12.5	0.0700	2.05	0.98	0.11	0.0090	6.52
RBC x10^6/µl	1	4.33	4.31	8.64	8.41	0.0130	0.65	0.02	0.04	0.0030	-0.34
Hb g/dl	1	12.1	12	24.1	23.6	0.0280	0.75	0.1	0.1	0.0090	0.00
HCT%	1	35	34.9	69.9	74	0.1930	-0.80	0.1	0.4	0.0280	-0.67
MCV-fl	1	81.2	80.5	161.7	177.4	0.3730	-1.50	0.7	0.3	0.0230	1.08
MCH-Pg	1	28	27.7	55.7	56.4	0.0820	-0.35	0.3	0.2	0.0220	0.34
MCHC-g/dl	1	34.7	34.2	68.9	63.7	0.1580	1.23	0.5	0.3	0.0220	0.67
Plt. x10^3/µl	1	182	175	357	593	3.16	-2.53	7	11	0.73	-0.34
Retic %	2	3.6	3.2	6.8	7.18	0.17	-0.08	0.4	0.4	0.03	0.00

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs= , Poly=05 L=92, E=00, Mono/Promono=03 , B1=00 P.M.=00, Mye=00, Meta=00, Other=SMUDGE CELLS ARE PRESENT	Blast: 44-90, Lympho: 4-21, Poly: 1-6, nRBC/Eos/Baso/Mono /Myelo/Meta/ Promyelo: 0-5
RBC Morphology	3	NORMOCYTIC NORMOCHROMIC RBCs ARE NOTED. ANISOPOIKILOCYTOSIS PRESENT.	Predominantly: Normocytic/ Normochromic, Moderate: Anisocytosis, Microcytic
Diagnosis	3	CHRONIC LYMPHOCYTIC LEUKAEMIA	Acute Leukemia (AL)

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 157--L	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	312	300	77.33	90	6.33	2.33	16.34	7.67
RBC $x10^6/\mu l$	1	312	312	88.14	83.65	3.85	5.45	8.01	10.9
Hb g/dl	1	312	312	84.29	82.69	5.45	5.77	10.26	11.54
HCT%	1	312	301	90.03	87.04	6.31	5.65	3.66	7.31
MCV-fl	1	312	301	93.02	89.37	4.65	6.64	2.33	3.99
MCH-Pg	1	312	301	87.71	90.03	7.97	2.66	4.32	7.31
MCHC-g/dl	1	312	301	92.36	91.03	5.98	2.99	1.66	5.98
Plt. $x10^3/\mu l$	1	312	297	93.27	92.26	4.38	3.7	2.35	4.04
ReticCount%	2	312	206	88.83	89.81	5.83	7.28	5.34	2.91
PS Assessment	3	312	199	Satisfactory :90.04%, Borderline Sat. :3.21%, Unsatisfactory :6.75%					

Comments:

1). Among Lab (EQA) : **PS Diagnosis wrongly 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. 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

LUPIN DIAGNOSTICS
Good health starts here

Date of Investigation: 01/11/2022

PT/EQAS Set Identification: ISHTM AIIMS – 1574 (Distribution No.)
Date of PT/EQAS: 15/10/2022
Acceptable/ Unacceptable Results: 15.74
Acceptable Result Range: 12.5 ± 0.07
Previous Trends/ Unacceptable Results from this Analyte/ Test: unacceptable with negative bias.

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: NIL

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:

Nil

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:

NIL

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 Explanation: Attributed to Random Error

Any Others (explain)

Summary of Investigation: RCA for outlier was done in Consent with the applicant chemist of HORIBA, since the principle of detection of WBC's is impendence with flow cytometry as based the degredation WBC Cells are not Count and give bias.
To verify the same a Study was Conducted at NRL and nearest satellite laboratory using fresh Sample and result found satisfactory.

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

No. The patient Sample are analysed immediately in reported it was verified and outlair was found.

Corrective/ Preventive action taken to prevent Reoccurrence

As a part of Corrective action and Inter laboratory Comparison is also done at local laboratory using fresh EDTA Sample and results are within acceptable limit.

Conclusions

Degradation is specimen and peer group discrepency leading to negrate bias in the patient Sample. Inter lab Comparision with fresh Sample shows that their is no issue with lab analysis or methodology.

Quality Manager/ Team Leader Sushadeep Pal Date: 08/02/2023

Lab Head Koushik Samanta Date: 08/02/2023

CAMR+

Medical Laboratory Report

LUPIN DIAGNOSTICS
Good health starts here

Patient Information		Specimen Information		Client/Doctor Information	
Name	: Mrs.ANITA DAN	Visit ID	: LCAM22100	Client Code	: HLM0005
Age/Gender	: 61Y 0M 0D/Female	Collected	: 08/Feb/2023 10:52	Client Name	: HLM CAMRI - CGHS
MobileNo	: 9474552780	Received	: 08/Feb/2023 10:54	Client Add.	:
UHID	: LDAA00321674	Reported	: 08/Feb/2023 11:41	Client No.	:
Address	:	IP/OP/Barcode	: FW1-231340	Ref Doctor	: Dr.A.D. BOSE (MD)
		Report Status	: Final Report		

Test Name	Result	Bio. Ref. Range	Unit	Method
Complete Blood Count (CBC) , *WHOLE BLOOD EDTA*				
Hemoglobin (Hb)	**12.3**	13-17	g/dL	Spectrophotometry
Red Blood Cell (RBC) Count	4.26	3.8-4.8	Million/cu.mm	Impedence
Packed Cell Volume (PCV) / Hematocrit	37.8	36-46	%	Calculated
Mean Corpuscular Volume (MCV)	88.7	83-101	fL	Calculated
Mean Corpuscular Hemoglobin (MCH)	28.8	27-32	pg	Calculated
Mean Corpuscular Hb Concentration (MCHC)	32.4	31.5-34.5	g/dL	Calculated
Red Cell Distribution Width (RDW)	**14.5**	11.6-14	%	Calculated
Total Leucocyte Count (TLC)	7,320	4000-10000	Cells/cu.mm	Impedence
Differential Leucocyte Count (DLC)				
Neutrophils	78.0	40-80	%	Impedence & FCM
Lymphocytes	**18.0**	20-40	%	Impedence & FCM
Monocytes	2.0	2-10	%	Impedence & FCM
Eosinophils	2.0	1-6	%	Impedence & FCM
Basophils	0.0	0-2	%	Impedence & FCM
Absolute Leucocyte Count				
Neutrophils	5,710	2000-7000	Cells/cu.mm	Calculated
Lymphocytes	1,318	1000-3000	Cells/cu.mm	Calculated
Monocytes	**146**	200-1000	Cells/cu.mm	Calculated
Eosinophils	146	20-500	Cells/cu.mm	Calculated
Platelet Count	214,000	150000-410000	per cu.mm	Impedence
Mean Platelet Volume (MPV)	11.3	7.4-12.0	fL	Impedence

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

Reports to follow-
Kidney/Renal Function Tests (KFT/RFT), Liver Function Test (LFT)

Koushik Samanta

DR. KOUSHIK SAMANTA
MBBS, MD (PATHOLOGY)
CHIEF OF LAB
REG. NO. – 68035 (WBMC)

SIN No:HA00212761

This test has been performed at Lupin Diagnostics Laboratory, HLM CAMRI Bamchandaipur, GT Rd, NH2, Gangpur

KRISHNA DIAGNOSTICS (P) LTD

Where You Matter Most

AN ISO CERTIFIED LABORATORY

UID: 1141983 Nationality: Indian

Patient ID:	012302080608	Primary SampleCollection Time:	08/Feb/2023 19:19:48
Name:	Ms. ANITA DAN	Collection Date/Time:	08/Feb/2023 07:20PM
Age/Gender:	61 Y/Female	Received Date/Time:	08/Feb/2023 07:21PM
Referred By:	Self	Approved Date/Time:	08/Feb/2023 07:53PM
LabID:	11141767	Print Date/Time:	08/Feb/2023 07:54PM
SpecimenType:	Whole Blood EDTA	Client Grp.:	LUPIN DIAGNOSTICS LIMITED

DEPARTMENT OF HAEMATOLOGY

Test Description	Observed Value	Unit	Method	Biological Ref. Interval
Complete Blood Count (CBC)				
Haemoglobin (Hb)	12.5	g/dL	Colorimetric	12.5-16.00
RBC Count	4.37	million/µL	Sheath fluid impedence	4.2-5.4
Packed Cell Volume	**38.6***	%	Calculated	41-53
MCV	88.4	fL	Sheath fluid impedence	80-100
MCH	28.5	pg	Calculated	26-34
MCHC	32.2	g/dL	Calculated	31-37
Platelet Count	1.90	L/cumm	Sheath fluid impedence / Microscopy	1.50-4.50
TLC (Total Leucocyte Count)	7,450	/cumm	Laser flowcytometry/ Microscopy	4000-11000
Differential Leucocyte Count				
Neutrophil	79	%	Laser flowcytometry/ Microscopy	40-80
Lymphocyte	**17***	%	Laser flowcytometry / Microscopy	20-40
Monocytes	3	%	Laser flowcytometry / Microscopy	3-6
Eosinophils	1	%	Laser flowcytometry / Microscopy	01-06
Basophils	0	%	Laser flowcytometry / Microscopy	0-1
Absolute Neutrophil Count	5,885.5	/cumm	Calculated / Microscopy	2000-7000
Absolute Lymphocyte Count	**1,266.50***	/cumm	Calculated / Microscopy	1500-4000
Absolute Monocyte Count	224	/cumm	Calculated / Microscopy	100-1000
Absolute Eosinophil Count	74.50	/cumm	Calculated / Microscopy	00-500
RDW-CV	14.3	%	Calculated	11.5-17.0

DR.PARTHA PRATIM PURKAIT
MBBS, MD(PATH)
CONSULTANT PATHOLOGIST

MC-4154

Dr.Ratnadipa Banerjee
MBBS, DNB (PATH)
Consultant Pathologist

Entered By:SINTU DAS

UID: 1141983 Nationality: Indian

Patient ID:	012302080608	Primary SampleCollection Time:	08/Feb/2023 19:19:48
Name:	Ms. ANITA DAN	Collection Date/Time:	08/Feb/2023 07:20PM
Age/Gender:	61 Y/Female	Received Date/Time:	08/Feb/2023 07:21PM
Referred By:	Self	Approved Date/Time:	08/Feb/2023 07:53PM
LabID:	11141767	Print Date/Time:	08/Feb/2023 07:54PM
SpecimenType:	Whole Blood EDTA	Client Grp.:	LUPIN DIAGNOSTICS LIMITED

DEPARTMENT OF HAEMATOLOGY

Test Description	Observed Value	Unit	Method	Biological Ref. Interval
RDW-SD	47.3	fl	Cell Counter	37.0-49.0
Mean Platelet Volume	13.70*	fl	Calculated	8.0-11.0
NLR-Ratio	4.65*			1-3 Normal 3-6 Stress 6-9 Mild Stress 9-18 Moderate Stress

Disclaimer: The test result mentioned here should be interpreted in view of clinical condition of the patient. In case of any clinical suspicion regarding any parameter, repeat test with fresh sample essential to conclude.

*** End Of Report ***

DR.PARTHA PRATIM PURKAIT
MBBS, MD(PATH)
CONSULTANT PATHOLOGIST

Dr.Ratnadipa Banerjee
MBBS, DNB (PATH)
Consultant Pathologist

Entered By:SINTU DAS

CAMR+

Medical Laboratory Report

LUPIN DIAGNOSTICS
Good health starts here

Patient Information		Specimen Information		Client/Doctor Information	
Name	: Mrs.JYOSTANA MONDAL	Visit ID	: LCAM22097	Client Code	: HLM0003
Age/Gender	: 63Y 0M 0D/Female	Collected	: 08/Feb/2023 10:04	Client Name	: HLM CAMRI
MobileNo	: 9749878528	Received	: 08/Feb/2023 10:06	Client Add.	: GANGPUR
UHID	: LDAA00551184	Reported	: 08/Feb/2023 13:37	Client No.	:
Address	:	IP/OP/Barcode	: OPD-ESI	Ref Doctor	: Dr.B.GHOSH
		Report Status	: Final Report		

Test Name	Result	Bio. Ref. Range	Unit	Method
Complete Blood Count (CBC) , *WHOLE BLOOD EDTA*				
Hemoglobin (Hb)	**11.1**	13-17	g/dL	Spectrophotometry
Red Blood Cell (RBC) Count	**3.79**	3.8-4.8	Million/cu.mm	Impedence
Packed Cell Volume (PCV) / Hematocrit	**34.0**	36-46	%	Calculated
Mean Corpuscular Volume (MCV)	89.8	83-101	fL	Calculated
Mean Corpuscular Hemoglobin (MCH)	29.2	27-32	pg	Calculated
Mean Corpuscular Hb Concentration (MCHC)	32.5	31.5-34.5	g/dL	Calculated
Red Cell Distribution Width (RDW)	**14.2**	11.6-14	%	Calculated
Total Leucocyte Count (TLC)	4,900	4000-10000	Cells/cu.mm	Impedence
Differential Leucocyte Count (DLC)				
Neutrophils	62.0	40-80	%	Impedence & FCM
Lymphocytes	30.0	20-40	%	Impedence & FCM
Monocytes	2.0	2-10	%	Impedence & FCM
Eosinophils	6.0	1-6	%	Impedence & FCM
Basophils	0.0	0-2	%	Impedence & FCM
Absolute Leucocyte Count				
Neutrophils	3,038	2000-7000	Cells/cu.mm	Calculated
Lymphocytes	1,470	1000-3000	Cells/cu.mm	Calculated
Monocytes	**98**	200-1000	Cells/cu.mm	Calculated
Eosinophils	294	20-500	Cells/cu.mm	Calculated
Platelet Count	270,000	150000-410000	per cu.mm	Impedence
Mean Platelet Volume (MPV)	**12.4**	7.4-12.0	fL	Impedence

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

Koushik Samanta

DR. KOUSHIK SAMANTA
MBBS, MD (PATHOLOGY)
CHIEF OF LAB
REG. NO. – 63035 (WBMC)

SIN No:HA00212709

This test has been performed at Lupin Diagnostics Laboratory, HLM CAMRI Bamchandaipur, GT Rd, NH2, Gangpur

UID: 1141981 Nationality: Indian

Patient ID:	012302080607	Primary SampleCollection Time:	08/Feb/2023 19:19:48
Name:	Ms. JYOSTNA MONDAL	Collection Date/Time:	08/Feb/2023 07:20PM
Age/Gender:	63 Y/Female	Received Date/Time:	08/Feb/2023 07:21PM
Referred By:	Self	Approved Date/Time:	08/Feb/2023 07:54PM
LabID:	11141765	Print Date/Time:	08/Feb/2023 07:54PM
SpecimenType:	Whole Blood EDTA	Client Grp.:	LUPIN DIAGNOSTICS LIMITED

DEPARTMENT OF HAEMATOLOGY

Test Description	Observed Value	Unit	Method	Biological Ref. Interval
Complete Blood Count (CBC)				
Haemoglobin (Hb)	10.9*	g/dL	Colorimetric	12.5-16.00
RBC Count	3.80*	million/µL	Sheath fluid impedence	4.2-5.4
Packed Cell Volume	34.3*	%	Calculated	41-53
MCV	90.3	fL	Sheath fluid impedence	80-100
MCH	28.8	pg	Calculated	26-34
MCHC	31.9	g/dL	Calculated	31-37
Platelet Count	1.70	L/cumm	Sheath fluid impedence / Microscopy	1.50-4.50
TLC (Total Leucocyte Count)	5,160	/cumm	Laser flowcytometry/ Microscopy	4000-11000
Differential Leucocyte Count				
Neutrophil	63	%	Laser flowcytometry/ Microscopy	40-80
Lymphocyte	28	%	Laser flowcytometry / Microscopy	20-40
Monocytes	2*	%	Laser flowcytometry / Microscopy	3-6
Eosinophils	7*	%	Laser flowcytometry / Microscopy	01-06
Basophils	0	%	Laser flowcytometry / Microscopy	0-1
Absolute Neutrophil Count	3,263.4	/cumm	Calculated / Microscopy	2000-7000
Absolute Lymphocyte Count	1,450.40*	/cumm	Calculated / Microscopy	1500-4000
Absolute Monocyte Count	104	/cumm	Calculated / Microscopy	100-1000
Absolute Eosinophil Count	362.60	/cumm	Calculated / Microscopy	00-500
RDW-CV	13.3	%	Calculated	11.5-17.0

DR.PARTHA PRATIM PURKAIT
MBBS, MD(PATH)
CONSULTANT PATHOLOGIST

Dr.Ratnadipa Banerjee
MBBS, DNB (PATH)
Consultant Pathologist

Entered By:SINTU DAS

UID: 1141981 Nationality: Indian

Patient ID:	012302080607	Primary SampleCollection Time:	08/Feb/2023 19:19:48
Name:	Ms. JYOSTNA MONDAL	Collection Date/Time:	08/Feb/2023 07:20PM
Age/Gender:	63 Y/Female	Received Date/Time:	08/Feb/2023 07:21PM
Referred By:	Self	Approved Date/Time:	08/Feb/2023 07:54PM
LabID:	11141765	Print Date/Time:	08/Feb/2023 07:54PM
SpecimenType:	Whole Blood EDTA	Client Grp.:	LUPIN DIAGNOSTICS LIMITED

DEPARTMENT OF HAEMATOLOGY

Test Description	Observed Value	Unit	Method	Biological Ref. Interval
RDW-SD	45.0	fl	Cell Counter	37.0-49.0
Mean Platelet Volume	14.10*	fl	Calculated	8.0-11.0
NLR-Ratio	2.25			1-3 Normal 3-6 Stress 6-9 Mild Stress 9-18 Moderate Stress

Disclaimer: The test result mentioned here should be interpreted in view of clinical condition of the patient. In case of any clinical suspicion regarding any parameter, repeat test with fresh sample essential to conclude.

*** End Of Report ***

DR.PARTHA PRATIM PURKAIT
MBBS, MD(PATH)
CONSULTANT PATHOLOGIST

Dr.Ratnadipa Banerjee
MBBS, DNB (PATH)
Consultant Pathologist

Entered By:SINTU DAS

Lupin Diagnostics ,Camri (HLM)
Inter laboratory comparison study report of WBC

Reference Laboratory- Krishna Diagnostics,Kolkata
Date of study conducted- 08.02.2023

Sample No	Parameter	Date	Lupin Results (cells/cumm)	Krishna Diagnostics (ILC Lab) (cells/ cumm)	Bias%
1	WBC	08-02-2023	7320	7450	1.78
2	WBC	08-02-2023	4900	5180	5.71

Reference Range-

Lupin Diagnostics	4000-10000 (cells/cumm)
Krishna Diagnostics	4000-11000 (cells/cumm)

Observations-
-100% Clinical correlation noted in both samples.
-%Bias found < 10% in both sample for WBC parameter.
-Hence Inter laboratory comparison study successfully passed for WBC parameter.

Subhadeep Pal
Documented By
(Mr Subhdeep Pal)

Koushik Samanta
Approved by
(Dr Koushik S)

Lupin Diagnostics ,National Reference Laboratory (NRL)	LUPIN DIAGNOSTICS Good health starts here
WBC Root Cause Analysis report	

Purpose of study: Consistence unacceptable performance noted for WBC In last three surveys in AIIMS Hematology PT program

Root Cause Analysis:

- ✓ No any issue noted w.e.f clerical, methodological, technical and equipment.
- ✓ RCA was done in coordination with the Application chemist of Horiba and due to the method of detection in Horiba analyzers is Impedance along with flowcytometry the deterioration in WBC cells results to negative bias.
- ✓ As a part of preventive action Inter laboratory comparison study performed with different time interval to check the results recovery and precision and the results were found to be satisfactory.

Reference Laboratory- Lupin Diagnostics, SL Andheri
Date of study conducted- 01.02.2023

Sample no	Parameter	0 hrs			6 Hrs			12 hrs			24hrs			Reference range	Clinical inference
		01.02.2023						02.02.2023							
		NRL	Andheri	%Diff	NRL	Andheri	%Diff	NRL	Andheri	%Diff	NRL	Andheri	%Diff		
Sample-1	WBC	7.06	7.08	-0.28	7.11	7.23	-1.66	5.98	6.36	-5.97	7.07	6.36	11.16	3.5-10 × 10^3/ul	Correlating
Sample-2	WBC	6.43	6.72	-4.32	6.43	6.32	1.74	6.27	6.72	-6.70	6.27	6.72	-6.70		Correlating
Sample-3	WBC	9.8	9.83	-0.31	9.91	10.45	-5.17	9.94	10.34	-3.87	9.58	6.72	42.56		Correlating

Location- NRL	Sample no	Parameter	Run-1	Run-2	Run-3	Run-4	Mean	SD	%CV
	Sample-1	WBC	7.06	7.11	5.98	7.07	6.80	0.55	8.09
	Sample-2	WBC	6.43	6.43	6.27	6.27	6.35	0.09	1.45
	Sample-3	WBC	9.8	9.91	9.94	9.58	9.80	0.16	1.66

Observations-

- ✓ 100% clinical correlation in all three specimens
- ✓ %Difference found in all intervals for all samples except for last interval.
- ✓ Precision %CV found < 10% in all three samples.

Conclusion:

Based on obtained result recovery Inter laboratory comparison study successfully passed for WBC test parameter and no any major value variation noted in patient sample.

This is for your update.

Sagar Damani
02/02/23

Regards,