

HORIBA

HORIBA India Private Limited

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http://www.horiba.com
CIN : U72900DL2006PTC183202

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.


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



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 x10 ³ /µl	1	2.63	2.55	5.18	11.17	0.067	-3.41	0.08	0.1	0.008	-0.17
RBC x10 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. x10 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 /µl	1	287	282	87.59	81.91	5.67	7.45	6.74	10.64
RBC x10 ⁶ /µl	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 /µl	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-----

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



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 - 25wv → -34
Acceptable Result Range:	< 2 25wv.
Previous Trends/ Unacceptable Results from this Analyte/ Test:	Previous trend of WBC outlier
Classification of Problems: (Please tick) Clerical:	<input type="checkbox"/> Transcription error (may be pre- or post-analytical factors) <input type="checkbox"/> Wrong method has been registered for analysis or method change not updated.
Details of Investigation:	Transcription error & method reviewed No discrepancy found.
Methodological	<input type="checkbox"/> Instrument function checks (e.g., temperatures, blank readings, pressures) not performed as necessary, or results not within acceptable range. <input type="checkbox"/> Scheduled instrument maintenance not performed appropriately. <input type="checkbox"/> Incorrect instrument calibration. <input type="checkbox"/> Standards or reagents improperly reconstituted and stored, or inadvertently used beyond expiration date. <input type="checkbox"/> Instrument probes misaligned. <input type="checkbox"/> Problem with instrument data processing functions. The laboratory may need to contact the manufacturer to evaluate such problems. <input type="checkbox"/> Problem in manufacture of reagents / standards, or with instrument settings specified by manufacturer <input type="checkbox"/> Carry-over from previous specimen. <input type="checkbox"/> Automatic pipettor not calibrated to acceptable precision and accuracy. <input type="checkbox"/> Imprecision from result being close to detection limit of method. <input type="checkbox"/> QC material not run within expiration date, or improperly stored.

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- 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 in fill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens.
- Non-viable samples for microbiology PT/EQAS program.
- Haemolysis on an immune-haematology program samples.

Details of Investigation:

Matrix effect can be attributed to this
major outlier

Title	PT/ EQAS EVALUATION RECORD
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Version	02
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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:

Reviewed Evaluation & suggestion from Horiba team \rightarrow limited peer group results in the outliers

No Explanation: Attributed to Random Error

Any Others (explain) -

Summary of Investigation:

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

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

No. IDC 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.

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<p>Conclusions 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</p>	
Quality Manager/ Team Leader <u>Mustakim</u>	Date: 17/8/23
Lab Head <u>Barayn</u>	Date: 17/8/23

Controlled Copy

NPL ← Sample 1

Results

Run Date 03/04/2023 05:28:52 PM

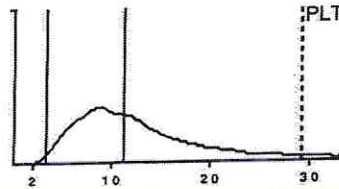
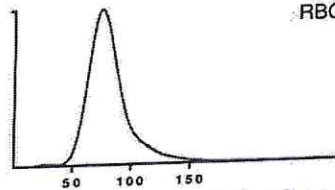
Operator LUPIN

Last Name
First Name
Gender
Patient ID
Birth Date
Sample comments

Age

Sample ID PRIYA
Rack/Pos
Department
Physician
Type Standard

			Range
RBC	4.76	10 ⁹ /μL	3.80 - 6.00
HGB	13.0	g/dL	11.5 - 17.0
HCT	38.6	%	35.0 - 52.0
MCV	81.0	μm 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	μm ³	37.0 - 49.0
Range			
PLT	290	* 10 ³ /μL	150 - 400
PCT	0.33	* %	0.15 - 0.40
MPV	11.2	h* μm ³	8.0 - 11.0
PDW	20.3	* μm ³	11.0 - 22.0
P-LCC	133	10 ³ /μL	44 - 140
P-LCR	45.9	%	18.0 - 50.0



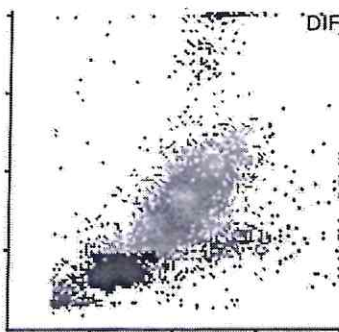
Recommended actions

Slide review

Alarms

WBC
LYM Interference
Susp. Pathologies
PLT aggregate or NRBC ?
Left shift

WBC 10.30 h* 10³/μL 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

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 :

NPL sample - 2

144 h23

Results

Run Date 03/04/2023 05:37:15 PM

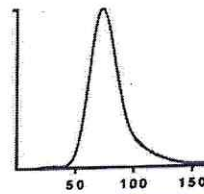
Operator LUPIN

Last Name
First Name
Gender
Patient ID
Birth Date
Sample comments

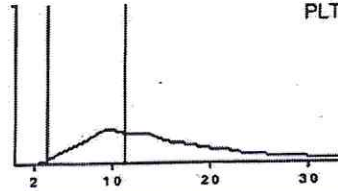
Age

Sample ID DANISH
Rack/Pos
Department
Physician
Type Standard

			Range
RBC	5.45	10 ⁶ /μL	3.80 - 6.00
HGB	14.4	g/dL	11.5 - 17.0
HCT	43.2	%	35.0 - 52.0
MCV	79.3	μm ³	76.0 - 100.0
MCH	26.5	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	μm ³	37.0 - 49.0
Range			
PLT	212	* 10 ³ /μL	150 - 400
PCT	0.29	* %	0.15 - 0.40
MPV	13.6	H* μm ³	8.0 - 11.0
PDW	27.2	H* μm ³	11.0 - 22.0
P-LCC	129	10 ³ /μL	44 - 140
P-LCR	60.8	h %	18.0 - 50.0



RBC



PLT

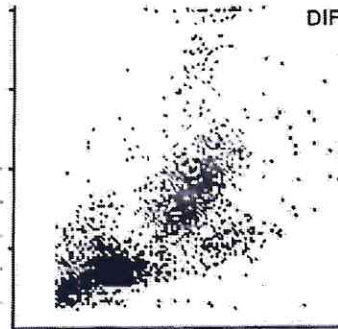
Recommended actions

Slide review

Alarms

- WBC**
- Background Noise
- LYM Interference
- PLT**
- RBC PLT Interference
- Susp. Pathologies**
- Macroplatelets
- PLT aggregate or NRBC ?
- Neutropenia

			Range			
WBC	4.09	* 10 ³ /μL	3.50 - 10.00			
Range						
	#		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



DIF

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

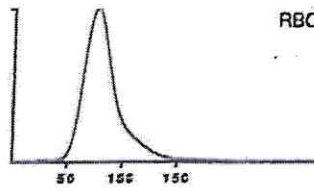
Run Date 03/05/2023 04:07:10 PM

Results

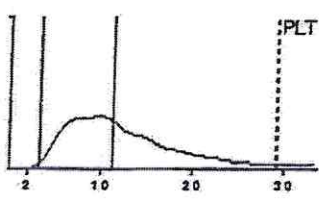
Last Name
First Name
Gender
Patient ID
Birth Date
Sample comments

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

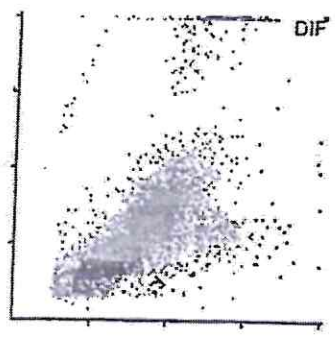
			Range
RBC	4.63	10 ⁹ /μL	3.80 - 6.00
HGB	12.9	g/dL	11.5 - 17.0
HCT	39.6	%	35.0 - 52.0
MCV	85.4	μm ³	76.0 - 100.0
MCH	27.9	pg	27.0 - 34.0
MCHC	32.6	g/dL	32.0 - 35.0
RDW-CV	15.5	%	11.0 - 17.0
RDW-SD	50.4	h μm ³	37.0 - 49.0
PLT	267	* 10 ⁹ /μL	150 - 400
PCT	0.31	* %	0.15 - 0.40
MPV	11.6	h* μm ³	8.0 - 11.0
PDW	21.6	* μm ³	11.0 - 22.0
P-LCC	122	10 ³ /μL	44 - 140
P-LCR	45.7	%	18.0 - 50.0



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



			Range		Range
WBC	9.53	* 10 ⁹ /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 :

Andhan Samyru - 2

Results

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

Operator LUPIN

Last Name

Sample ID DS VALI DAY-6

First Name

Rack/Pos

Gender

Age

Department

Patient ID

Physician

Birth Date

Type Standard

Sample comments

Recommended actions

Slide review

Alarms

Control failed

RBC

WBC

LYM Interference

Abnormal Differentiation

PLT

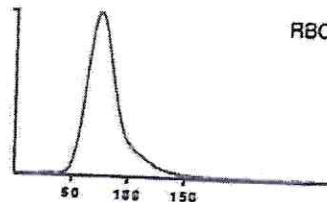
RBC PLT Interference

Susp. Pathologies

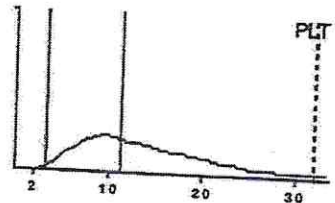
Macroplatelets

PLT aggregate or NRBC ?

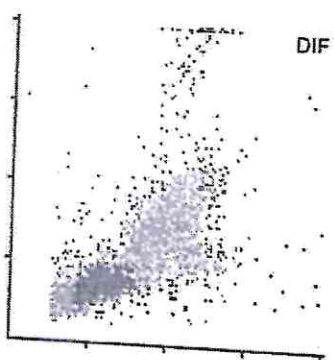
			Range
RBC	5.30	10 ⁶ /μL	3.80 - 6.00
HGB	14.4	g/dL	11.5 - 17.0
HCT	44.6	%	35.0 - 52.0
MCV	84.1	μm ³	76.0 - 100.0
MCH	27.1	pg	27.0 - 34.0
MCHC	32.2	g/dL	32.0 - 35.0
RDW-CV	15.3	%	11.0 - 17.0
RDW-SD	49.6	h μm ³	37.0 - 49.0



			Range
PLT	208	* 10 ³ /μL	150 - 400
PCT	0.28	* %	0.15 - 0.40
MPV	13.4	H* μm ³	8.0 - 11.0
PDW	26.0	H* μm ³	11.0 - 22.0
P-LCC	121	10 ³ /μL	44 - 140
P-LCR	58.0	h %	18.0 - 50.0



			Range		Range
WBC	4.32	* 10 ³ /μL	3.50 - 10.00		
	#			%	
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



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 :

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: 25th / 11 / 2024

PT/EQAS Set Identification:	AIIMS Hematology (sample - Oct-2023)
Date of PT/EQAS:	19/11/2023
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.

Lupin Diagnostics (Lupin Diagnostics Limited)

Page 1 of 4

Site: All Locations

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



- 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 in fill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens.
- Non-viable samples for microbiology PT/EQAS program.
- Haemolysis on an immune-haematology program samples.

Details of Investigation:

Due to det WBC method of detection i.e. Flow cytometry

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



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 analyzer due to method of detection i.e. flowcytometry. Low count of WBC found due to degenerated 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.

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



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<p>Conclusions</p> <p>Due to degeration of WBC cell in EQAS sample leads to unacceptable performance.</p>	
<p>Quality Manager/ Team Leader</p> <p><i>Mr. Mustkin</i></p>	<p>Date:</p> <p><i>25/01/2024</i></p>
<p>Lab Head</p> <p><i>Sharayu</i></p>	<p>Date:</p> <p><i>25/1/24</i></p>

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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 x10 ³ /µl	1	4.38	4.2	8.58	12.77	0.038	-4.71	0.18	0.1	0.010	0.72
RBC x10 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. x10 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 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
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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 ***



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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	Report Status : Final Report	

Test Name	Result	Bio. Ref. Range	Unit	Method
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Dr. Sharayu Patil
MD Pathologist



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
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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

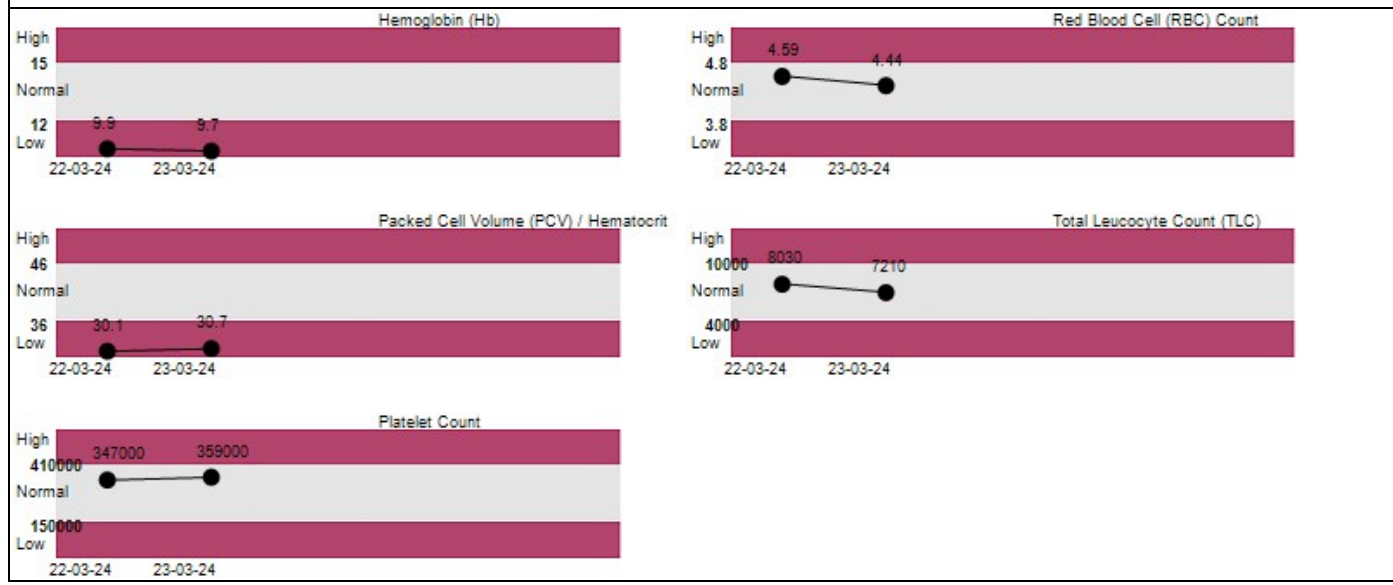


Patient Information	Specimen Information	Client/Doctor Information
Name : Mrs.JAYSHRI MAROTI PHAD	Visit ID : LGRG15473	Client Code : HLM0010
Age/Gender : 35 Y 0 M 0 D /Female	Collected : 22/Mar/2024 14:18	Client Name : HLM LATUR FERTILITY PRIVATE LIMITED
MobileNo : 7507900871	Received : 23/Mar/2024 09:09	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
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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

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



MC-5498



Reference Laboratory- Lupin Diagnostics, NRL

Date of study conducted- 23.03.2024

Sr No	Parameters	Sample-1			Reference range
		Mrs. Jayashri Phad			
		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 P
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



Date of Investigation: 27/03/2024

PT/EQAS Set Identification:	ATMS 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.

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



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- 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 in fill volumes, inadequate mixing, or inconsistent heating of lyophilized specimens.
- Non-viable samples for microbiology PT/EQAS program.
- Haemolysis on an immune-haematology program samples.

Details of Investigation:

Due to transition of sample, WBC cell degenerated

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

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

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 w.r.t analyzer, reagents, calibration*
- The 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 where verify with ILE study and found to within satisfactory range. Also laboratory decided to shift in other of EQAP program to check performance closely.

Title	PT/ EQAS EVALUATION RECORD
Document Number	FRM.QCM.03
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Conclusions	
Based on finding concluding WBC unacceptable performance due to a method of detection re flowcy to mercury.	
Quality Manager/ Team Leader	<u>Multhakim</u> Date: 27/03/2024
Lab Head	<u>Sharayu</u> Date: 27/3/24

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