

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



Date of Investigation:

PT/EQAS Set Identification:	RML EQAS.
Date of PT/EQAS:	26-09-23.
Acceptable/ Unacceptable Results	Hb.
Acceptable Result Range:	11.0 - 12.2.
Previous Trends/ Unacceptable Results from this Analyte/ Test:	First time reported.
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:	None.
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:

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:

None.

Lupin Diagnostics (Lupin Diagnostics Limited)	Page 2 of 4
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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  $\pm 2$  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)

*Random Error.*

Summary of Investigation:

*Reported value is slightly lower than target mean. As on the day of sample processing was acceptable. All other factors including analyzer maintenance, reagent, temperature were found to be acceptable.*

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

*No.*

Corrective/ Preventive action taken to prevent Reoccurrence

*PIE was performed using 2 samples with parent lab. Both the samples were correlating and had similar values.*

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Conclusions	
The study found to be acceptable.	
Quality Manager/ Team Leader <i>Ashita</i>	Date: <i>28/11/23</i>
Lab Head <i>Ashithy</i>	Date: <i>28/11/23</i>

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PC 1001

**RML- Quality Assurance Program (RML-QAP)****HEMATOLOGY  
PEER GROUP REPORT  
HORIBA INSTRUMENTS- H500/H550**Cycle-12/2023  
Round -5

Date: 24/11/2023

Lab Code: 3113

**Complete Blood Count (CBC)**

Parameters	Instrument Group	No. of Participants	Robust Mean	Robust Standard deviation (RSD)	Uncertainty of Assign Values	Range ( $\pm 2$ SD)	Your Value	Z Score
Hb gm/dl	Horiba	46	11.6	0.3	0.06	11.0-12.2	*10.4	-4.0
WBC $\times 10^3/\mu\text{l}$ .	Horiba	45	8.1	1.2	0.22	5.7-10.5	6.2	-1.6
RBC $\times 10^9/\mu\text{l}$ .	Horiba	46	4.2	0.2	0.04	3.8-4.5	3.76	-2.2
Hct%	Horiba	46	34.5	1.6	0.29	31.3-37.8	32.1	-1.5
MCV fl.	Horiba	46	83.0	2.3	0.42	78.5-87.6	85.5	1.1
MCH pg.	Horiba	46	28.2	0.9	0.17	26.5-29.9	27.7	-0.6
MCHC gm/dl	Horiba	46	33.9	1.3	0.24	31.3-36.5	32.4	-1.2
Platelet $\times 10^3/\mu\text{l}$ .	Horiba	46	268.9	19.0	3.50	231.0-306.9	244	-1.3

**Interpretation of Z Score:**

Z Score Value(+/-)	$ Z  \leq 2.0$	$2.0 <  Z  < 3.0$	$ Z  \geq 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
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Chief Coordinator

Dr. Sanjay Mehrotra

Checked By:

Programme Director

Dr. Bandana Mehrotra

**\*\*End of Report\*\***

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Continuous Efforts And Execution Leads To Quality Excellence

Title	INTER- INSTRUMENT / INTER-TECHNOLOGY ANALYSIS
Document Number	FRM.QCM.20
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Department Hematology. Month November. Year 2023

Date	Sample No. & Type	Parameter/ Analyte	SI Unit	Details of Instrument/ Technology-1	Results	Details of Instrument/ Technology-2	Results	Difference	%Difference	Acceptable Criteria as per ALP/ CLIA subpart 1	Acceptable/ Not Acceptable	Remarks (if any)
26/11/23	1.	HB	gm/dl	Yuvigen H555b	15.1	Yuvigen H555b	15.0	0.1	0.67%	± 1.0	Acceptable	
26/11/23	2.	HB	gm/dl	Yuvigen H555b	14.4	Yuvigen H555b	14.1	0.3	2.13%	± 1.0	Acceptable	

Performed By: [Signature] Reviewed By: N. Sanjay Kumar Approved By: [Signature]

### Results

**Run Date** 11/26/2023 11:09:14 AM

**Operator** LUPINLAB

**Last Name**

**Sample ID** HA00548106

**First Name**

**Rack/Pos** 039572/1

**Gender**

**Age**

**Department**

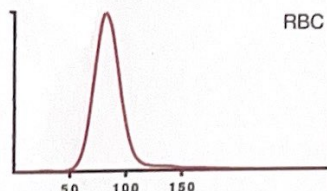
**Patient ID**

**Physician**

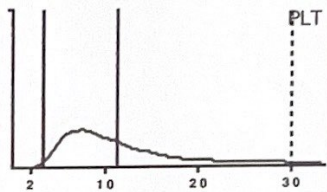
**Birth Date**

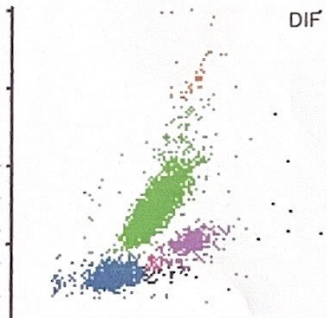
**Type** Standard

**Sample comments**

			Range	
<b>RBC</b>	4.93	10 <sup>6</sup> /μL	3.80 - 6.00	 <p style="text-align: right;">RBC</p>
<b>HGB</b>	15.1	g/dL	11.5 - 17.0	
<b>HCT</b>	44.6	%	35.0 - 52.0	
<b>MCV</b>	90.4	μm <sup>3</sup>	76.0 - 100.0	
<b>MCH</b>	30.6	pg	27.0 - 34.0	
<b>MCHC</b>	33.9	g/dL	32.0 - 35.0	
<b>RDW-CV</b>	10.7	%	11.0 - 17.0	
<b>RDW-SD</b>	36.1	μm <sup>3</sup>	37.0 - 49.0	

#### Alarms

			Range	
<b>PLT</b>	172	10 <sup>3</sup> /μL	150 - 400	 <p style="text-align: right;">PLT</p>
<b>PCT</b>	0.19	%	0.15 - 0.40	
<b>MPV</b>	11.1	h μm <sup>3</sup>	8.0 - 11.0	
<b>PDW</b>	17.1	μm <sup>3</sup>	11.0 - 22.0	
<b>P-LCC</b>	66	10 <sup>3</sup> /μL	44 - 140	
<b>P-LCR</b>	38.3	%	18.0 - 50.0	

			Range		
<b>WBC</b>	5.61	10 <sup>3</sup> /μL	3.50 - 10.00	 <p style="text-align: right;">DIF</p>	
	#				
<b>NEU</b>	2.95	1.60 - 7.00	52.6		40.0 - 73.0
<b>LYM</b>	2.05	1.00 - 3.00	36.7		15.0 - 45.0
<b>MON</b>	0.49	0.20 - 0.80	8.8		4.0 - 12.0
<b>EOS</b>	0.06	0.00 - 0.50	1.0		0.5 - 7.0
<b>BAS</b>	0.05	0.00 - 0.15	0.9		0.0 - 2.0
<b>LIC</b>	0.01	0.00 - 0.10	0.2		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

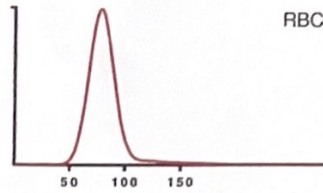
Sickle Cell

Platelet Clumps

**Results**

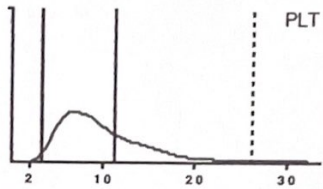
<b>Run Date</b>	11/26/2023 11:11:52 AM	<b>Operator</b>	LUPINLAB
<b>Last Name</b>		<b>Sample ID</b>	HA00548000
<b>First Name</b>		<b>Rack/Pos</b>	039572/3
<b>Gender</b>	<b>Age</b>	<b>Department</b>	
<b>Patient ID</b>		<b>Physician</b>	
<b>Birth Date</b>		<b>Type</b>	Standard
<b>Sample comments</b>			

			Range
<b>RBC</b>	5.06	10 <sup>6</sup> /μL	3.80 - 6.00
<b>HGB</b>	14.4	g/dL	11.5 - 17.0
<b>HCT</b>	43.4	%	35.0 - 52.0
<b>MCV</b>	85.7	μm <sup>3</sup>	76.0 - 100.0
<b>MCH</b>	28.4	pg	27.0 - 34.0
<b>MCHC</b>	33.1	g/dL	32.0 - 35.0
<b>RDW-CV</b>	12.0	%	11.0 - 17.0
<b>RDW-SD</b>	37.0	μm <sup>3</sup>	37.0 - 49.0

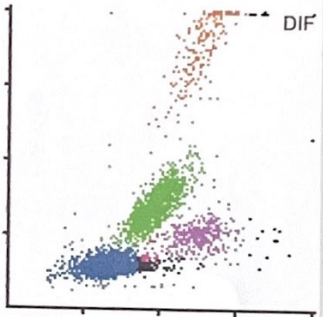


**Alarms**  
**Susp. Pathologies**  
 Neutropenia

			Range
<b>PLT</b>	211	10 <sup>3</sup> /μL	150 - 400
<b>PCT</b>	0.20	%	0.15 - 0.40
<b>MPV</b>	9.6	μm <sup>3</sup>	8.0 - 11.0
<b>PDW</b>	15.9	μm <sup>3</sup>	11.0 - 22.0
<b>P-LCC</b>	64	10 <sup>3</sup> /μL	44 - 140
<b>P-LCR</b>	30.3	%	18.0 - 50.0



			Range
<b>WBC</b>	6.73	10 <sup>3</sup> /μL	3.50 - 10.00
	<b>#</b>	<b>Range</b>	<b>%</b>
<b>NEU</b>	1.56 L	1.60 - 7.00	23.3   40.0 - 73.0
<b>LYM</b>	4.26 h	1.00 - 3.00	63.4 h   15.0 - 45.0
<b>MON</b>	0.51	0.20 - 0.80	7.7   4.0 - 12.0
<b>EOS</b>	0.32	0.00 - 0.50	4.8   0.5 - 7.0
<b>BAS</b>	0.05	0.00 - 0.15	0.8   0.0 - 2.0
<b>LIC</b>	0.03	0.00 - 0.10	0.5   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 |