HEMATOLOGY

ALL METHOD REPORT

Cycle-12/2023
Round -3

Lab Code: 1926

Date: 30/06/2023

Complete Blood Count (CBC)

Parameters	No.of Participants	Robust Mean	Robust Standard deviation (SD)	Uncertainty of Assign Values	Range (± 2 SD)	Your Value	Z Score
Hb gm/dl	289	11.6	0.4	0.03	10.8-12.4	11.3	-0.7
WBC × 10^3/µl.	287	11.3	0.7	0.05	9.9-12.7	*8.2	-4.4
RBC × 10^6/µl.	287	4.0	0.1	0.01	3.8-4.2	4.01	0.1
Hct%	286	35.1	2.4	0.18	30.4-39.8	32.8	-1.0
MCV fl.	286	86.9	4.9	0.36	77.1-96.7	81.8	-1.0
MCH pg.	286	28.9	1.0	0.07	26.9-31.0	28.2	-0.7
MCHC gm/dl	286	33.1	2.1	0.16	28.9-37.3	34.5	0.7
Platelet × 10^3/µl.	287	263.1	19.3	1.42	224.6-301.6	272	0.5

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

Peripheral Blood Smear(PBS):

	Your Result	Consensus Result
DLC	S-10, P-70, L-17, E-01, Mono-02	P-56.7-84.2, L-6.6-25.7, E-1.1-4.6, Mono- 1.1-4.5
Morphology	RBC are Normocytic and Normochromic predominantly. TLC- Increased. Platelets are markedly increased	ΔThrombocytosis (208/289) ΔNormocytic/ Normochromic (184/289) ΔLeukocytosis (173/289) ΔMicrocytic/Microcytosis/Microcytes (126/289) ΔHypochromia/Hypochromic (105/289)
Diagnosis	Leucocytosis with Thrombocytosis? Hemolytic Anemia	Thrombocytosis/Thrombocythemia/ Essential Thrombocytosis

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:

Doc. No.: ASS / FR / 06 / R 01 / Dt.: 05.01.2022

End of Report

RML Research Foundation
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HEMATOLOGY

METHOD WISE REPORT

Cycle-12/2023
Round -3

Lab Code: 1926

Date: 30/06/2023

Note: @ parameter is not the part of this Method Group

Complete Blood Count (CBC)

Parameters	Method Group	No.of Participants	Method Wise Robust Mean	Method Wise Robust Standard deviation (SD)	Method Wise Uncertainty of Assign Values	Method Wise Range (± 2 SD)	Your Value	Method Wise Z Score
Hb gm/dl@	Photometric	182	11.6	0.4	0.04	10.8-12.3	-	-
WBC × 10^3/µl. @	Electrical impedance	164	11.4	0.7	0.07	10.0-12.7	-	-
RBC × 10^6/µl. @	Electrical impedance	182	4.0	0.1	0.01	3.8-4.24	-	-
Hct% @	Calculated	177	35.2	2.3	0.22	30.5-39.8	-	-
MCV fl.	Calculated	122	86.8	5.5	0.62	75.9-97.8	81.8	-0.9
MCH pg.	Calculated	184	28.8	1.0	0.09	26.9-30.8	28.2	-0.6
MCHC gm/dl	Calculated	187	33.1	2.1	0.19	29.0-37.3	34.5	0.7
Platelet × 10^3/µl. @	Electrical impedance	177	263.3	18.7	1.76	225.8-300.8	-	-

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: LG

End of Report

Doc. No.: ASS / FR / 06A / R 01 / Dt.: 05.01.2022

RML Research Foundation

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Email: rmlresearchfoundation@gmail.com Website: www.rmlpathology.com

CORRECTIVE ACTION (CA) FORM

LABORATORY NAME:CSIR-Central Drug Research Institute

EPA ID: 1926

DEPARTMENT OR ANALYSIS TYPE: Submit corrective action report on Hematology outlier in the WBC report of May month 2023.

RESPONSIBLE SUPERVISOR / MANAGER: Dr Vivek V. Bhosale

PERSON COMPLETING CA FORM (NAME, TITLE): Dr (Mrs) Shail Singh

DATE: 19/07/2023

RECORD INFORMATION BELOW OR ATTACH ADDITIONAL SHEETS.
PROVIDE DOCUMENTATION WHENEVER POSSIBLE.

EVENT DESCRIPTION:

Problem: WBC found outlier in the WBC report of RML EQAS of May month 2023.

Corrective action:

1. Unsatisfactory performance of WBC needed action immediately
2. Instrument found in working condition.
3. Registered the call for an engineer visit. The engineer visited and ran controls of all levels i.e. normal, high, and low levels, and all the control, resulting in a mean range.
4. All the control resulted in mean range [16.6 in high level (18.8 to 16.4), 3.3 in low level (3.7 to 2.9) and 6.8 in normal level (7.5 to 6.5)]. He asked for calibration of the machine on an urgent basis as per corrective action.

Advice: Ask to RML EQAS from (Pear group mean)

EVENT RESPONSE / INVESTIGATION STEPS:

Registered the call for an engineer visit. The engineer visited and ran controls of all levels i.e. normal, high, and low levels, and all the control, resulting in a mean range. He asked for calibration of the machine on an urgent basis as per corrective action.

ROOT CAUSE DETERMINATION:

First list all possibilities of non conformities, and then select the most probable cause or causes.)

CORRECTIVE ACTION (CA) FORM

ACTION(S) TAKEN TO RESOLVE ISSUE AND PREVENT RECURRENCE: *Include SOP revision, stafftraining, purchase of standards, document/form revision, etc.*

Corrective Action(s)	Contact Person Responsible	Proposed Implementation Date	Date Completed	Evidence Of Completion
1. Unsatisfactory performance of WBC needed action immediately 2. Instrument found in working condition. 3. Registered the call for an engineer visit. The engineer visited and ran controls of all levels i.e. normal, high, and low levels, and all the control, resulting in a mean range. He gave some instructions related to the machine, which needs calibration on an urgent basis.	Mr Shashikant	19/7/23	19/7/23	Report attached
Additional Comments/Supplemental Information:				

Submitted By:		Date: 19-7-23
Reviewed By:	Responsible Supervisor or Manager	Date:

By signature and comments below, the QA Manager and Laboratory Director or Technical Manager approve thiscorrective action plan and the proposed implementation date(s) given. The QA Manager or designee will provide followupuntil the corrective action is closed with documentation/evidence of completion as noted above.

Approved By:
Quality Assurance Manager
Date:

Approved By:
Laboratory Director or Technical Manager
Date:

Reviewer Comments or Additional Actions Recommended:

Closing the Corrective Action: The QA Manager is responsible for effectiveness review. The CA should stay OPEN for a sufficient time to ensure all stated actions were taken and address/solve the initial issue.
Follow-up Review Notes:

Date:

Corrective Action Closed By QA Manager: Signature: Date: