

#### 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.: 1120 Distribution No.: 155-D Month/Year: February/2022

Instrument ID: Sysmax XN 3100 (41728)

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: 27-04-2022[Final].

#### **CBC** and Retic Assessment

				Amo	ng Lab (Ac	curacy Testi	ng)	With	in Lab (Pre	ecision Testin	ng)
Test Parameters	S.No.	Your Result 1	Your Result 2	Your Results Sum of 2 Value	Consensus result sum of 2 values (Assigned Value)	Uncertainty of Assigned Values		Yours Results Diff. of 2 Values	Consensus Result Diff. of 2 values (Assigned Value)	Uncertainty of Assigned Values	
WBC x10³/μl	1	3.24	3.21	6.45	7	0.0290	-0.69	0.03	0.1	0.0070	-0.56
RBC x10 <sup>6</sup> /μl	1	3.69	3.65	7.34	7.33	0.0080	0.04	0.04	0.03	0.0020	0.27
Hb g/dl	1	13.5	13.5	27	26.7	0.0210	0.51	0	0.1	0.0070	-0.67
НСТ%	1	42.8	42.6	85.4	84	0.1430	0.32	0.2	0.4	0.0230	-0.45
MCV-fl	1	116.7	116	232.7	227	0.2950	0.58	0.7	0.3	0.0250	0.90
МСН-Рд	1	37	36.6	73.6	72.8	0.0800	0.37	0.4	0.3	0.0190	0.45
MCHC-g/dl	1	31.7	31.5	63.2	63.65	0.1130	-0.13	0.2	0.3	0.0180	-0.34
Plt. x10³/μl	1	196	194	390	401.5	1.40	-0.30	2	5	0.31	-0.58
Retic %	2	12	11.5	23.5	16	0.28	1.09	0.5	0.5	0.03	0.00

#### P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3		Poly: 40 - 60, Myelo: 10 - 25, Meta: 5 - 20, Promyelo: 1-10, nRBC/Lympho/Blast/Eos/Baso/Mono: 0 - 5
RBC Morphology	3		Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, hypochromia, Microcytosis; Mild: Macrocytosis, Poikilocytosis
Diagnosis	3	Chronic Myeloid Leukemia (Chronic Phase)	Chronic Myeloid Leukemia (Chronic Phase)

#### COMBINED DATA VALUES OF TOTAL PARTICIPANTS

T	C.N.	Total participants	Total No.	% of Lab		% of Lab	os with Z e 2-3	% of Lab Scor	
Test parameters	5.NO.	covered in the current dist. 155D	responded	Among labs	Within lab	Among labs	Within lab	Among labs	Within lab
WBC x10³/μl	1	354	347	87.61	86.46	4.03	3.75	8.36	9.79
RBC x10 <sup>6</sup> /μl	1	354	354	88.98	88.7	5.08	3.67	5.94	7.63
Hb g/dl	1	354	354	84.18	84.75	5.93	5.93	9.89	9.32
HCT%	1	354	347	94.24	90.2	3.17	3.46	2.59	6.34
MCV-fl	1	354	346	96.53	89.6	1.16	3.76	2.31	6.64
MCH-Pg	1	354	347	87.9	87.61	6.63	5.76	5.47	6.63
MCHC-g/dl	1	354	347	94.81	85.3	3.75	5.19	1.44	9.51
Plt. x10³/μl	1	354	347	88.76	91.64	8.36	2.88	2.88	5.48
ReticCount%	2	354	354	83.33	85.59	5.65	4.52	11.02	9.89
PS Assessment	3	354	333	Satisfactory	:93.58%, Bo	orderline Sat	t. :4.53%, Uı	nsatisfactory	:1.89%

\*Comments:

1). Among Lab (EQA): Results acceptable.

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  $\pm$ 2: Acceptable, Z score  $\pm$ 2 to  $\pm$ 3: Warning Signal, Z score >  $\pm$ 3: Unacceptable [As per ISO/IEC 13528:2015 standard]

Note-4: Z score value between "0 to  $\pm 2$ " are texted in green colour. Z score value between " $\pm 2$  to  $\pm 3$ " are texted in orange colour. Z score value  $> \pm 3$  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  $(\overline{x}-\overline{y})$  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.

Report authorized by,

Lyle

Dr. Seema Tyagi (Prof.)

PT Co-ordinator: ISHTM-AIIMS-EQAP

Department of Hematology, AIIMS, New Delhi

-----End Of Report-----



## **Unacceptable Results Investigation**

Accident /Incident Reporting form

## 1.Accident reporting

The WBC parameter in the AIIMS hematology EQA was found to be unsatisfactory with Z score of 2.58 among labs and Z score of 8.81 within lab which was released on 22-02-2022.

Reported by

Name & Sign: Dr Nikhil Sanjay Deshpande

Date & Time: 23-02-2022 at 10.00am.

## 2. Immediate action taken

The EQA report was analysed. Routine IQC samples were run and were found satisfactory. Further to find out the cause for EQA unsatisfactory result root cause analysis was undertaken in a step wise manner.

Action taken by

Name & Sign: Dr Nikhil Sanjay Deshpande

Date & Time: 23-02-2022 at 10.30am.

Reviewed by: Dr N N Angarkar

#### 3. Root cause analysis

The following steps were analysed to reach the root cause analysis of the unsatisfactory results.

i. Check for transcription errors

ii. Check for pre survey issues

iii. Sample receipt / handling

iv. Test performance

v. Data handling by EQA provider



# **Unacceptable Results Investigation**

### vi. Report and Interpretation.

As per these steps, after thorough discussion, it was concluded that the unsatisfactory results may be due to overmixing of the EQA sample before the run may be the cause for the deviation of WBC parameter. Rest all steps were satisfactory.

Action taken by

Name & Sign: Dr Nikhil Sanjay Deshpande

Date & Time: 24-02-2022 at 11.00am.

Reviewed by: Dr N N Angarkar

### 4. Corrective and preventive measures

To prevent the same from happening again, in next cycle EQA samples will be handled carefully and according the EQA guidelines. Proper mixing of the sample will be insured by the technical persons and supervised by the lab manager.

Designation

Dr.Nikhil S.Deshpande
Associate Professor
Department of Pathology
Dr.Balasaheb Vikhe Patil
Rural Medical College, Loni
PIMS (DU), Loni Bk, 413236

5. N. Jayle 24/02/2022 11.30 am

**Dr.S.N.JANGLE**Prof. & H.O.D. Biochemistry
Rural Medical College, PMT

Tal.Rahata, Dist. A'Nagar-413736

Incharge CCL- Blochemistry PMT,RMC,Loni