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

NABL Certificate No. PC - 1002

Duration of stability testing - minimum upto 8 days at ambient temp. after dispatch of specimens

EQAP CODE No. : 3654 **Distribution No.:** 151-J **Month/Year:** December/2020

Instrument ID: XP 100 B7428

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: 11-01-2021[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	4.2	4.2	8.4	8.4	0.0310	**0.00**	0	0.1	0.0110	**-0.81**
RBC x10^6/µl	1	5.19	5.18	10.37	10.21	0.0160	**0.40**	0.01	0.04	0.0350	**-0.52**
Hb g/dl	1	9.7	9.7	19.4	19	0.0310	**0.67**	0	0.1	0.0080	**-1.35**
HCT%	1	31.5	31.4	62.9	60.2	0.1690	**0.70**	0.1	0.3	0.0330	**-0.45**
MCV-fl	1	60.7	60.6	121.3	118.4	0.2120	**0.62**	0.1	0.3	0.0270	**-0.45**
MCH-Pg	1	18.7	18.7	37.4	37.4	0.0680	**0.00**	0	0.2	0.0120	**-1.35**
MCHC-g/dl	1	30.9	30.8	61.7	63.5	0.1590	**-0.51**	0.1	0.3	0.0260	**-0.45**
Plt. x10^3/µl	1	201	197	398	417.5	2.09	**-0.40**	4	8.5	0.65	**-0.47**
Retic %	2	19.8	18.4	38.2	17.4	0.41	**2.21**	1.4	0.6	0.05	**1.54**

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=NIL , Poly=04 L=96, E=NIL, Mono/Promono=NIL , B1=NIL P.M.=NIL, Mye=NIL, Meta=NIL, Other=	Blasts: 70-80, Lymph: 5-15, Poly: 2-5, nRBC/Eo/Mono/Pro/My/Meta: 0-5
RBC Morphology	3	Normocytic Normochromic	Predominantly: Normocytic Normochromic, Moderate: Anisocytosis, Mild: Microcytic.
Diagnosis	3	Chronic Lymphoproliferative Disorder2020	Acute Leukemia (Lymphoblastic).

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COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist.	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	350	224	82.59	80.8	3.13	4.02	13.84	14.29
RBC x10^6/µl	1	350	224	88.39	89.29	4.02	3.57	6.7	6.25
Hb g/dl	1	350	224	82.59	91.07	6.7	3.57	10.27	4.91
HCT%	1	350	224	89.29	89.73	5.8	2.23	4.02	7.14
MCV-fl	1	350	224	87.05	90.18	6.7	4.02	5.36	4.91
MCH-Pg	1	350	224	86.61	85.27	7.14	4.46	5.36	9.38
MCHC-g/dl	1	350	224	88.39	87.05	8.48	6.25	2.23	5.8
Plt. x10^3/µl	1	350	224	93.3	93.3	3.57	3.13	2.23	3.13
ReticCount%	2	350	199	93.97	81.91	4.52	16.08	1.51	4.02
PS Assessment	3	350	209	Acceptable:81.9%,Warning Signal:8.6%,Unacceptable :9.5%					

***Comments:**

1). Among Lab (EQA) : Wrongly Reported PS ,remaining 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 ±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.

Report authorized by,

Dr. Seema Tyagi (Prof.)
PT Co-ordinator: ISHTM-AIIMS-EQAP
Department of Hematology, AIIMS, New Delhi

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

Response of mail dated 24th february to Sure diagnostic specialized lab

Dr. Sumedha Mengi <surediagnosticlab@gmail.com>

Sat 2/27/2021 11:24 AM

To: NABL M(EL)T <nablmelt@nabl.qcin.org>

5 attachments (2 MB)

calibration data.pdf; raw data calibration.pdf; precision report.pdf; raw data precision.pdf; installation report haematology analyzer.jpg;

Dear Concerned,
Please find below response against each point mentioned by NABL

NABL Query : Please send the raw data that has been observed during calibration for the Haematology Analyzer as requested
Lab response : please find attached herewith calibration Raw data of Haematology analyzer.

NABL Query : Haematology EQAS result. Wrongly reported PS (Peripheral smear) is mentioned ,please check and clarify the same.
Lab Response : As a part of corrective action after receiving an outlier in reporting of PS,we have re-reviewed the provided slide for PS Reporting .It was observed that there were lots of staining artifacts which leads to wrong reporting.We have contacted EQAS provider through mail and shared our concern with our feedback to EQAS provider. copy of the same attached herewith for your quick reference.

NABL Query : Please send Installation Qualification, operational qualification and performance qualification for the haematology analyzer.
Lab Response : Instrument was installed about 2 years back (02-01-2019) and at the time of installation we have received only installation report (copy attached) .We are maintaining instrument by calibrating the same as per manufacturer recommendations ie once on a year (copy of calibration report attached) and by running IQC on regular basis.Also we are participating in AIIMS EQAS ,results of the same already provided.

Dr Sumedha Mengi
Director cum Chief Pathologist
Sure Diagnostic specialized Lab
Bahu Plaza
9419211194, 0191-2476194

PS reporting of EQAP 3654

Add label

Dr. Sumedha Mengi 6:54 pm

to EQAP

Dear Team
We have reviewed the slide send by EQAS team and found staining artifact in the slide due to which Blast couldn't be diagnosed properly.
We are requested to review the process of sending stained slides to avoid these kind of challenges .

Sure Diagnostic Specialized lab
Enrollment no 3654

Draft 6:54 pm

--------- Forwarded message --------- From: Dr. Sumedha Mengi Date: Mon, 22 Feb 2021, 6:54