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. : 598 **Distribution No.:** 164-B **Month/Year:** May/2024

Instrument ID: Horiba **Model Name.:** Yumizenh550 **Serial No.:** 302YADr105317

Name & Contact No. of PT Co-ordinator: Dr. Manoranjan Mahapatra (Prof. & Head), Hematology, AIIMS, Delhi, Tel: 9013085730 , E-Mail : info@ishtmaiimseqap.com

Date of issue & status of the report: 15-07-2024[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	4.8	3.8	8.6	11.24	0.052	**-1.80**	1	0.1	0.006	**7.59**
RBC x10^6/µl	1	3.17	3.16	6.33	6.39	0.011	**-0.20**	0.01	0.03	0.002	**-0.67**
Hb g/dl	1	10.4	10.4	20.8	20.7	0.035	**0.10**	0	0.1	0.006	**-1.35**
HCT%	1	30.7	30	60.7	63.6	0.177	**-0.56**	0.7	0.3	0.016	**1.35**
MCV-fl	1	97	97	194	197.9	0.340	**-0.38**	0	0.3	0.019	**-1.01**
MCH-Pg	1	33	30.2	63.2	64.8	0.066	**-0.86**	2.8	0.2	0.014	**8.77**
MCHC-g/dl	1	34	34	68	65.1	0.138	**0.71**	0	0.3	0.017	**-1.01**
Plt. x10^3/µl	1	87	82	169	216	1.010	**-1.67**	5	4	0.199	**0.27**
Retic %	2	12	10	22	30	0.416	**-0.60**	2	0.6	0.042	**1.84**

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=05 , Poly=07 L=04, E=08, Mono/Promono=01 , B1=04 P.M.=02, Mye=25, Meta=12, Other=Nill	Poly: 19 – 36, Myelo: 20 - 37, Lympho: 5 – 12, Meta: 7–17, Promyelo: 2-10, Eosino: 2-7, Mono: 1-3, Blast: 2 - 5, Baso: 0-5
RBC Morphology	3	Normocytic normochromic rbc with 5n rbc/100 wbc seen	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, Mild: Polychromatophils (+), Poikilocytosis, Macrocytes
Diagnosis	3	Myeloproliferative neoplasm : chronic myelogenous leukemia - chronic phase	MPN likely CML-CP

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 164--B	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	389	388	86.6	87.37	6.19	5.41	7.21	7.22
RBC x10^6/µl	1	389	389	83.03	88.17	3.34	4.37	13.63	7.46
Hb g/dl	1	389	389	81.49	93.83	3.6	3.08	14.91	3.09
HCT%	1	389	389	87.4	88.43	9.25	7.46	3.35	4.11
MCV-fl	1	389	389	91.52	86.12	3.34	8.74	5.14	5.14
MCH-Pg	1	389	389	86.89	92.8	7.2	3.86	5.91	3.34
MCHC-g/dl	1	389	389	89.72	93.83	6.94	3.6	3.34	2.57
Plt. x10^3/µl	1	389	389	87.15	93.57	9.51	3.34	3.34	3.09
ReticCount%	2	389	362	95.58	93.92	3.59	2.76	0.83	3.32
PS Assessment	3	389	363	Satisfactory :92.02%, Borderline Sat. :3.09%, Unsatisfactory :4.89%					

***Comments:**

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

2). Within Lab (IQA) : Difference in the CBC measurement values for *WBC & MCH* unacceptable, please check precision/human error. Remaining 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----------

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

PC-1002

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

EQAP CODE No. : 598 **Distribution No.:** 163-B **Month/Year:** February/2024

Instrument ID: HORIBA **Model Name.:** YUMIZEN H550 **Serial No.:** 302YADH05317

Name & Contact No. of PT Co-ordinator: Dr. Manoranjan Mahapatra (Prof. & Head), Hematology, AIIMS, Delhi, Tel: 9013085730 , E-Mail : info@ishtmaiimseqap.com

Date of issue & status of the report: 29-04-2024[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	5.73	4.73	10.46	13.75	0.022	**-5.54**	1	0.1	0.007	**7.14**
RBC x10^6/µl	1	5.24	5.23	10.47	10.26	0.008	**0.81**	0.01	0.04	0.002	**-0.81**
Hb g/dl	1	13	12.8	25.8	25.4	0.017	**1.08**	0.2	0.1	0.007	**1.35**
HCT%	1	35.9	35.8	71.7	78.8	0.111	**-2.19**	0.1	0.3	0.021	**-0.67**
MCV-fl	1	68.7	68.3	137	153.7	0.180	**-3.04**	0.4	0.2	0.018	**0.67**
MCH-Pg	1	24.9	24.4	49.3	49.6	0.040	**-0.25**	0.5	0.2	0.011	**2.02**
MCHC-g/dl	1	36.2	35.7	71.9	64.4	0.096	**2.53**	0.5	0.3	0.011	**0.67**
Plt. x10^3/µl	1	116	113	229	220	1.479	**0.19**	3	5	0.320	**-0.34**
Retic %	2	8	5	13	24	0.321	**-1.13**	3	0.5	0.032	**4.22**

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=04 , Poly=17 L=06, E=03, Mono/Promono=02 , B1=67 P.M.=01, Mye=03, Meta=01, Other=	Blast: 38-66, Poly: 11.75-20, Myelo: 4-15, Meta: 3-10, Promyelo: 1-10, Lympho: 3-7, Mono: 1-4, nRBC/Eos/Baso : 0-5
RBC Morphology	3	Normocytic Normochromic with few macrocytes, polychromatophils and 4 RBS/100 WBC seen	Predominantly: Normocytic/Normochromic, Moderate: Anisocytosis, Mild: Macrocytes, poikilocytosis
Diagnosis	3	Acute Leukemia Morphologically Myeloid(AML)	Acute Leukemia likely Acute Myeloid Leukemia

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 163--B	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	379	378	85.19	88.1	5.03	7.41	9.78	4.49
RBC x10^6/µl	1	379	379	91.29	91.29	5.8	3.43	2.91	5.28
Hb g/dl	1	379	379	83.91	92.35	7.65	3.17	8.44	4.48
HCT%	1	379	378	92.33	89.15	5.29	4.76	2.38	6.09
MCV-fl	1	379	377	93.1	86.21	5.04	8.75	1.86	5.04
MCH-Pg	1	379	377	88.59	95.76	6.63	1.59	4.78	2.65
MCHC-g/dl	1	379	377	94.16	91.51	3.98	3.98	1.86	4.51
Plt. x10^3/µl	1	379	378	91.8	87.83	7.67	7.14	0.53	5.03
ReticCount%	2	379	352	95.17	85.51	3.69	10.23	1.14	4.26
PS Assessment	3	379	358	Satisfactory :93.42%, Borderline Sat. :1.84%, Unsatisfactory :4.74%					

***Comments:**

1). Among Lab (EQA) : CBC result for *WBC & MCV* unacceptable, please check calibration/human error.Remaining results acceptable.

2). Within Lab (IQA) : *WBC & RETIC* unacceptable, please check precision/human error. Remaining precision acceptable.

Note-1: EQA (External Quality Assurance) : Your Performance among various of participating labs in PT, to determine the accuracy of your results.
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Report authorized by,

Dr. Manoranjan Mahapatra (Prof. & Head)
PT Co-ordinator: ISHTM-AIIMS-EQAP
Department of Hematology, AIIMS, New Delhi

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

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1st April 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) programs and Metropolis(MHL). There are large number of users across the globe including India using Bio-Rad(EQAS)& Randox(RIQAS) and Metropolis(MHL)successfully.

However, we had received few concerns from users regarding 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.

Thank you for your continued trust in HORIBA Medical products & let us know should you need any additional information.

HORIBA INDIA PVT. LTD. NEW DELHI

Thanking with Regards

Parul Babbar
Product Manager