Neu-QAP

(an EXTERNAL QUALITY ASSURANCE PROGRAMME)

PC-1047

PARTICIPANT FINAL ASSESSMENT REPORT (SUMMARY)

PT SCHEME:HEMATOLOGY

Cycle No	*C3*
Ref.No.	NEUQAP109
Sample ID	*NEUQAP HEM BLOOD/2021/7/C3/S7*

Report Date : 10/08/2021

Sample : JUL 2021

All Methods

	Parameters	Labs (n)	Lab Value	Unit	Assigned value	SDPA	Um	Z-Score	Remarks
1	TOTAL COUNT	42	**2.43**	10^3/cumm	5.57	1.00	0.194	3.12	Unsatisfactory
2	Eosinophils	38	**4.70**	%	2.93	0.63	0.129	2.78	Questionable
3	HEMOGLOBIN	44	**10.90**	g/dL	10.69	0.20	0.038	1.03	Satisfactory
4	RBC	45	**3.79**	10^6/cumm	3.70	0.06	0.012	1.35	Satisfactory
5	AEC	30	**0.11**	10^3/cumm	0.17	0.04		1.32	Satisfactory
6	Lymphocyte	38	**56.60**	%	47.05	8.30	1.683	1.15	Satisfactory
7	PLATELET COUNT	42	**301.00**	10^3/cumm	281.90	21.16	4.082	0.90	Good
8	MCV	45	**87.90**	fl	89.81	2.50	0.466	0.77	Good
9	MCH	44	**28.80**	pg	28.73	0.62	0.117	0.11	Good
10	MCHC	45	**32.80**	g/dL	31.94	1.08	0.200	0.80	Good
11	Neutrophils	38	**32.90**	%	41.65	12.24	2.482	0.72	Good
12	Monocyte	38	**5.00**	%	5.44	2.30	0.466	0.19	Good
13	Basophils	38	**0.80**	%	1.32	1.09	0.221	0.47	Good
14	Hematocrit	36	**33.30**	%	33.37	0.87	0.181	0.08	Good
15	ANC	30	**Not Recvd.**	10^3/cumm	2.49	0.90	0.206		N/A
16	ALC	30	**Not Recvd.**	10^3/cumm	2.63	0.38	0.086		N/A
17	CD4	0	**Not Recvd.**	cells/dl					N/A

* denotes adjusted SDPA as per ISO 13528:2015(E)

SDPA - Standard Deviation for Proficiency Assessment

Authorised Signatory

Dr. Sujay Prasad

Technical Manager and Program coordinator

An external quality assurance program from
NEUBERG ANAND ACADEMY OF LABORATORY MEDICINE PVT.LTD.

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RCA FORM OF ILC / PT / EQAS OUTLIERS

Department: HEMATOLOGY **Date:** 31/08/2021.

1. Proficiency test exception for: TOTAL WBC COUNT & EOSINOPHIL COUNT.
2. Proficiency test provider: NEV-QAP
3. Proficiency test analyte group:
4. Cause for PT exception:

   Machine Related

5. How did the section investigate the cause:

   QC of the day along with 24hr retention on random sample were analysed & found to be satisfactory

6. What was the status of the internal QC on the day PT initially analysed:

   QC passed and within acceptable limits.

7. Category into which the cause will fit into:

   A. Method
   B. Technical
   C. Clerical
   D. Problem with PT material Other
   (E.) No explanation after investigation

   (1) Yumizen H500 provider was contacted for the same who has provided an explanation for the recurring outlier. The certificate is enclosed herewith.

8. Evidence that the problem was corrected successfully:

9. Specific corrections taken to prevent the recurrence if possible:

   (2) Interlab comparison done & reports enclosed.

10. Signatures :

    (3) We are also participated with AIIMS PT report attached

    Quality manager:

    Pathologist:

Troubleshooting Guidelines

Method	Technical	Clerical	Problem with PT material	No explanation after investigation
Equipment function checks	Misinterpretation / Wrong identification / Wrong labeling	Transcription error	Leaked / broken vial / not fit for analysis	Use this choice only when the investigation has yielded no satisfactory explanation
Scheduled maintenance not carried out or out of acceptable range	Dilution error / incorrect pipetting	Registration of wrong method or method change is not updated	Bacterial contamination	
Problem with data processing functions	Time delay between reconstitution and analysis		Perceived survey bias / inappropriate target value	
Faulty standard or other reagent	Calculation error			
Incorrect calibration	Analysis accepted in nonlinear range		Unstable material	
Carry over from previous specimen	Analysis done even though controls were out of range or controls not assayed		Matrix effect incompatible with method	
Result close to the detection limit of method	QC data within acceptable limits but showed trend suggestive of problem with the assay		No comparable peer group	
			Acceptable range too low	
	Sample mix up		Late shipment	
Other method related problem	Other technical problem		Improper package and temperature control	

Note: When all identifiable sources of error have been excluded, a single unacceptable result may be attributed to random error, particularly when the result of repeat analysis is acceptable. In such cases, no corrective action should be taken; as such an action may actually increase the probability of a future unacceptable result.

HORIBA

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https://www.horiba.com
CIN : U73100DL2006PTC153232

14th, April 2021

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. There are large number of users across the globe including India using Bio-Rad (EQAS) & Randox (RIQAS) successfully.

However, we had received few concerns specially with non-correlation of WBC counts from customers enrolled with 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. However, our technical team is working on the same and any development would be shared shortly.

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

HORIBA India Private Limited New Delhi

Thanking with Regards

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. : 2888 **Distribution No.:** 152-G **Month/Year:** March/2021

Instrument ID: PD-YH/LME/HEM/01-803YOXH01348

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: 12-05-2021[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	9.34	9.24	18.58	29.12	0.0870	-5.79	0.1	0.2	0.0150	-0.59
RBC x10^6/µl	1	4.52	4.45	8.97	9.12	0.0090	-0.72	0.07	0.04	0.0020	0.81
Hb g/dl	1	11.9	11.8	23.7	23.4	0.0260	0.58	0.1	0.1	0.0080	0.00
HCT%	1	39.7	38.3	78	77.8	0.1760	0.05	1.4	0.4	0.0280	2.70
MCV-fl	1	87.7	86	173.7	171.3	0.3280	0.30	1.7	0.3	0.0250	3.78
MCH-Pg	1	26.6	26.3	52.9	51.5	0.0620	0.98	0.3	0.2	0.0140	0.45
MCHC-g/dl	1	30.9	30	60.9	59.85	0.1410	0.30	0.9	0.3	0.0200	2.02
Plt. x10^3/µl	1	814	805	1619	1723.5	5.77	-0.80	9	12	0.95	-0.23
Retic %	2	17.7	17	34.7	23.5	0.46	0.99	0.7	0.5	0.05	0.24

P.S . Assesment

	YOUR REPORT		CONSENSUS REPORT
DLC%	3	Nrbcs=03 , Poly=05 L=03, E=00, Mono/Promono= , B1=55 P.M.=03, Mye=06, Meta=08, Other=Monocytoid cells-20	Blast: 20-80, Mono: 1-30, Poly: 10-25, Lympho: 5-15, Myelo/Promyelo/Meta: 1-5, nRBC/Eos: 0-1
RBC Morphology	3	Normocytic hypochromic with few microcytes, elliptocytes and tear drop cells	Predominantly: Normocytic/Normochromic; Moderate: Microcytosis, Hypochromia; Mild: Anisocytosis, Macrocytosis
Diagnosis	3	Acute Myeloid Leukemia(M4). Suggested flow cytometry for confirmation.	Acute Myeloid Leukemia (AML)

EQAP Code No.: 2888 *Distribution No.: 152-G* *Month/Year: March/2021* *Instrument ID: PD-YH/LME/HEM/01-803YOXH01348*

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 $x10^3/\mu l$	1	214	232	87.5	90.95	3.02	3.02	9.48	5.6
RBC $x10^6/\mu l$	1	214	232	88.79	92.24	6.9	2.59	4.31	4.74
Hb g/dl	1	214	231	85.71	149.35	6.93	4.76	7.36	0.87
HCT%	1	214	232	93.53	89.22	5.6	5.6	0.86	5.17
MCV-fl	1	214	232	96.55	84.48	3.45	9.48	0	6.03
MCH-Pg	1	214	232	86.64	77.16	8.19	18.53	5.17	3.88
MCHC-g/dl	1	214	232	93.53	88.36	4.74	6.03	1.72	4.74
Plt. $x10^3/\mu l$	1	214	232	85.78	89.22	9.91	3.45	4.31	7.33
ReticCount%	2	214	214	96.73	92.99	2.34	5.14	0.93	2.34
PS Assessment	3	214	214	Acceptable:80.8,Warning Signal:10.3,Unacceptable :8.9					

***Comments:**

1). Among Lab (EQA) : CBC result for *WBC* unacceptable, may be due to random/human error

2). Within Lab (IQA) : Difference in the CBC measurement values for *MCV* unacceptable, may be due to random/human error.

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----------

PRIMA DIAGNOSTICS
JAYANAGAR
ISO 9001 : 2015 Certified

Name	: Mr. INTERLAB COMPARTION -2	Ref. Doctor	: DR. SELF	Registered Date	: 26/08/2021 02:46 PM
Age / Sex	: 23 Year(s) / Male	Client	: Yelahanka	Collected On	: 26/08/2021 03:20 PM
Patient ID	: PDY052063			Received On	: 26/08/2021 03:21 PM
Visit No.	: 21YP99164			Reported On	: 26/08/2021 06:46 PM

21YP99164

Report Type : Final

Test	Results	Units	Biological Reference Range
HEMATOLOGY			
CBC - Complete Blood Count			
CBC			
Haemoglobin - Whole Blood Photometric (SLS Hemoglobin)	15.3	g/dL	13.5-18.0
Red blood cell count - Whole Blood Electrical impedance	4.97	million/cu.mm	4.2-6.5
Hematocrit(PCV) - Whole Blood Electrical impedance	46.1	%	39-54
Mean Corpuscular Volume(MCV) - Whole Blood Calculated from HCT and RBC	92.8	fL	75-95
Mean Corpuscular Hemoglobin(MCH) - Whole Blood Calculated from RBC and Hb	30.8	pg	26-32
Mean Corpuscular Hemoglobin Concentration (MCHC) - Whole Blood Calculated from HCT and Hb	33	g/dL	30-35
Red cell distribution width (RDW)-CV - Whole Blood Calculated	14.3	%	11.6-14.6
Platelet count - Whole Blood Electrical impedance	1.88	lakh/cu.mm	1.50-4.40
Total WBC count - Whole Blood	9400	cells/cu.mm	4000-11000
Absolute Basophil Count - Whole Blood Flow Cytometry	**0.10**	10^3 / µl	0.01-0.05
Absolute Eosinophil Count - Whole Blood Flow Cytometry	**1.20**	10^3 / µl	0.02-0.50
Absolute Lymphocyte Count - Whole Blood	2.40	10^3 / µl	1-3

Dr. Shreya Prabhu,
Pathologist
KMC-No:114274

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21YP99164

Report Type : Final

Flow Cytometry			
Absolute Neutrophil Count - Whole Blood Flow Cytometry	4.90	10^3 / µl	2-7
Absolute Monocyte Count - Whole Blood Flow Cytometry	0.70	10^3 / µl	0.2-1.0
DIFFERENTIAL COUNT - DC - Whole Blood Flow Cytometry/Microscopy			
Neutrophils	52.5	%	40-75
Lymphocytes	26.1	%	20-45
Monocytes	7.7	%	1-10
Eosinophils	**13.0**	%	1-6
Basophils	0.7	%	0-1

IMMUNOLOGY

T3 (TOTAL) - Serum CLIA	1.59	ng/mL	Newborn : 0.7-2.0 < 1 Year: 1.0-2.4 1 - 5 Years : 1.0-2.4 6 - 10 Years: 0.9-2.4 11 - 50 Years: 0.7-2.0 > 50 Years: 0.4-1.8 First Trimester: 0.8-1.9 Second Trimester: 1.0-2.6

SEROLOGY

RAPID PLASMA REAGIN (RPR) / VDRL - Serum
Slide Flocculation

RAPID PLASMA REAGIN RPR / VDRL	Non Reactive		

Dr. Shreya Prabhu,
Pathologist
KMC No:114274

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21YP99164

Report Type : Final

Test	Results	Units	Biological Reference Range
BIOCHEMISTRY			
Alanine Transaminase(ALT/ SGPT) - Serum IFCC without P-5-P	14.0	U/L	0-55
Alkaline Phosphatase - Serum IFCC PNPP	51.0	U/L	Male: 13 - 15 Year(s) : < 750 Both: 0 - 12 Year(s) : < 500 Both: 16 - 120 Year(s) : 40 - 150
Cholesterol Total - Serum CHOD-POD	158.00	mg/dl	Desirable: < 200 Borderline High: 200-239 High: > 240
Gamma-Glutamyl Transferase (GGT) - Serum Gamma--Glutamyl-p-nitroanilide IFCC	9.0	U/L	12-64
HDL Cholesterol - Serum Accelerator selective detergent	42.00	mg/dL	40-60
ELECTROLYTES (Na+, K+, Cl) - Serum ISE indirect			
SODIUM (Na+)	139	mmol/L	135-148
POTASSIUM (K+)	3.9	mmol/L	3.5-5.3
CHLORIDE(Cl-)	106	mmol/L	98-107

-- End of Report --

Kindly correlate clinically. If necessary discuss/repeat

Ramakrishna

Mr. Ramakrishna.B,
Biochemist

PRIMA DIAGNOSTICS
YELAHANKA

Name	: Mr. INTERLAB COMPARTION -1	Ref. Doctor	: DR. SELF	Registered Date	: 26/08/2021 02:42 PM
Age / Sex	: 22 Year(s) / Male	Client	: Walk-in	Collected On	: 26/08/2021 02:43 PM
Patient ID	: PDY052062			Received On	: 26/08/2021 02:43 PM
Visit No.	: 21YP99163			Reported On	: 27/08/2021 12:08 PM

21YP99163

Report Type : Final

Test	Results	Units	Biological Reference Range
HEMATOLOGY			
CBC - Complete Blood Count			
CBC			
Haemoglobin - EDTA Whole Blood Spectrophotometry	15.8	g/dL	13.5-18
Red blood cell count - EDTA Whole Blood RBC Histogram(Volume)	4.8	million/cu.mm	Male: 4.2-6.5 Female: 3.7-5.6
Hematocrit(PCV) - EDTA Whole Blood RBC Pulse Height detection	44.7	%	Male: 39-54 Female: 34-48
Mean Corpuscular Volume(MCV) - EDTA Whole Blood Calculate From RBC Histogram	94.2	fL	75-95
Mean Corpuscular Hemoglobin(MCH) - EDTA Whole Blood Calculated From RBC and HGB	32.0	pg	26-32
Mean Corpuscular Hemoglobin Concentration (MCHC) - EDTA Whole Blood Calculated From HGB and HCT	35.0	g/dL	30-35
Red cell distribution width (RDW)-CV - EDTA Whole Blood Calculated	13.2	%	11.6-14.6
Platelet count - EDTA Whole Blood Platelet Histogram(Volume)	2.05	lakh/cu.mm	1.50-4.40
Total WBC count - EDTA Whole Blood Double Hydrodynamic Sequential System(DHSS)	8880	cells/cu.mm	4000-11000
Absolute Basophil Count - EDTA Whole Blood Flow Cytometry	0.02	10^3 / µl	0.01-0.05
Absolute Eosinophil Count - EDTA Whole Blood	1.06	cells/cu.mm	0.01-0.50

Dr. Seema Umarji
MBBS MD, Pathologist.
KMC NO:95296

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21YP99163

Report Type : Final

Double Hydrodynamic Sequential System(DHSS) Absolute Lymphocyte Count - EDTA Whole Blood Double Hydrodynamic Sequential System(DHSS) -	2.29	cells/cu.mm	1-3
Absolute Neutrophil Count - EDTA Whole Blood Flow Cytometry	4.90	10^3 / µl	2-7
Absolute Monocyte Count - EDTA Whole Blood Flow Cytometry	0.61	10^3 / µl	0.2-1.0

DIFFERENTIAL COUNT - DC

Neutrophils - EDTA Whole Blood DHSS / Microscopy	55	%	40-75
Lymphocytes - EDTA Whole Blood DHSS / Microscopy	26	%	20-45
Monocytes - EDTA Whole Blood Flow Cytometry/Microscopy	06	%	1-10
Eosinophils - EDTA Whole Blood DHSS / Microscopy	12	%	1-6
Basophils - EDTA Whole Blood DHSS / Microscopy	01	%	0-1

BIOCHEMISTRY

Alanine Transaminase(ALT/ SGPT) - Serum UV with P-5-P Dry Chemistry	15.0	U/L	Adult: < 45
Alkaline Phosphatase - Serum Para Nitro Phenyl Phosphate,AMP Buffer Dry Chemistry	52.0	U/L	53-128
Cholesterol Total - Serum Cholesterol Oxidase Dry Chemistry	153.0	mg/dl	Desirable: < 200 BorderLine High: 200-239 High: >= 240

Dr. Seema Umarji
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KMC NO:95296

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21YP99163

Report Type : Final

Gamma-Glutamyl Transferase (GGT) - Serum ?-glutamyl-p-nitroanilide Dry Chemistry	14.0	U/L	< 55
HDL Cholesterol - Serum Colorimetric: non HDL Precipitation Method	**43.0**	mg/dL	Low: < 40.0 High: >= 60.0
ELECTROLYTES (Na+, K+, Cl) - Serum DIRECT ISE			
SODIUM (Na+)	141.5	mmol/L	137-145
POTASSIUM (K+)	3.81	mmol/L	3.5-5.1
CHLORIDE(Cl-)	105.5	mmol/L	98-107
IMMUNOLOGY			
T3 (TOTAL) - Serum Enhanced Chemiluminescence	1.27	ng/mL	Newborn: 0.7-2.0 < 1 Year: 1.0-2.4 1 - 5 Years: 1.0-2.4 6 - 10 Years: 0.9-2.4 11 - 50 Years: 0.7-2.0 > 50 Years: 0.4-1.8 First Trimester: 0.8-1.9 Second Trimester: 1.0-2.6
SEROLOGY			
RAPID PLASMA REAGIN (RPR) / VDRL			
RAPID PLASMA REAGIN RPR / VDRL - Serum, Slide Flocculation	Non Reactive		
INTERPRETATION - Serum	Non Reactive		

-- End of Report --

Dr. Seema Umarji
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21YP99163

Report Type : Final

Kindly correlate clinically. If necessary discuss/repeat

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