

PARTICIPANT FINAL ASSESSMENT REPORT (SUMMARY)

PT SCHEME:HEMATOLOGY



PC-1047

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 <sup>3</sup> /c umm	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 <sup>6</sup> /c umm	3.70	0.06	0.012	1.35	Satisfactory
5	AEC	30	0.11	10 <sup>3</sup> /c umm	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 <sup>3</sup> /c umm	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 <sup>3</sup> /c umm	2.49	0.90	0.206		N/A
16	ALC	30	Not Recvd.	10 <sup>3</sup> /c umm	2.63	0.38	0.086		N/A
17	CD4	0	Not Recvd.	cells/dl					N/A

Authorised Signatory

Dr. Sujay Prasad  
Technical Manager and Program coordinator

\* denotes adjusted SDPA as per ISO 13528:2015(E)  
SDPA - Standard Deviation for Proficiency Assessment

This report is for use only by the intended participant.



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 24 hr 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.

8. Evidence that the problem was corrected successfully:

The certificate is enclosed herewith.

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

② Interlab comparison done & reports enclosed.

10. Signatures :

Quality manager:

Pathologist:

③ We are also participated with AIIMS PT reports attached

### 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

14<sup>th</sup>, 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.



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



*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 &amp; 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 <sup>3</sup> /µl	1	9.34	9.24	18.58	29.12	0.0870	-5.79	0.1	0.2	0.0150	-0.59
RBC x10 <sup>6</sup> /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 <sup>3</sup> /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 Distribution No.: Month/Year:  
No.: 2888 152-G 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 <sup>3</sup> /µl	1	214	232	87.5	90.95	3.02	3.02	9.48	5.6
RBC x10 <sup>6</sup> /µl	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 <sup>3</sup> /µl	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](http://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-----



Name : Mr. INTERLAB  
COMPARTION -2  
Age / Sex : 23 Year(s) / Male  
Patient ID : PDY052063  
Visit No. : 21YP99164

Ref. Doctor : DR. SELF  
Client : Yelahanka

Registered Date : 26/08/2021 02:46 PM  
Collected On : 26/08/2021 03:20 PM  
Received On : 26/08/2021 03:21 PM  
Reported On : 26/08/2021 06:46 PM



Report Type : Final

Test	Results	Units	Biological Reference Range
<b>HEMATOLOGY</b>			
<b><u>CBC - Complete Blood Count</u></b>			
<b><u>CBC</u></b>			
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 <sup>3</sup> / μl	0.01-0.05
Absolute Eosinophil Count - Whole Blood Flow Cytometry	1.20	10 <sup>3</sup> / μl	0.02-0.50
Absolute Lymphocyte Count - Whole Blood	2.40	10 <sup>3</sup> / μl	1-3

Dr. Shreya Prabhu,  
Pathologist  
KMC No: 114274

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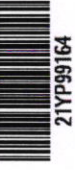
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Name : Mr. INTERLAB  
COMPARTION -2  
Age / Sex : 23 Year(s) / Male  
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Report Type : Final

Flow Cytometry

Absolute Neutrophil Count - Whole Blood Flow Cytometry	4.90	$10^3 / \mu\text{l}$	2-7
Absolute Monocyte Count - Whole Blood Flow Cytometry	0.70	$10^3 / \mu\text{l}$	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	<b>13.0</b>	%	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
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**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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Name : Mr. INTERLAB  
COMPARTION -2  
Age / Sex : 23 Year(s) / Male  
Patient ID : PDY052063  
Visit No. : 21YP99164

Ref. Doctor : DR. SELF  
Client : Yelahanka

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Received On : 26/08/2021 03:21 PM  
Reported On : 26/08/2021 06:46 PM



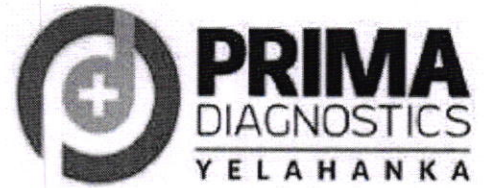
Report Type : Final

Test	Results	Units	Biological Reference Range
<b>BIOCHEMISTRY</b>			
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	<u>9.0</u>	U/L	12-64
HDL Cholesterol - Serum Accelerator selective detergent	42.00	mg/dL	40-60
<b><u>ELECTROLYTES (Na+, K+, Cl)</u></b> - 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



Name : Mr. INTERLAB COMPARTION -1  
 Ref. Doctor : DR. SELF  
 Age / Sex : 22 Year(s) / Male  
 Client : Walk-in  
 Patient ID : PDY052062  
 /isit No. : 21YP99163

Registered Date : 26/08/2021 02:42 PM  
 Collected On : 26/08/2021 02:43 PM  
 Received On : 26/08/2021 02:43 PM  
 Reported On : 27/08/2021 12:08 PM



Report Type : Final

Test	Results	Units	Biological Reference Range
<b>HEMATOLOGY</b>			
<b><u>CBC - Complete Blood Count</u></b>			
<b><u>CBC</u></b>			
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	<b>35.0</b>	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)	<b>8880</b>	cells/cu.mm	4000-11000
Absolute Basophil Count - EDTA Whole Blood Flow Cytometry	0.02	10 <sup>3</sup> / µl	0.01-0.05
Absolute Eosinophil Count - EDTA Whole Blood	<b>1.06</b>	cells/cu.mm	0.01-0.50

*Seema Umarji*

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

Page 1 / 4

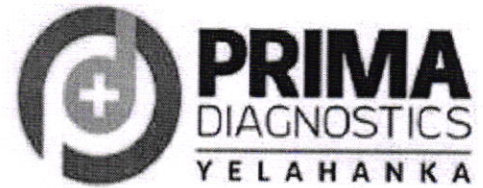
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 COMPARTION -1 Ref. Doctor : DR. SELF  
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Report Type : Final

Double Hydrodynamic Sequential System(DHSS)

Absolute Lymphocyte Count - EDTA Whole Blood 2.29 cells/cu.mm 1-3  
 Blood  
 Double Hydrodynamic Sequential System(DHSS)

Absolute Neutrophil Count - EDTA Whole Blood 4.90  $10^3 / \mu\text{l}$  2-7  
 Flow Cytometry

Absolute Monocyte Count - EDTA Whole Blood 0.61  $10^3 / \mu\text{l}$  0.2-1.0  
 Flow Cytometry

**DIFFERENTIAL COUNT - DC**

Neutrophils - EDTA Whole Blood 55 % 40-75  
 DHSS / Microscopy

Lymphocytes - EDTA Whole Blood 26 % 20-45  
 DHSS / Microscopy

Monocytes - EDTA Whole Blood 06 % 1-10  
 Flow Cytometry/Microscopy

Eosinophils - EDTA Whole Blood 12 % 1-6  
 DHSS / Microscopy

Basophils - EDTA Whole Blood 01 % 0-1  
 DHSS / Microscopy

**BIOCHEMISTRY**

Alanine Transaminase(ALT/ SGPT) - Serum 15.0 U/L Adult: < 45  
 UV with P-5-P Dry Chemistry

Alkaline Phosphatase - Serum 52.0 U/L 53-128  
 Para Nitro Phenyl Phosphate,AMP Buffer Dry Chemistry

Cholesterol Total - Serum 153.0 mg/dl Desirable: < 200  
 Cholesterol Oxidase Dry Chemistry BorderLine High: 200-239  
 High: >= 240

*Seema Umarji*

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

Page 2 / 4

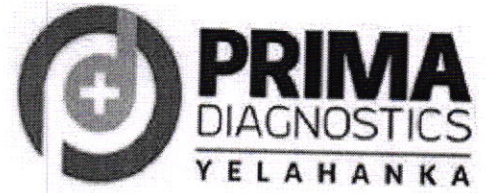
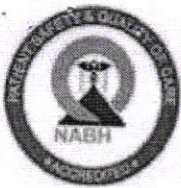
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Report Type : Final

Gamma-Glutamyl Transferase (GGT) - Serum ?-glutamyl-p-nitroanilide Dry Chemistry	14.0	U/L	< 55
HDL Cholesterol - Serum Colorimetric: non HDL Precipitation Method	<b>43.0</b>	mg/dL	Low: < 40.0 High: >= 60.0
<b><u>ELECTROLYTES (Na+, K+, Cl)</u></b> - 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
<b><u>IMMUNOLOGY</u></b>			
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, Non Reactive  
Slide Flocculation  
INTERPRETATION - Serum Non Reactive

-- End of Report --

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

Page 3 / 4

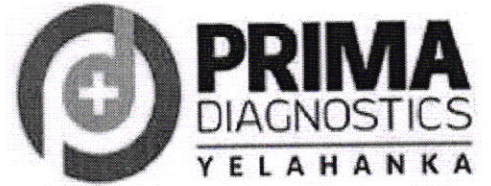
**PRIMA DIAGNOSTICS YELAHANKA**

A UNIT OF GURURAJGOVIND LIFESCIENCE YELAHANKA LLP

Reg. Office : #93, 1st A Min Road, 1st Phase, A Sector, Yelahanka New Town, Bengaluru - 560064. Tel 080 - 4624 5555

(Head Office : 4/16, 9th Main Road, 3rd Block, Jayanagar, Bengaluru - 560011. Tel : 080 - 46282333)

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Name : Mr. INTERLAB  
COMPARTION -1 Ref. Doctor : DR. SELF  
Age / Sex : 22 Year(s) / Male Client : Walk-in  
Patient ID : PDY052062  
/isit No. : 21YP99163

Registered Date : 26/08/2021 02:42 PM  
Collected On : 26/08/2021 02:43 PM  
Received On : 26/08/2021 02:43 PM  
Reported On : 27/08/2021 12:08 PM



Report Type : Final

Kindly correlate clinically. If necessary discuss/repeat