Neu-QAP

(an EXTERNAL QUALITY ASSURANCE PROGRAMME)

PC-1047

PARTICIPANT FINAL ASSESSMENT REPORT

PT SCHEME:SEROLOGY

Cycle No	C5
Ref.No.	NEUQAP561
Sample ID	NEUQAP SERO SERUM/2023/4/C5/S1

Report Date : 18/05/2023

Sample : April 2023

All Methods

Parameters	Lab Report	No of Participants	Consensus Report	%	Remarks
Brucella Antibody	Not Recvd.	23	Non Reactive - 23		
Brucella IgG	Not Recvd.	16	Non Reactive - 16		
Brucella IgM	Not Recvd.	17	Non Reactive - 17		
Chikungunya	Negative	56	Negative - 56	100	Within Consensus
CMV IgG	Not Recvd.	42	Non Reactive - 1 Reactive - 41		
CMV IgM	Not Recvd.	42	Non Reactive - 41 Reactive - 1		
HBsAg	Reactive	90	Non Reactive - 6 Reactive - 84	93	Within Consensus
HCV	Reactive	90	Equivocal - 1 Non Reactive - 2 Reactive - 87	97	Within Consensus
HIV-1 & 2	Reactive	90	Reactive - 90	100	Within Consensus
Rubella IgG	Not Recvd.	40	Reactive - 40		
Rubella IgM	Not Recvd.	37	Non Reactive - 37		
Toxoplasma IgG	Not Recvd.	38	Reactive - 38		
Toxoplasma IgM	Not Recvd.	38	Non Reactive - 38		
Weil Felix OX19	Not Recvd.	37	Negative - 37		
Weil Felix OX2	Not Recvd.	38	Negative - 38		
Weil Felix OXK	Not Recvd.	37	Negative - 37		
Widal	Negative	69	Negative - 69	100	Within Consensus

Authorised Signatory

Dr. Sujay Prasad
Technical Manager and Program coordinator

This report is for use only by the intended participant.

Technical Advisor

Dr Divya

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

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CIN: U85300KA2018PTC115147

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Cycle No	C5
Ref.No.	NEUQAP561
Sample ID	NEUQAP SERO SERUM/2023/4/C5/S1

Report Date : 18/05/2023

Sample : April 2023

Peer group

Parameters	Lab Report	No of Participants	Consensus Report	%	Remarks
Chikungunya (Immunochromatography)	Negative	36	Negative - 36	100	Within Consensus
HBsAg (Card Method)	Reactive	15	Non Reactive - 5 Reactive - 10	67	Within Consensus
HCV (Card method)	Reactive	16	Non Reactive - 1 Reactive - 15	94	Within Consensus
HIV-1 & 2 (Card method)	Reactive	14	Reactive - 14	100	Within Consensus
RPR (Flocculation)	Reactive	72	Equivocal - 1 Non Reactive - 14 Reactive - 57	79	Within Consensus
Widal (Tube Agglutination)	Negative	46	Negative - 46	100	Within Consensus

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Cycle No	C5
Ref.No.	NEUQAP561
Sample ID	NEUQAP SERO SERUM/2023/4/C5/S1

Report Date : 18/05/2023

Sample : April 2023

All Methods

Parameters	Lab Report	No of Participants	Consensus Report	%	Remarks
ASO	Negative	41	Negative - 38 Positive - 3	93	Within Consensus
Brucella Antigen	Not Recvd.	6	Non Reactive - 6		
CRP	Negative	50	Negative - 19 Positive - 31		Out of Consensus
RF	Negative	49	Negative - 49	100	Within Consensus

Authorised Signatory

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Technical Manager and Program coordinator

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PT SCHEME:SEROLOGY.

Cycle No	C5
Ref.No.	NEUQAP561
Sample ID	NEUQAP SERO SERUM/2023/4/C5/S1

Report Date : 18/05/2023

Sample : April 2023

Peer group

Parameters	Lab Report	No of Participants	Consensus Report	%	Remarks
ASO (Latex Agglutination)	Negative	21	Negative - 18 Positive - 3	86	Within Consensus
CRP (Immunoturbidometry)	Negative	30	Negative - 9 Positive - 21		Out of Consensus
RF (Immunoturbidometry)	Negative	27	Negative - 27	100	Within Consensus

Note: Sample generation, homogeneity and stability testing are subcontracted to accredited laboratories

**End of report **

Authorised Signatory

Dr. Sujay Prasad
Technical Manager and Program coordinator

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Lab Code No. 2391

BASIC SEROLOGY

FINAL RESULT ASSESSMENT

CYCLE NO. : 12 ROUND: 2 TOTAL PARTICIPANT: 429 DATE: 29/04/2023

Parameter	Total Responses	Your Result	All Lab Result	Consensus %	Remarks
S1- ASO	259	Negative	Negative : 257 Positive : 2	99.2%	Within Consensus
S2- TYPHOID	366	Non- Reactive	Non-Reactive : 359 Reactive : 7	98.0%	Within Consensus

Chief Coordinator

Dr. Sanjay Mehrotra

Programme Director

Dr. Bandana Mehrotra

Checked By:

Prepared by: SV

End of Report

RML Research Foundation
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Email: rmlresearchfoundation@gmail.com Website: www.rmlpathology.com

TATA 1mg	TATA 1mg Labs TATA 1mg Technologies Private Limited	
	Form Name	Proficiency Testing - Action Needed Form
	Form No.	Gen / FR / 59
	Issue Date & Version No.	01-Jul-2022 V2

Section 1 - Initiation of ANF (to be filled by the person who raising the ANF)

PT/EQAS Agency ☐ CAP ☐ AIIMS ☐ BIORAD ☐ CMC ☐ RML ☐ Other

Survey name & distribution ID: Neu-QAP Serology EQAP Cycle- 5

Date on agency report: 18-May-2023

ANF No: KOL/MAY/23/01	Issued by: Prashant Singh	Issue Date:22-May-2023	Due date: 01-Jun-2023

Department: Serology

ANALYTE or EXAMINATION: CRP (Immunoturbidometry)

Sample ID	Result submitted	PT targets	PT acceptable range	Problem/Performance
Sample no. S1	Negative	Positive	Positive	Out of Consensus

Comment /Observations: (e.g. trend, previously missed within last 12 months, lab in regulatory jeopardy for this analyte?)

This is a repeat outlier.

Section 2 - Investigation of Non Conformance- Checklist

Sl	ANF-CHECKLIST	Yes	No	N/A
1	Specimen temperature check, as per kit instructions	√		
2	Specimen storage condition check, as per kit instructions	√		
3	Specimen physical condition check	√		
4	Sample integrity up to arrival in lab: any shipping, delay or other sample problems?		√	
5	Sample integrity in-house: any problems with sample handling in the lab?		√	
6	Were there any instrument problem?		√	
7	Were there any method problem?			
8	Were there any faulty reagent/QC and Calibrator?		√	
9	Were there QC trends / problems at time of assay?		√	
10	Was Peer group data checked, if required	√		
11	Were there any Calibration (Intercept/slope) problems at time of assay?		√	
12	Was water quality checked?	√		
13	Did any technical errors occur due to pipetting error		√	
14	Did any technical errors occur due to sample mix-up		√	
15	Did any technical errors occur due to incorrect process, other than reconstitution, dilution or calculation errors,		√	
16	Did any technical errors occur due to misinterpretations		√	
17	Was the instrument checked for daily, Weekly, Monthly, semiannually and Annual maintenance	√		
18	Was there a lab clerical error? (e.g. error in unit conversion needed for survey only, transcription error onto result form, wrong method details submitted, Factor		√	

	removal)			
19	Was there a clerical error by the PT / EQA agency?		√	
20	Were there Patient data trends / problems at time of assay?		√	
21	Were there any gaps / issues in training or competency assessment?		√	
22	Was the sample condition appropriate at time of retesting (mention temperature…)			√
23	Has sample been re-tested / re-examined?			√
24	Has the lab perform Interlaboratory Comparison		√	

Questions 4-22 give details for any Yes answers

Water quality checked,No issue found.Instrument checked for weekly, monthly, semiannually and annual maintenance.

No issue found.

Question 23/24: if answer is yes, give results of repeat testing

Sample ID	Original result	Repeat value/ Lab Result	PT Targets/ Referral Lab Result	PT/ILC Acceptable Range	Status (Acceptable/Not acceptable)

Section 3 Root cause (Refer to Non-conformance error Reason)

	Instrument specific reference range

Why do you think the non-conformance / error occurred? Use this area to explain your findings.

The outlier is due to the different reference range of the kit used in Siemens instrument which is 0 -10 mg/L while the reference range provided by EQAS provider is 0- 5 mg/L

Assessment of the impact of root cause on patient results (Patient results may be affected before, during or after the PT event). Describe how the conclusion of impact was made and any corrective actions made to the patient result(s); "If No" - Explain why there was no patient impact?

No patient impact as the values along with the reference range is given in the report and the report is analysed accordingly.

Describe any previous proficiency testing issues with this test in the last sample:Yes

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Section 4: Department - Conclusion & Corrective / Preventive Action

What corrective action have you carried out?
Evaluation was done on the Lab Level and found that all the Siemens user values are concordant within the group both quantitatively and qualitatively.
Preventive action put into place?
The EQAS for CRP quantitative is shifted to IAMM (SGRH/CMC) in case of Siemens instruments and NeuQAP in case of Abbott instruments from NeuQAP for all the labs.
Due date for closure of proposed corrective and preventive action: NA

Person Investigated **Department Manager** **Lab Head**

Signature with Date: _____ _____ _____

Note: After signatures please hand over the form along with supporting documents to QA.

Date when ANF received to QA along with supporting documents: _____ **by:** _____