RCA FORM OF ILC / PT / EQAS OUTLIERS

Department: SEROLOGY **Date:** 20/8/21

1. Proficiency test exception for: HCV ANTIBODY [JULY 2021 NEUQAP EQAS] Report on 10/8/21
2. Proficiency test provider: NEUQAP
3. Proficiency test analyte group: PEER / METHOD
4. Cause for PT exception:
   - NEUQAP Explanation letter attached. They state that since the Antibody titres are low, Methods like CLIA are highly sensitive whereas Immunochromatography due to low titres can yield false negative results.
5. How did the section investigate the cause:
   - PEER group participants of NEUQAP Serology encountered this issue.
   - PEER group participants of NEUQAP Report HCV Immunochromatography too passed.
6. What was the status of the internal QC on the day PT initially analysed:
   PASSED
7. Category into which the cause will fit into:

   Method ☐ Technique ☐

   Clerical ☐ No explanation after investigation ☐

   Problem with PT material ☐ Other ☑
8. Evidence that the problem was corrected successfully:
   PEER group Immunochromatography HCV Passed report attached
9. Specific corrections taken to prevent the recurrence if possible:
   - Participants for Card Method for HCV is more than 10 hence as per peer group result we are in Consensus.
10. Signatures ::

    Quality manager: M. MC

    Pathologist: M. MC

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.

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PARTICIPANT FINAL ASSESSMENT REPORT

PT SCHEME:SEROLOGY

Cycle No	**C3**
Ref.No.	**NEUQAP189**
Sample ID	**NEUQAP SERO SERUM/2021/7/C3/S3**

Report Date : **10/08/2021**

Sample : July 2021

All Methods

Parameters	Lab Report	No of Participants	Consensus Report	%	Remarks
Brucella	Not Recvd.	24	Non Reactive - 24		
Brucella Antigen	Not Recvd.	3	Non Reactive - 3		
Brucella IgG	Not Recvd.	17	Non Reactive - 17		
Brucella IgM	Not Recvd.	18	Non Reactive - 18		
Chikungunya	Not Recvd.	42	Negative - 41		
			Positive - 1		
CMV IgG	Not Recvd.	42	Reactive - 42		
CMV IgM	Not Recvd.	43	Non Reactive - 43		
HBsAg	Reactive	91	Non Reactive - 4		
			Reactive - 87	96	Within Consensus
HCV	Non Reactive	91	Non Reactive - 16		Out of Consensus
			Reactive - 75		
HIV-1	Reactive	91	Non Reactive - 1		
			Reactive - 90	99	Within Consensus
RPR	Reactive	88	Non Reactive - 68		
			Reactive - 20		Out of Consensus
Rubella IgG	Not Recvd.	41	Reactive - 41		
Rubella IgM	Not Recvd.	39	Non Reactive - 39		
Toxoplasma IgG	Not Recvd.	40	Non Reactive - 1		
			Reactive - 39		
Toxoplasma IgM	Not Recvd.	39	Non Reactive - 39		
Weil Felix OX19	Not Recvd.	36	Negative - 35		
			Positive - 1		

Authorised Signatory

Dr. Sujay Prasad
Technical Manager and Program coordinator

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

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PT SCHEME:SEROLOGY

Cycle No	**C3**
Ref.No.	**NEUQAP189**
Sample ID	**NEUQAP SERO SERUM/2021/7/C3/S3**

Report Date : **10/08/2021**

Sample : July 2021

All Methods

Parameters	Lab Report	No of Participants	Consensus Report	%	Remarks
Weil Felix OX2	Not Recvd.	37	Negative - 35		
			Positive - 2		
Weil Felix OXK	Not Recvd.	36	Negative - 34		
			Positive - 2		
Widal	Negative	65	Negative - 65	100	Within Consensus

Authorised Signatory

Dr. Sujay Prasad
Technical Manager and Program coordinator

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PT SCHEME:SEROLOGY

Cycle No	**C3**
Ref.No.	**NEUQAP189**
Sample ID	**NEUQAP SERO SERUM/2021/7/C3/S3**

Report Date : **10/08/2021**

Sample : July 2021

Peer group

Parameters	Lab Report	No of Participants	Consensus Report	%	Remarks
HBsAg (Card Method)	Reactive	13	Non Reactive - 2		
			Reactive - 11	85	Within Consensus
HCV (Card method)	Non Reactive	15	Non Reactive - 10	67	Within Consensus
			Reactive - 5		
HIV-1 (Card method)	Reactive	11	Non Reactive - 1		
			Reactive - 10	91	Within Consensus
RPR (Others)	Reactive	1	Reactive - 1	100	Within Consensus
Widal (Slide agglutination)	Negative	20	Negative - 20	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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From: seema inamdar <s.inamdar@naalm.com>
Sent: Wednesday, September 1, 2021 11:50 AM
To: Ashwini MC <ashwini.mc@primadiagnostics.com>
Cc: QAP NAALM <qap@naalm.com>; Dr. Spoorthi K U <spoorthi_ku@anandlab.com>
Subject: Query for NEUQAP April and July Serology Report

Dear Madam,

Thanks for the verbal communication for your queries regarding the April and July Serology report.**NEUQAP 189** has submitted the HCV report by CARD METHOD for NEUQAP April and July Serology samples.
We had discussion with our advisory committee ,following are the analysis for your queries.

- Serology participants submitted the HCV results for the month of April and July by ELISA ,Chemiluminescence,CMIA and ELFA methods which are highly sensitive whereas Immunochromatography card method are known to give false negative results ,if the antibody titres are low .This could be the reason for Non Reactive results or out of consensus results for card method.
- We recommend the participant to use higher sensitive methods to avail the accurate results.

Please feel free to contact us for any queries.

Thanks & Regards

Ms.Seema Inamdar
Quality Manager

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PARTICIPANT FINAL ASSESSMENT REPORT

PT SCHEME:SEROLOGY

Cycle No	**C3**
Ref.No.	**NEUQAP189**
Sample ID	**NEUQAP SERO SERUM/2021/1/C3/S1**

Report Date : 11/03/2021

Sample : January 2021

Peer group

Parameters	Lab Report	No of Participants	Consensus Report	%	Remarks
HBsAg (Card Method)	Reactive	14	Reactive - 14	100	Within Consensus
HCV (Card method)	Non Reactive	15	Equivocal - 2		
			Non Reactive - 7	47	Within Consensus
			Reactive - 6		
HIV-1 (Card method)	Reactive	13	Equivocal - 2		
			Non Reactive - 4		
			Reactive - 7	54	Within Consensus
RPR (Others)	Reactive	2	Non Reactive - 1		
			Reactive - 1	50	Within Consensus
Widal (Slide agglutination)	Negative	20	Negative - 20	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

Kindly refer last page for a note on VDRL TEST

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