

Instrument : Manual

Analyte	Standard Unit	Result Value	Accepted Value
X HIV Ag + Ab	S/CO	Non-reactive	Reactive
X HBsAg	IU/mL	Equivocal	Reactive
# C-Reactive Protein Qualitative	mg/L	Normal	
X HIV Ab	S/CO	Non-reactive	HIV-1 Ab Reactive
@ HCV	IU/mL	Reactive	Reactive
@ Rheumatoid Factor Qualitative	IU/mL	Normal	Normal
@ ASO Qualitative	IU/mL	Normal	Normal

Legend @ : Acceptable

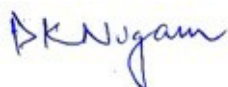
@ : Acceptable

X : Unacceptable

: Not Evaluated

⌚ : Delayed Result Entry

Total Parameters	7
Not Evaluated Parameters	1
Evaluated Parameters	6
Outlier Parameters (X)	3
EQAS Score Immunoassay Extended	50.00 %



Dr Puneet Kumar Nigam
PT coordinator & Technical Manager, MHL EQAS

Unit No. 409-416.

Commercial Building - 1A

Kohinoor Mall, Kiroi Road, Kurla (W),

Mumbai - 400070

CORRECTIVE & PREVENTIVE ACTIONS FORM



ROOT CAUSE ANALYSIS, CORRECTIVE AND PREVENTIVE ACTION (CAPA)

Non Compliance Reference

No. Samp-3 Dated 7/12/2023

Dept: Microbiology [HIV Ag-Ab]

Date: 21/12/23

Incident :- Deviating EOA results.
EOAs Sample for HIV Ag-Ab (Microbiology-Serology) was run but didnot obtain the reactive result.

Root cause analysis/Investigation :- The kit (card) used detect only antibody of the test, Report the wrong test card. it was man made error.

Done By: Manisha Date & Sign: Manisha 21/12/23

Tool Used/ Risk Assessment : why-why method.

Immediate Correction : Couldn't correct as it was not availability of kit.

Corrective Action : Requested to purchaser provide availability of new kit (card) which can detect both antigen as well as antibody result of HIV Ag-Ab test

Done By: Manisha Date & Sign: Manisha 21/12/23

Preventive Action : will make sure that will use the kit (card) which can detect both antigen & antibody result of HIV Ag-Ab test.

: Training gives to Lab technicians. to use proper kit (card) for test

Verification of CAPA Done

Done By: Dr. Anita Seervi Date & Sign: Anita 21/12/23

Manisha

Anita

Anita

Prepared By

Immediate Incharge

HOD



Metropolis Healthcare Ltd., EQAS

VYAS SUPER SPECIALITY HOSPITAL (1067)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 230310 and Sample No 03

Report Date : 19/12/2023

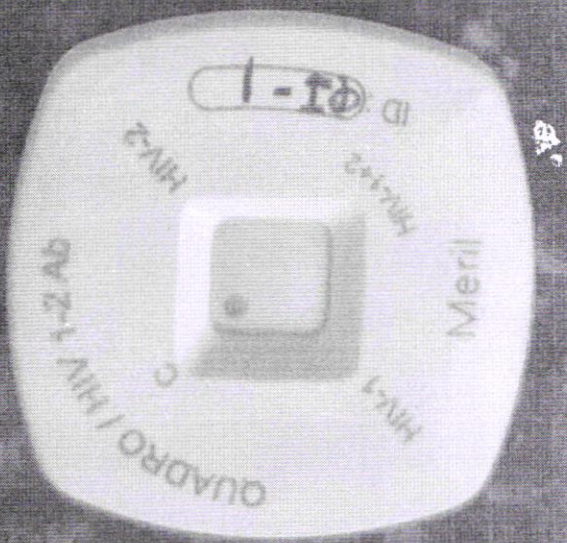
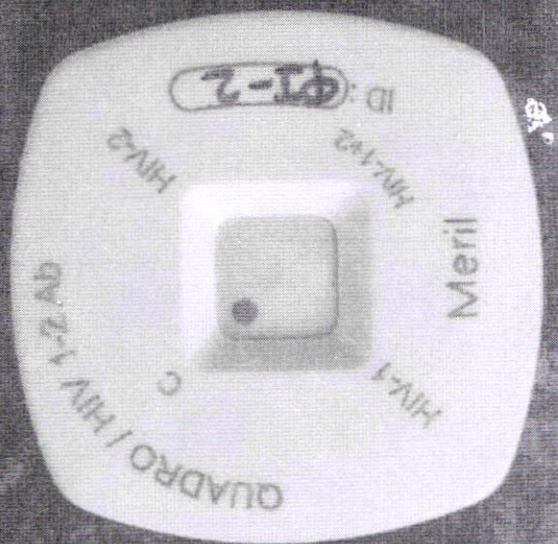
Analyte	Instrument	Result Value	Standard Unit
X HIV Ag + Ab	Manual	Non-reactive	-
X HBsAg	Manual	Equivocal	-
# C-Reactive Protein Qualitative	Manual	Normal	-
X HIV Ab	Manual	Non-reactive	-
Legend @ : Acceptable X : Unacceptable # : Not Evaluated ⌚ Delayed Result Entry			

Problem Classification: _____

Corrective Action: _____

Reviewed by: _____

Dated: _____



ATTENDANCE SHEET



Topic Of Training:	Interpretations of the card Tests.		
Name Of The Trainer:	Dr. Ashok Kumar Shah,	Date:	25/12/2023
Venue:	Central Research Lab VMCH.	Time:	1pm to 2pm

SN	Name	Designation	Department	Sign
1.	Hemant Pandit	Lab. Tech.	Central Lab	Hemant
2.	Indrajeet	Lab Tech.	Central Lab	Indrajeet
3.	Sharwari	SR. Lab Tech.	CENTRAL LAB	Sharwari
4.	Manisha Benival	Lab technician	Central lab	Manisha
5.	Anupam Maity	Lab Tech	Central Lab	Anupam
6.	Divya Bhati	Lab Tech.	Central Lab	Divya

S. No.	Name	Designation	Department	Sign

Signature of Trainer: 

ATTENDANCE SHEET



Topic Of Training:	Transcription of reports.		
Name Of The Trainer:	Dr. Anitha Seethu	Date:	26/12/2023
Venue:	Central Research Lab vmcsh	Time:	1pm to 2pm.

SN	Name	Designation	Department	Sign
1	MANISHA BENIWAL	Lab technician	Central Lab	<u>Manisha</u>
2	Hemant Pandit	Lab. Tech.	Central Lab	Hemant
3	INDRAJEET	Lab Techs	Central Lab	Indrajeet
4	SHAWAN GAGLOT	SR. Lab Techs	Central Lab	<u>Shawan</u>
5	Divya Bhati	Lab technician	Central Lab	<u>Divya</u>
6	Anupam Maity.	Lab Tel	Central Lab	Anupam

S. No.	Name	Designation	Department	Sign

Signature of Trainer: *Anil K S*


ATTENDANCE SHEET



Topic Of Training: Standardization, calibration & Internal QC (EQAS)	
Name Of The Trainer: Dr. Ashok Kumar Shah	Date: 27/12/2023
Venue: Central Research Lab Vmesh	Time: 1pm to 3pm.

SN	Name	Designation	Department	Sign
1	INDRAJEET	LAB TECHNICIAN	CENTRAL LAB	Indrajeet
2	SHARWAN UCHHOT	SR. LAB TECHNICIAN	CENTRAL LAB	
3	Hemant Pandit	Lab. Tech.	Central lab.	Hemant
4	Manisha Beniwal	Lab. technician	Central lab.	Manishg
5	Anupam maity	Lab Tech.	Central lab	Anupam
6	Divya Bhati	Lab Tech.	Central lab	Divya

S. No.	Name	Designation	Department	Sign

Signature of Trainer: 

CORRECTIVE & PREVENTIVE ACTIONS FORM



ROOT CAUSE ANALYSIS, CORRECTIVE AND PREVENTIVE ACTION (CAPA)

Non Compliance Reference

No. Samp-3 Dated 7/12/2023

Dept: Microbiology [HBSAg]

Date: 21/12/23

Incident :- Error in reporting test result. EQAS Sample for HBSAg (micro-serology) was run but interpreted as equivocal because the result showed faint line on the card. Error in reporting test result to EQA organizations.

Root cause analysis/Investigation The test card showed faint line on the card. It was man made error instead of interpreting positive result it was reported equivocal.

Done By: Manisha Date & Sign: Manisha 21/12/23

Tool Used/ Risk Assessment :- Why why method.

Immediate Correction :- Couldn't correct as it was already done

Corrective Action :- It was first time mistake, we shall be more careful while interpreting the result in the future.

Done By: Manisha Date & Sign: Manisha 21/12/23

Preventive Action :- Should make sure to run the test with 1 more or new card before final interpretation. in case of faint line develop in card.
:- Training given to Lab technician to repeat the test in such situations.

Verification of CAPA Done

Done By: Dr. Anil Seervi Date & Sign: Anil 21/12/23

Manisha

Anil

Anil

Prepared By

Immediate Incharge

HOD



Metropolis Healthcare Ltd., EQAS

VYAS SUPER SPECIALITY HOSPITAL (1067)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 230310 and Sample No 03

Report Date : 19/12/2023

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X HIV Ab	Manual	Non-reactive	-
Legend @ : Acceptable			
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Ⓞ Delayed Result Entry			

Problem Classification: _____

Corrective Action: _____

Reviewed by: _____

Dated: _____

