

SHRI MATA SHEETLA DEVI SWARNA JAYANTI DIAGNOSTIC CENTRE (549)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 220104 and Sample No 02

Report Date : 23/05/2022

Analyte	Instrument	Result Value	Standard Unit
No Outlier			
Legend @ : Acceptable X : Unacceptable # : Not Evaluated 🕒 : Delayed Result Entry			

Problem Classification: Nil

Corrective Action: Nil

Reviewed by: Visharma

Dated: 23-05-22

SHRI MATA SHEETLA DEVI SWARNA JAYANTI DIAGNOSTIC CENTRE (549)

Outlier And Analyte Summary Report
Result Details For Cycle No 220104 and Sample No 02

Report Date : 23/05/2022

Instrument : Manual

Analyte	Standard Unit	Result Value	Accepted Value
@ HBsAg	IU/mL	Reactive	Reactive
# HCV	IU/mL	Reactive	
@ Rheumatoid Factor Qualitative	IU/mL *	Normal	Normal
@ Dengue NS 1	RU/ml	Negative	Negative
@ HIV Ab	S/CO	HIV-1 Ab Reactive	HIV-1 Ab Reactive
@ Widal test - Typhi O antigen (TO)	-	No Agglutination	No Agglutination
@ Widal test - Typhi H antigen (TH)	-	No Agglutination	No Agglutination
@ Widal test - ParaTyphi A-H antigen (AH)	-	No Agglutination	No Agglutination
@ Widal test - ParaTyphi B-H antigen (BH)	-	No Agglutination	No Agglutination

Legend @ : Acceptable
X : Unacceptable
: Not Evaluated
⌚ : Delayed Result Entry

Total Parameters	9
Not Evaluated Parameters	1
Evaluated Parameters	8
Outlier Parameters (X)	0
EQAS Score Immunoassay Extended	100.00 %

Dr Puneet Kumar Nigam

Dr Puneet Kumar Nigam
PT coordinator & Technical Manager, MHL EQAS
Unit No. 409-416,
Commercial Building - 1A,
Kohinoor Mall, Kirof Road, Kurla (W),
Mumbai - 400070

Visharma
23.5.22

End of Report

SHRI MATA SHEETLA DEVI SWARNA JAYANTI DIAGNOSTIC CENTRE (549)

Outlier And Analyte Summary Report
Result Details For Cycle No 220104 and Sample No 01

Report Date : 23/05/2022

Instrument : Manual

Analyte	Standard Unit	Result Value	Accepted Value
@ HBsAg	IU/mL	Non-reactive	Non-reactive
@ HCV	IU/mL	Non-reactive	Non-reactive
@ Rheumatoid Factor Qualitative	IU/mL	Normal	Normal
@ Dengue NS 1	RU/ml	Negative	Negative
@ HIV Ab	S/CO	Non-reactive	Non-reactive
@ Widal test - Typhi O antigen (TO)	-	No Agglutination	No Agglutination
@ Widal test - Typhi H antigen (TH)	-	No Agglutination	No Agglutination
@ Widal test - ParaTyphi A-H antigen (AH)	-	No Agglutination	No Agglutination
@ Widal test - ParaTyphi B-H antigen (BH)	-	No Agglutination	No Agglutination

Legend @ : Acceptable
X : Unacceptable
: Not Evaluated
🕒 : Delayed Result Entry

Total Parameters	9
Not Evaluated Parameters	0
Evaluated Parameters	9
Outlier Parameters (X)	0
EQAS Score Immunoassay Extended	100.00 %

Dr Puneet Kumar Nigam

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PT coordinator & Technical Manager, MHL EQAS
Unit No. 409-416,
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Mumbai - 400070

Visharma
23.05.22

End of Report

SHRI MATA SHEETLA DEVI SWARNA JAYANTI DIAGNOSTIC CENTRE (549)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 210512 and Sample No 01

Report Date : 30/12/2021

Analyte	Instrument	Result Value	Standard Unit
No Outlier			
Legend @ : Acceptable X : Unacceptable # : Not Evaluated ⌚ : Delayed Result Entry			

Problem Classification: nil

Corrective Action:

Reviewed by: Visharma

Dated: 30-12-21

SHRI MATA SHEETLA DEVI SWARNA JAYANTI DIAGNOSTIC CENTRE (549)

Outlier And Analyte Summary Report
Result Details For Cycle No 210512 and Sample No 01

Report Date : 30/12/2021

Instrument : Manual

Analyte	Standard Unit	Result Value	Accepted Value
@ HBsAg	IU/mL	Non-reactive	Non-reactive
@ HCV	IU/mL	Non-reactive	Non-reactive
@ Rheumatoid Factor Qualitative	IU/mL	Normal	Normal
@ RPR (Syphilis Serology)	-	Non-reactive	Non-reactive
@ Dengue NS 1	RU/ml	Negative	Negative
@ HIV Ab	S/CO	Non-reactive	Non-reactive
@ Typhidot IgM	-	Negative	Negative
@ Widal test - Typhi O antigen (TO)	-	No Agglutination	No Agglutination
@ Widal test - Typhi H antigen (TH)	-	No Agglutination	No Agglutination
@ Widal test - ParaTyphi A-H antigen (AH)	-	No Agglutination	No Agglutination
@ Widal test - ParaTyphi B-H antigen (BH)	-	No Agglutination	No Agglutination

Legend @ : Acceptable
X : Unacceptable
: Not Evaluated
🕒 : Delayed Result Entry

Total Parameters	11
Not Evaluated Parameters	0
Evaluated Parameters	11
Outlier Parameters (X)	0
EQAS Score Immunoassay Extended	100.00 %

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End of Report

SHRI MATA SHEETLA DEVI SWARNA JAYANTI DIAGNOSTIC CENTRE (549)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 210512 and Sample No 02

Report Date : 30/12/2021

Analyte	Instrument	Result Value	Standard Unit
X Typhidot IgM	Manual	Positive	-
Legend @ : Acceptable X : Unacceptable # : Not Evaluated ⌚ : Delayed Result Entry			

Problem Classification: Typhidot - IgM - false positive.

Corrective Action: Requested for replacement,
stopped testing in-house.

Reviewed by: Visharma.

Dated: 30.12.21

SHRI MATA SHEETLA DEVI SWARNA JAYANTI DIAGNOSTIC CENTRE (549)

Outlier And Analyte Summary Report
Result Details For Cycle No 210512 and Sample No 02

Report Date : 30/12/2021

Instrument : Manual

Analyte	Standard Unit	Result Value	Accepted Value
@ HBsAg	IU/mL	Non-reactive	NR
@ HIV Ab	S/CO	HIV-1 Ab Reactive	HIV-1
X Typhidot IgM	-	Positive	Negative
@ HCV	IU/mL	Non-reactive	Non-reactive
@ Rheumatoid Factor Qualitative	IU/mL	Normal	Normal
@ RPR (Syphilis Serology)	-	Non-reactive	Non-reactive
@ Dengue NS 1	RU/ml	Negative	Negative
@ Widal test - Typhi O antigen (TO)	-	No Agglutination	No Agglutination
@ Widal test - Typhi H antigen (TH)	-	No Agglutination	No Agglutination
@ Widal test - ParaTyphi A-H antigen (AH)	-	No Agglutination	No Agglutination
@ Widal test - ParaTyphi B-H antigen (BH)	-	No Agglutination	No Agglutination

Legend @ : Acceptable
X : Unacceptable
: Not Evaluated
🕒 : Delayed Result Entry

Total Parameters	11
Not Evaluated Parameters	0
Evaluated Parameters	11
Outlier Parameters (X)	1
EQAS Score Immunoassay Extended	90.91 %

Dr Puneet Kumar Nigam

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PT coordinator & Technical Manager, MHL EQAS
Unit No. 409-416,
Commercial Building - 1A,
Kohinoor Mall, Kiroli Road, Kuria (W),
Mumbai - 400070

End of Report

Re: Regarding certain sub standard test kits

1 message

Thu, Jan 6, 2022 at 2:37 PM

vijayksharma HLL <vijayksharma@lifecarehll.com>

To: raghulc HLL <raghulc@lifecarehll.com>

Cc: sijo joy <sijojoyhll@gmail.com>, Vsrthk LifecareHLL <vsrthk@lifecarehll.com>, deepika chatterjee <deepika_chatterjee@yahoo.com>, "hindlabsgurugram.haryana HLL" <hindlabsgurugram.haryana@lifecarehll.com>, pranita HLL <pranita@lifecarehll.com>

Dear Sir,

In reference to the trailing email, We want to inform you, the result from Enterocheck WB Rapid kit is also not qualified for the current EQAS sample from M/s Metropolis Health.

Currently we have stopped to use the current kits and outsource the test till the availability of kit from different manufacturers.

Kindly replace the same as soon as possible.

Regards

DR VIJAY KUMAR SHARMA
SENIOR MANAGER (QUALITY)

Hindlabs-HCS Division | HLL Lifecare Limited

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vijayksharma@lifecarehll.com

CHO, Mahilamandiram Road, Poojappura, Thiruvananthapuram - 695 012 Kerala, India

On Wed, Dec 22, 2021 at 4:14 PM vijayksharma HLL <vijayksharma@lifecarehll.com> wrote:

Dear Raghul Ji,

In concern of trailing email, Please find below the details of kits having ambiguous results.

Product Name	Meril Meriscreen HIV 1-2 WB (Rapid kit)	Meril Meriscreen HIV 1-2 TREDRO	Enterocheck-WB (Rapid kit)
PO number	#203 dated 17.07.2021	#694 dated 22.03.2021	#666 dated 09.03.2021
Date of receipt	22.07.2021	26.07.2021	09.04.2021
Batch number	MI042155	MI072145	151302, 151293
Expiry date	03.2023	09.2022	09.2022, 05.2023
Quantity to be replaced	Kits-295 Nos	Kits-42 Nos	Kits-135 Nos
Images of the issue	Enclosed	Enclosed	Enclosed
Description of the complaint about the item Actual scenario	False Positive or Weak Positive	False Negative	False Positive or Weak Positive
Expected	True Positive with clear bands	True Positive with clear dots	True Positive with clear bands

Kindly Support.

DR VIJAY KUMAR SHARMA
SENIOR MANAGER (QUALITY)

Hindlabs-HCS Division | HLL Lifecare Limited

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CHO, Mahilamandiram Road, Poojappura, Thiruvananthapuram - 695 012 Kerala, India

SHRI MATA SHEETLA DEVI SWARNA JAYANTI DIAGNOSTIC CENTRE (549)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 210410 and Sample No 01

Report Date : 02/11/2021

Analyte	Instrument	Result Value	Standard Unit
# HIV Ab	Manual	HIV-1 Ab Reactive	-
Legend @ : Acceptable X : Unacceptable # : Not Evaluated ⌚ : Delayed Result Entry			

Problem Classification: HIV Ab result submitted but not evaluated by EQAS
Provider due to late peers.

Corrective Action: _____

Reviewed by: Vishama

Dated: 23-11-21

Instrument :	Manual	Standard Unit	Result Value	Accepted Value
Analyte				
@ HBsAg		IU/mL	Non-reactive	NR
@ HCV		IU/mL	Non-reactive	NR
# HIV Ab		S/CO	HIV-1 Ab Reactive	
@ Rheumatoid Factor		IU/mL	Normal	Normal
@ RPR (Syphilis Serology)		-	Non-reactive	Non-reactive
@ Dengue NS 1		RU/ml	Negative	Negative
@ Typhidot IgM		-	Negative	Negative
@ Widal test - Typhi O antigen (TO)		-	No Agglutination	No Agglutination
@ Widal test - Typhi H antigen (TH)		-	No Agglutination	No Agglutination
@ Widal test - ParaTyphi A-H antigen (AH)		-	No Agglutination	No Agglutination
@ Widal test - ParaTyphi B-H antigen (BH)		-	No Agglutination	No Agglutination

Legend @ : Acceptable
 X : Unacceptable
 # : Not Evaluated
 ⌚ : Delayed Result Entry

Total Parameters	11
Not Evaluated Parameters	1
Evaluated Parameters	10
Outlier Parameters (X)	0
EQAS Score Qualitative Immunoassay	100.00 %

Dr Puneet Kumar Nigam

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 PT coordinator & Technical Manager, MHL EQAS
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