



Metropolis Healthcare Ltd., EQAS

KRSNAA DIAGNOSTICS LTD KAPURTHALA (1043)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 240104 and Sample No 01

Report Date : 10/07/2024

Analyte	Instrument	Result Value	Standard Unit
X Widal test - Typhi O antigen (TO)	Manual	1:80	-
X Widal test - Typhi H antigen (TH)	Manual	1:80	-
Legend @ : Acceptable X : Unacceptable # : Not Evaluated ⌚ Delayed Result Entry			

Problem Classification: _____

Corrective Action: _____

Reviewed by: _____

Dated: _____

Instrument : Manual

Analyte	Standard Unit	Result Value	Accepted Value
X Widal test - Typhi O antigen (TO)	-	1:80	No Agglutination
X Widal test - Typhi H antigen (TH)	-	1:80	No Agglutination
@ RPR (Syphilis Serology)	-	Non-reactive	Non-reactive
@ Dengue NS 1	RU/ml	Negative	Negative
@ Widal test - ParaTyphi A-H antigen (AH)	-	No Agglutination	No Agglutination
@ Widal test - ParaTyphi B-H antigen (BH)	-	No Agglutination	No Agglutination
@ Dengue IgM	RU/ml	Negative	Negative
@ Dengue IgG	RU/ml	Negative	Negative

Instrument : J Mitra

Analyte	Standard Unit	Result Value	Accepted Value
@ HBsAg	IU/mL	Non-reactive	Non-reactive
@ HCV	IU/mL	Non-reactive	Non-reactive
@ HIV Ab	S/CO	Non-reactive	Non-reactive

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

Total Parameters	11
Not Evaluated Parameters	0
Evaluated Parameters	11
Outlier Parameters (X)	2
EQAS Score Immunoassay Extended	81.82 %



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



Metropolis Healthcare Ltd., EQAS

KRSNAA DIAGNOSTICS LTD KAPURTHALA (1043)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 240104 and Sample No 02

Report Date : 10/07/2024

Analyte	Instrument	Result Value	Standard Unit
X Widal test - Typhi O antigen (TO)	Manual	1:160	-
X Widal test - Typhi H antigen (TH)	Manual	1:160	-
X Widal test - ParaTyphi A-H antigen (AH)	Manual	1:160	-
X Widal test - ParaTyphi B-H antigen (BH)	Manual	1:80	-
Legend @ : Acceptable X : Unacceptable # : Not Evaluated ⌚ : Delayed Result Entry			

Problem Classification: _____

Corrective Action: _____

Reviewed by: _____

Dated: _____

Instrument : Manual

Analyte	Standard Unit	Result Value	Accepted Value
X Widal test - Typhi O antigen (TO)	-	1:160	No Agglutination
X Widal test - Typhi H antigen (TH)	-	1:160	No Agglutination
X Widal test - ParaTyphi A-H antigen (AH)	-	1:160	No Agglutination
X Widal test - ParaTyphi B-H antigen (BH)	-	1:80	No Agglutination
@ RPR (Syphilis Serology)	-	Non-reactive	Non-reactive
@ Dengue NS 1	RU/ml	Negative	Negative
@ Dengue IgM	RU/ml	Negative	Negative
@ Dengue IgG	RU/ml	Negative	Negative

Instrument : J Mitra

Analyte	Standard Unit	Result Value	Accepted Value
@ HBsAg	IU/mL	Reactive	Reactive
@ HCV	IU/mL	Non-reactive	NR
@ HIV Ab	S/CO	HIV-1/HIV-2 Ab Reactive	HIV-1/HIV-2 Ab Reactive

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

Total Parameters	11
Not Evaluated Parameters	0
Evaluated Parameters	11
Outlier Parameters (X)	4
EQAS Score Immunoassay Extended	63.64 %



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



Metropolis Healthcare Ltd., EQAS

KRSNAA DIAGNOSTICS LTD KAPURTHALA (1043)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 240104 and Sample No 03

Report Date : 10/07/2024

Analyte	Instrument	Result Value	Standard Unit
# HIV Ab	J Mitra	Non-reactive	-
Legend @ : Acceptable X : Unacceptable # : Not Evaluated 🕒 Delayed Result Entry			

Problem Classification: _____

Corrective Action: _____

Reviewed by: _____

Dated: _____

Instrument : J Mitra

Analyte	Standard Unit	Result Value	Accepted Value
# HIV Ab	S/CO	Non-reactive	
@ HBsAg	IU/mL	Reactive	Reactive
@ HCV	IU/mL	Reactive	Reactive

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

Total Parameters	3
Not Evaluated Parameters	1
Evaluated Parameters	2
Outlier Parameters (X)	0
EQAS Score Immunoassay Extended	100.00 %



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



Krusna Diagnostics Ltd,
Sultanpur Road Civil
Hospital Kapurthala
Pin Code- 144601

INTER LABORATORY COMPARISON RESULTS

Sr. No	Date	Analyte Name	Barcode ID	Lab Result	Unit	HC Lab Result	Unit	Acceptability Criteria	Observed CV %	Acceptability range	Result Acceptable Yes / No	Done by	Reviewed by
1	19/7/24	Widal Typhi (Co)	116328903	1:160	-	1:166	-	-	-	-	Yes	Blu	Blu
2	19/7/24	Typhi (H)	116328903	1:80	-	1:80	-	-	-	-	Yes	Blu	Blu
3	19/7/24	Typhi AH	116328903	1:80	-	1:80	-	-	-	-	Yes	Blu	Blu
4	19/7/24	Typhi BH	116328903	1:40	-	1:40	-	-	-	-	Yes	Blu	Blu
5	19/7/24	HIV	116329921	N/R	-	N/R	-	-	-	-	Yes	Blu	Blu

Qualitative: Clinically comparable results shall be Concordance.
Clinically not comparable results shall be Discordance.

Quantitative: Acceptability: 10% (As per NABL-112)

Sign of Doctor

Issued By: Vinod Kumar Version No: 1
 App. used by: Dr. Manish Kumar Approval No: --
 Date: 19/7/24 Issue Date: 01.05.2023

Proficiency Testing Outlier Investigation Form

Laboratory Name : Krsnaa Diagnostics PB Kapurthala

Date 17/7/24 Department Serology Test Analyte Widal Typhi (O) Reported Results 28/06/24
Acceptable Results No Agglutination

Sample receipt

	YES	NO	NA
- Was the kit received in good condition?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Was the correct program/cycle received?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Was the kit stored at the proper temperature following receipt?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Preparation:

Who Prepared sample? Bhawna Date Prepared 26/6/24

	YES	NO	NA
- Was the correct reconstitution instruction followed (handling, time, temperature)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Was a volumetric Class A (or calibrated) pipette used for reconstitution?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
- Was distilled or deionized water used for reconstitution?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
- Was the sample mixed according to the package insert prior to testing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Processing:

Who processed test? Bhawna Date of processing 26/6/24

	YES	NO	NA
- Was the correct sample number tested?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Was the sample at room temperature?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Was the person running the test current in their training?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Was the affected test run within the stability claim listed in the package insert	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Reporting Results:

Who reported Results Bhawna Date reported 28/6/24

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Issued by: <u>Vinod Lonkar</u> <i>Vinod</i>	Issue Date: <u>01/03/2023</u>
Approved by: <u>Dr. Manish Karekar</u> <i>Manish</i>	
Doc No: <u>GEN 03</u>	Version No: <u>1</u>
Amend No: <u>--</u>	Amend Date: <u></u>

- Was the test configuration correct (instrument, method and reagent)?
- Have the results been reported correctly (match instrument print out)?
- Was the correct unit reported?
- Was the decimal symbol placed correctly when reported?
- Was the reported result within the instrument's linear range?
- Was the calculation of the reported result done correctly?

YES	NO	NA
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Internal QC:

- Was IQC within an acceptable range on the day that the EQAS sample was run?
- Where there any shifts or trends in IQC just before/after the EQAS sample was run?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

C on the day on EQAS sample

	Reading	MEAN	SD	CV	Z Score
level-I	_____	_____	_____	_____	_____
level-II	_____	_____	_____	_____	_____
level-III	_____	_____	_____	_____	_____

Previous month IQC

	Mean	SD	CV	Z Score
level-I	_____	_____	_____	_____
level-II	_____	_____	_____	_____
level-III	_____	_____	_____	_____

Previous three month EQAS reports

	Z score	BIAS	RMZ
Month-I	_____	_____	_____
Month-II	_____	_____	_____
Month-III	_____	_____	_____

Calibration:

- Was the last calibration acceptable?
- Was the last calibration within the manufacturer's recommended dating?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Reagent:

Reagent lot / exp.

Lot _____ Expiration _____

Issued by : Vinod Lonkar <i>Vinod</i>		Issue Date : 01/03/2023	
Approved by : Dr. Manish Karekar <i>Manish</i>		Amend Date : _____	
Doc No : GEN 03	Version No : 1	Amend No : --	Amend Date : _____

YES	NO	NA
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Instrument:

- Was daily maintenance performed on the day that the EQAS sample was run?
- Was the person performing maintenance current on training?
- Was the instrument operating correctly on the day the sample was tested?
- Was the lab environment acceptable for the instrument (temperature, humidity, electrical, etc)?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Retest:

Who retested sample?

Date tested

- Was the EQAS sample retested following receipt of EQAS sample report?
- If yes, was the result within acceptable limits for the EQAS sample?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

EQAS Evaluation:

- Inappropriate peer group or comparator?
- Inappropriate evaluation criteria, e.g. narrow limits due to use of a precise method or instrument

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issued by Vinod Lonkar <i>Vinod</i>		Issue Date 01.03.2023	
Approved by Dr. Manish Karekar <i>Manish</i>			
Doc No GEN 03	Version No 1	Amend No --	Amend Date

SOP

YES NO NA

Was the SOP followed correctly?

Staining performed and interpreted correctly?

YES NO NA

Interpretation of microscopic examination interpreted correctly?

YES NO NA

Lot Verification

Type of error Identified - Sample degenerated Due to High Temp.
Root cause of the problem

Sample Received with High Temp.

Corrective Action GLC Done for Typhi(O).

Comparable Result shall be Concordance.

Signature and Name of Technologist / Section Head

Bhawna

Review by QM / HO / TM: Sign and Name

Issued by Vinod Lonkar <u>Vinod</u>		Issue Date 01.03.2023	
Approved by Dr. Manish Karekar <u>Manish</u>	Version No. 1	Amend No. --	Amend Date
Doc No GEN 03			

Proficiency Testing Outlier Investigation Form

Laboratory Name : Krsnaa Diagnostics PB Kapurthala

Date 17/7/24 Department Serology Test Analyte widal Typhi (H) Reported Results 28/06/24
Acceptable Results NO Aggulation

Sample receipt

	YES	NO	NA
- Was the kit received in good condition?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Was the correct program/cycle received?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Was the kit stored at the proper temperature following receipt?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Preparation:

Who Prepared sample? Bhawna Date Prepared 26/6/24

	YES	NO	NA
- Was the correct reconstitution instruction followed (handling, time, temperature)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Was a volumetric Class A (or calibrated) pipette used for reconstitution?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
- Was distilled or deionized water used for reconstitution?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
- Was the sample mixed according to the package insert prior to testing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Processing:

Who processed test? Bhawna Date of processing 26/6/24

	YES	NO	NA
- Was the correct sample number tested?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Was the sample at room temperature?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Was the person running the test current in their training?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
- Was the affected test run within the stability claim listed in the package insert	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Reporting Results:

Who reported Results Bhawna Date reported 28/6/24

Issued by <u>Vinod Lonkar</u> <u>Vinod</u>	Page 1 of 4	Issue Date <u>01/03/2023</u>
Approved by <u>Dr. Mamish Karekar</u> <u>Mamish</u>		
Doc No <u>GEN 03</u>	Version No <u>1</u>	Amend No <u>--</u>
		Amend Date

- Was the test configuration correct (instrument, method and reagent)?
- Have the results been reported correctly (match instrument print out)?
- Was the correct unit reported?
- Was the decimal symbol placed correctly when reported?
- Was the reported result within the instrument's linear range?
- Was the calculation of the reported result done correctly?

YES	NO	NA
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Internal QC:

- Was IQC within an acceptable range on the day that the EQAS sample was run?
- Where there any shifts or trends in IQC just before/after the EQAS sample was run?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

QC on the day on EQAS sample

	Reading	MEAN	SD	CV	Z Score
Level-I	_____	_____	_____	_____	_____
Level-II	_____	_____	_____	_____	_____
Level-III	_____	_____	_____	_____	_____

Previous month IQC

	Mean	SD	CV	Z Score
Level-I	_____	_____	_____	_____
Level-II	_____	_____	_____	_____
Level-III	_____	_____	_____	_____

Previous three month EQAS reports

	Z score	BIAS	RMZ
Month-I	_____	_____	_____
Month-II	_____	_____	_____
Month-III	_____	_____	_____

Calibration:

- Was the last calibration acceptable?
- Was the last calibration within the manufacturer's recommended dating?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Reagent:

Reagent lot / exp.

Lot _____ Expiration _____

Issued by : Vinod Lonkar <i>Vinod</i>		Issue Date 01.03.2023	
Approved by : Dr. Manish Karekar <i>Manish</i>		Amend Date .	
Doc No GEN 03	Version No : 1	Amend No : --	Amend Date .

- Was the test reagent stored correctly?
- Was the test reagent properly prepared?
- Was the test reagent within manufacturer's dating?

YES	NO	NA
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Instrument:

- Was daily maintenance performed on the day that the EQAS sample was run?
- Was the person performing maintenance current on training?
- Was the instrument operating correctly on the day the sample was tested?
- Was the lab environment acceptable for the instrument (temperature, humidity, electrical, etc)?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Retest:

Who retested sample?

Date tested

- Was the EQAS sample retested following receipt of EQAS sample report?
- If yes, was the result within acceptable limits for the EQAS sample?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

EQAS Evaluation:

- Inappropriate peer group or comparator?
- Inappropriate evaluation criteria, e.g narrow limits due to use of a precise method or instrument.

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issued by: Vinod Lonkar <i>Vinod</i>		Issue Date: 01/03/2023	
Approved by: Dr. Manish Karckar <i>Manish</i>			
Doc No: GEN 03	Version No: 1	Amend No: --	Amend Date:

SOP

YES NO NA

Was the SOP followed correctly?

Staining performed and interpreted correctly?

YES NO NA

Interpretation of microscopic examination interpreted correctly?

YES NO NA

Lot Verification

Type of error Identified

Root cause of the problem

Sample degenerated Due to high Temp
Sample Received with high Temp.

Corrective Action

ALC Done For Typhi (O)

Comparable Result Shall be Concordance.

Signature and Name of Technologist / Section Head

Bhawna

Review by QM / HO / TM: Sign and Name

Issued by: Vinod Lonkar <u>Vinod</u>	Issue Date: 01.03.2023
Approved by: Dr. Manish Karekar <u>Manish</u>	Amend No: --
Doc No: GEN-03	Version No: 1
	Amend Date:

Proficiency Testing Outlier Investigation Form

Laboratory Name : Krsnaa Diagnostic PB Kapurthala

Date 17/7/24 Department Serology Test Analyte Paratyphi(AH) Reported Results 1:160

Acceptable Results
No agglutination

Sample receipt

	YES	NO	NA
Was the kit received in good condition?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the correct program/cycle received?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the kit stored at the proper temperature following receipt?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Preparation:

Who Prepared sample? Bhawng Date Prepared 26/6/24

	YES	NO	NA
Was the correct reconstitution instruction followed (handling, time, temperature)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was a volumetric Class A (or calibrated) pipette used for reconstitution?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Was distilled or deionized water used for reconstitution?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Was the sample mixed according to the package insert prior to testing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Processing:

Who processed test? Bhawng Date of processing 26/6/24

	YES	NO	NA
Was the correct sample number tested?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the sample at room temperature?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the person running the test current in their training?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the affected test run within the stability claim listed in the package insert?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Reporting Results:

Who reported Results Bhawng Date reported 28/6/24



- Was the test configuration correct (instrument, method and reagent)?
- Have the results been reported correctly (match instrument print out)?
- Was the correct unit reported?
- Was the decimal symbol placed correctly when reported?
- Was the reported result within the instrument's linear range?
- Was the calculation of the reported result done correctly?

YES	NO	NA
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Internal QC:

- Was IQC within an acceptable range on the day that the EQAS sample was run?
- Where there any shifts or trends in IQC just before/after the EQAS sample was run?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

C on the day on EQAS sample

Reading	MEAN	SD	CV	Z Score
level-I				
level-II				
level-III				

Previous month IQC

Mean	SD	CV	Z Score
level-I			
level-II			
level-III			

Previous three month EQAS reports

Z score	BIAS	RMZ
Month-I		
Month-II		
Month-III		

Calibration:

- Was the last calibration acceptable?
- Was the last calibration within the manufacturer's recommended dating?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Reagent:

Reagent lot / exp.

Lot	Expiration

Issued by: Vinod Lomkar <i>Vinod</i>	Page 2 of 4	Issue Date: 01.03.2023
Approved by: Dr. Manish Kurekar <i>Manish</i>	Version No: 1	Amend No: --
Doc No: GDN-3		Amend Date:

- Was the test reagent stored correctly?
- Was the test reagent properly prepared?
- Was the test reagent within manufacturer's dating?

YES	NO	NA
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Instrument:

- Was daily maintenance performed on the day that the EQAS sample was run?
- Was the person performing maintenance current on training?
- Was the instrument operating correctly on the day the sample was tested?
- Was the lab environment acceptable for the instrument (temperature, humidity, electrical, etc.)?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Retest:

Who retested sample? _____ Date tested _____

- Was the EQAS sample retested following receipt of EQAS sample report?
- If yes, was the result within acceptable limits for the EQAS sample?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

EQAS Evaluation:

- Inappropriate peer group or comparator?
- Inappropriate evaluation criteria, e.g. narrow limits due to use of a precise method or instrument

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issued by: Vinod Lonkar	Issue Date: 14.12.23
Approved by: Dr. Manish Karekar	
Doc No: GLN 03	Version No: 1
Amend No: --	Amend Date: --

SOP

Was the SOP followed correctly?

YES NO NA

Staining performed and interpreted correctly?

YES NO NA

Interpretation of microscopic examination interpreted correctly?

YES NO NA

Lot Verification

Type of error Identified - Sample degenerated Due to High Temp.
Root cause of the problem

Sample Received with High Temp.

Corrective Action

GLC Done For Typhi [AH]
Para

Comparable Result shall be Concordance

Signature and Name of Technologist / Section Head

Bhawna

Review by QM / HO / TM: Sign and Name

Page No.:		Issue Date: 01/01/2023	
Issued by: Vinod Lonkar <i>Vinod</i>			
Approved by: Dr. Manish Karekar <i>Manish</i>			
Doc No: GLN-03	Version No: 1	Amend No: -	Amend Date:

Proficiency Testing Outlier Investigation Form

Laboratory Name: Krsnaa Diagnostic PB Kapurthala
 Date: 17/7/24 Department: Sexology Test Analyte: Paratyphi (BH) Reported Results: 1:80
 Acceptable Results: No Aggulation.

Sample receipt

	YES	NO	NA
Was the kit received in good condition?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the correct program/cycle received?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the kit stored at the proper temperature following receipt?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Preparation:

Who Prepared sample? Bhawng Date Prepared 26/6/24

	YES	NO	NA
Was the correct reconstitution instruction followed (handling, time, temperature)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was a volumetric Class A (or calibrated) pipette used for reconstitution?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Was distilled or deionized water used for reconstitution?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Was the sample mixed according to the package insert prior to testing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Processing:

Who processed test? Bhawng Date of processing 26/6/24

	YES	NO	NA
Was the correct sample number tested?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the sample at room temperature?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the person running the test current in their training?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the affected test run within the stability claim listed in the package insert?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Reporting Results:

Who reported Results Bhawng Date reported 28/6/24

Page 1 of 4

Issued by: <u>Vinod Lonkar</u>	Issue Date: <u>01/03/2023</u>
Approved by: <u>Dr. Manish Kurekar</u>	
Doc No: <u>GFN-03</u>	Version No: <u>1</u>
Amend No: <u>--</u>	Amend Date: <u>--</u>

- Was the test configuration correct (instrument, method and reagent)?
- Have the results been reported correctly (match instrument print out)?
- Was the correct unit reported?
- Was the decimal symbol placed correctly when reported?
- Was the reported result within the instrument's linear range?
- Was the calculation of the reported result done correctly?

YES	NO	NA
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Internal QC:

- Was IQC within an acceptable range on the day that the EQAS sample was run?
- Where there any shifts or trends in IQC just before/after the EQAS sample was run?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Con on the day on EQAS sample

Reading	MEAN	SD	CV	Z Score
level-I				
level-II				
level-III				

Previous month IQC

Mean	SD	CV	Z Score
level-I			
level-II			
level-III			

Previous three month EQAS reports

Z score	BIAS	RMZ
Month-I		
Month-II		
Month-III		

Calibration:

- Was the last calibration acceptable?
- Was the last calibration within the manufacturer's recommended timing?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Reagent:

Reagent lot / exp.

Lot _____ Expiration _____

Issued by: Vinod Lonkar <i>Vinod</i>	Issue Date: 01/05/2023
Approved by: Dr. Manish Karekar <i>Manish</i>	
Doc No: GEN 03	Version No: 1
Amend No: --	Amend Date: --

- Was the test reagent stored correctly?
- Was the test reagent properly prepared?
- Was the test reagent within manufacturer's dating?

YES	NO	NA
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Instrument:

- Was daily maintenance performed on the day that the EQAS sample was run?
- Was the person performing maintenance current on training?
- Was the instrument operating correctly on the day the sample was tested?
- Was the lab environment acceptable for the instrument (temperature, humidity, electrical, etc.)?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Retest:

Who retested sample?

Date tested

- Was the EQAS sample retested following receipt of EQAS sample report?
- If yes, was the result within acceptable limits for the EQAS sample?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

EQAS Evaluation:

- Inappropriate peer group or comparator?
- Inappropriate evaluation criteria, e.g. narrow limits due to use of a precise method or instrument

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issued by: Vinod Lonkar <i>[Signature]</i>	Issue Date: 01/07/2023
Approved by: Dr. Manish Karekar <i>[Signature]</i>	
Doc No: GEN-03	Version No: 1
Amend No: --	Amend Date: --



SOP

Was the SOP followed correctly?

YES NO NA

Staining performed and interpreted correctly?

YES NO NA

Interpretation of microscopic examination interpreted correctly?

YES NO NA

Lot Verification

Type of error Identified - Sample Degenerated Due to high Temp.

Root cause of the problem

Sample Received with high Temp.

Corrective Action

GLC Done For ParaTyph [BH]

Comparable Result shall be concordance

Signature and Name of Technologist / Section Head

Bhawna

Review by QM / HO / TM: Sign and Name

Issued by: Vinod Lonkar <i>Vinod</i>	Issue Date: 01/03/2023
Approved by: Dr. Manish Karjekar <i>Manish</i>	
Doc No: GIN/03	Version No: 1
Amend No: --	Amend Date:

Proficiency Testing Outlier Investigation Form

Laboratory Name : Krshna Diagnostic PB Kapurthala
 Date 17/7/24 Department Serology Test Analyte HIV Reported Results Non-Reactive
 Acceptable Results Not Given

Sample receipt

	YES	NO	NA
Was the kit received in good condition?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the correct program/cycle received?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the kit stored at the proper temperature following receipt?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Preparation:

Who Prepared sample? Bhawna Date Prepared 26/6/24

	YES	NO	NA
Was the correct reconstitution instruction followed (handling, time, temperature)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was a volumetric Class A (or calibrated) pipette used for reconstitution?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Was distilled or deionized water used for reconstitution?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Was the sample mixed according to the package insert prior to testing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Processing:

Who processed test? Bhawna Date of processing 26/6/24

	YES	NO	NA
Was the correct sample number tested?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the sample at room temperature?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the person running the test current in their training?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the affected test run within the stability claim listed in the package insert?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Reporting Results:

Who reported Results Bhawna Date reported 28/6/24

Issued by: <u>Vinod Lonkar</u>		Issue Date: <u>01/07/24</u>	
Approved by: <u>Dr. Manish Karekar</u>		Amend No: --	
Doc No: <u>GEN-03</u>	Version No: <u>1</u>	Amend Date: --	Amend Date: --

- Was the test configuration correct (instrument, method and reagent)?
- Have the results been reported correctly (match instrument print out)?
- Was the correct unit reported?
- Was the decimal symbol placed correctly when reported?
- Was the reported result within the instrument's linear range?
- Was the calculation of the reported result done correctly?

YES	NO	NA
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Internal QC:

- Was IQC within an acceptable range on the day that the EQAS sample was run?
- Where there any shifts or trends in IQC just before/after the EQAS sample was run?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

C on the day on EQAS sample

Reading	MEAN	SD	CV	Z Score
level-I				
level-II				
level-III				

Previous month IQC

Mean	SD	CV	Z Score
level-I			
level-II			
level-III			

Previous three month EQAS reports

Z score	BIAS	RMZ
Month-I		
Month-II		
Month-III		

Calibration:

- Was the last calibration acceptable?
- Was the last calibration within the manufacturer's recommended dating?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Reagent:

Reagent lot / exp.

Lot _____ Expiration _____

Issued by: Vinod Lonkar <i>Vinod</i>	Issue Date: 01/03/2023
Approved by: Dr. Manish Karekar <i>Manish</i>	
Doc No: GEN 03	Version No: 1
Amend No: --	Amend Date: .

- Was the test reagent stored correctly?
- Was the test reagent properly prepared?
- Was the test reagent within manufacturer's dating?

YES	NO	NA
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Instrument:

- Was daily maintenance performed on the day that the EQAS sample was run?
- Was the person performing maintenance current on training?
- Was the instrument operating correctly on the day the sample was tested?
- Was the lab environment acceptable for the instrument (temperature, humidity, electrical, etc.)?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sample Retest:

Who retested sample?

Date tested

- Was the EQAS sample retested following receipt of EQAS sample report?
- If yes, was the result within acceptable limits for the EQAS sample?

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

EQAS Evaluation:

- Inappropriate peer group or comparator?
- Inappropriate evaluation criteria, e.g. narrow limits due to use of a precise method or instrument.

YES	NO	NA
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Approved by: Dr. Manish Karekar <i>[Signature]</i>	
Doc No: GLN 03	Version No: 1
Amend No: -	Amend Date: -



Krsnaa Diagnostics Ltd,
Sultanpur Road Civil
Hospital Kapurthala
Pin Code-144601

SOP

Was the SOP followed correctly?

YES NO NA

Staining performed and interpreted correctly?

YES NO NA

Interpretation of microscopic examination interpreted correctly?

YES NO NA

Lot Verification

Type of error Identified - Random error

Root cause of the problem

Not Detected Because Result Not Given.

Corrective Action → gLC Done [Acceptable Result].

Signature and Name of Technologist / Section Head

Bhawna

Review by QM / HO / TM: Sign and Name

Issued by: Vinod Lonkar <i>Vinod</i>	Issue Date: 01/03/2023
Approved by: Dr. Manish Kataria <i>Manish</i>	
Doc No: GEN/03	Version No: 1
Amend No: -	Amend Date: -