

Reviewed by:

Metropolis Healthcare Ltd., EQAS

KRSNAA DIAGNOSTICS LTD KAPURTHALA (1043)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 240104 and Sample No 01

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

Report Date: 10/07/2024

Dated:



KRSNAA DIAGNOSTICS LTD KAPURTHALA (1043)

Outlier And Analyte Summary Report
Result Details For Cycle No 240104 and Sample No 01

ole No 01 Report Date : 10/07/2024

Outlier Parameters (X)

EQAS Score Immunoassay Extended

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/mI	Negative	Negative
@ Dengue IgG	RU/mI	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		Total Parameters	11
: Acceptable		Not Evaluated Parameters	0
X : Unacceptable		Evaluated Parameters	11
# : Not Evaluated		Evaluated Parameters	11

Akwagam

Dr Puneet Kumar Nigam PT coordinator & Technical Manager, MHL EQAS Unit No. 409-416. Commercial Building - 1A

① : Delayed Result Entry

Kohinoor Mall, Kirol Road, Kurla (W),

Mumbai - 400070

2

81.82 %



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			
O Delayed Result Entry			
Corrective Action:			
Reviewed by:		Dated:	



KRSNAA DIAGNOSTICS LTD KAPURTHALA (1043)

Outlier And Analyte Summary Report
Result Details For Cycle No 240104 and Sample No 02

Sample No 02 Report Date : 10/07/2024

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/mI	Negative	Negative
@ Dengue IgM	RU/mI	Negative	Negative
@ Dengue IgG	RU/mI	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

(9): Delayed Result Entry

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

AKNIgam

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



Reviewed by:

Metropolis Healthcare Ltd., EQAS

KRSNAA DIAGNOSTICS LTD KAPURTHALA (1043)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 240104 and Sample No 03

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:

Report Date: 10/07/2024

Dated:



KRSNAA DIAGNOSTICS LTD KAPURTHALA (1043)

Outlier And Analyte Summary Report
Result Details For Cycle No 240104 and Sample No 03

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		Total Parameters	3
@: Acceptable		Not Evaluated Parameters	1
X : Unacceptable		Evaluated Parameters	2
# : Not Evaluated		Outlier Parameters (X)	0
S: Delayed Result Entry		EQAS Score Immunoassay Extended	100.00 %

DKNogam

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 Report Date: 10/07/2024





Pin Code-144601

INTER LABORATORY COMPARISON RESULTS

S	7	W	p	_	2	
NIH hoftle	19/7/24	(१०) में	19/7/24	19 F P	. Todate	
	HB ind BH	Typhi AH	Typhi (H)	Typhi(o)	Name Name	
116329921	19/7/24 Typhi BH 116328903	19/7/24 TyphiAH 116328903	19/7/24 Typhi (H) 116328903	Typhico) 116328903	Barcode ID	
NIR	1: 40	08:1	1:80	1:160	Lab Result	
1	1	1	1	1	Unit	
2/2	1: HO	1:80	1:00	1:166	II.C lab Result	
ı	1	ı	1 1		Unit	
1	1	1	¥	ı	Acceptability Criteria	
1	1)	3	I	Observed CV %	
1	ī			1	Acceptability range	
Yes	yus	yes	Yes	Yes	Result Acceptable Yes / No	
She	R.	Sher	Bhow	The state of the s	Done by	
(be)	3)	(6)	0	(3)	Reviewed by	

Qualitative: Clinically comparable results shall be Concordance.

Clinically not comparable results shall be Disconcordance.

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

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America





Proficiency Testing Outlier Investigation Form

Laboratory Name :	K.10	ina solice DO	Valeral Abo	. 0.	
Date	Department D	rest Analyte	Repor	ted Re	sults
17/7/24	serology	widal Typhi			
Acceptable Results		wides 19 pio	(0)	10	012
No Aggulines	non				
	8 11	Sample receipt			
			YES.	Ю	NA
Was the kit received in good con			. 5	٥	٦
Was the correct program/cycle r			0	a	٥
Was the kit stored at the proper	temperature following receipt?		-		٥
	1. Au				
		Sample Preparation	ì:		
Who Prepared sample?	Date Prepared				
Bhawng	A -4 1	G.			
Drawing	26/6/2	9.			
Was the correct reconstruction in	: CU 10 W		YES N	0	NA
Was a volumetric Ches A car sel			3	J	
Was a volumetric Class A (or cal Was distilled or deionized water		stitution?	٥		3
			a		9
Was the sample mixed according	to the package insert prior to to	esting"	3		ם
101 8 4		Sample Processing			
		Jampie Processing			
Vho processed test?	Date of processi	ing			
Bhawna	26/6/24				
ordord	00/0154		YES N	3	NA
Was the correct sample number te	ested?			-	
Was the sample at room temperate			N.		0
Was the person running the test co			3		
Was the affected test run within th		ackage moon	3		a
	a sancing chapt make pe	and the second	3		- 0
		Reporting Results:			
ho reported Results	Date reported .				
Bhow ng	28/6/24.				
- Jawig	20 10 124.				
	1	Page 1 of 4			
Issued by Vinod Lonkar Urne		Issue Date (01 03 2023		
Approved by Dr. Manish Karek				-	
Doc No. GEN 03	Version No : I	Amend No	An	end Da	ie.





NA

NO

YES

							7		0
				method and reas					<u> </u>
Have the	esults been	reported con	recity (match	instrument prin	it out?"		V	. 0	5
Was the co	orrect unit r	reported?					S	0	
Was the d	ecimal sym	bol placed co	orrectly when	reported?			3	۵	0
Was the re	ported resu	ilt within the	instrument's	linear range?			3	, 0	<u> </u>
4	V-5		result done				3	0	-
		1	**						
					Int	ernal QC:			
							YES	NO	NA
		1		185 Ser 303 - WAVALO 400	and the second second second			0	3
					sample was run			0	3
Where the	re any shift	s or trends in	IQC just befo	ore/after the EQ	AS sample was	run?	. 0	3	States.
on the	day on I	EQAS san	ple	84					
	teading	MEAN	SD	CV	Z Score				
vel-l		0,030							
vel-II		<u> </u>			-				
1.									
vel-III		a. J				-			
1		41.5							
	month It	QC SD	CV	Z Score					
el-i						-			
rel-II						-			
el-III			-,						
11 2	A part and participate of the								
evious	three mo	onth EQA	S reports						
	Z score	BIAS	RMZ						
onth-I									
nth-H									
onth-UI									
				a					
- Hb							Vice	NO	NA
alibrati	ou;						YES		
Was the la	st calibratio	n acceptable	2				٦	٥	3
Was the la	st calibratio	n within the	manufacturer	's recommende	d dating ⁽⁾		٦	9	3
					ı	Reagent:			
	*								
eagent I	ot / exp.				• • • • • • • • • • • • • • • • • • • •				
			Lot	Expi	ration	Page 2 of 4			
			1			Page 2 of 4 Issue Date	01 03 2023		
Icened by	Vinod Le	onkar Um				1			
		tanish Karek							





NΛ

YES

NO

Was the test reagent stored correcti	y ?	Q	- 0	0
Was the test reagent properly prepare	ared?	13	a	3
Was the test reagent within manufa	cturer's dating?	Sr.	<u> </u>	0
Instrument:				
		YES	NO	NA
Was daily maintenance performed	on the day that the EQAS sample was run?		0	
Was the person performing mainter	nance current on training?	۵		3
- Was the instrument operating corre	ctly on the day the sample was tested	۵	٥	3/
Was the lab environment acceptable	e for the instrument (temperature, humidity, electrical, etc.) ⁹	S/		٥
	Sample Retest:	£		
Who retested sample?	Date tested			
		YES	NO	NA
Was the EQAS sample retested follows:	owing receipt of EQAS sample report?	٥	٥	3
If yes, was the result within accepta	ble limits for the EQAS sample?	۵	D	3
EQAS Evaluation:		YES	NO	NA
Inappropriate peer group or compar	ator?	0	٥	٦
	narrow limits due to use of a precise method or instrument	٥		2
	•			

		Page 3 of 4	
Issued by Vinod Lonkar -	Urnoc	Issue Date 01.03.	2023
	Larekar Lambar		1. 16
Doc No GEN 03	Version No 1	Amend No	Amend Date





OP

	-			
Mart	ha SO	P folle	wed o	orrectly?

YES NO NA

was are oscillation			9 23 3
Staining performed and inter	preted correctly?		
3 YES	NO	₽ NA	
Interpretation of microscopic	e examination interp	reted correctly?	
□ YES	. NO	T NA	
Lot Verification Type of error Identified - Root cause of the problem	Sample de	genorated Due	to Aigh Temp
Sample R	extreal wi	th Algh Tem	p
Corrective Action 9LC	Done Pa	or Typhi(o)	
Companyole	Result	shall be Cor	ocordance.

Signature and Name of Technologist / Section Head

Bhawk

Review by QM / HO / TM: Sign and Name

Issued by Vinod Lonkar Jenoul Issue Date 01.03 2023

Approved by Dr. Manish Karekar Version No. 1 Amend No. ... Amend Date





Proficiency Testing Outlier Investigation Form

ate D	Department	Test Analyte	Rapur tha	orted Re	sults
1717124 cceptable Results	Serology	widal Typhi			06/24
NO Aggulination					
- Light Mariot	C.	Commis			
		Sample receip	ŧ		
	117				
Was the kit received in good conditi	on'		YES.	NO	NA
Vas the correct program/cycle recer			.2	٦	٥
Vas the kit stored at the proper temp	perature following receipt?		2)	ū
				٥	ū
		Sample Preparati	on:		
o Prepared sample?	Date Prepared	and the same of th			
The second		4 (84			
Bhawna	26/6/2	99			
as the correct reconstitution incom			YES	NO	NA
as the correct reconstitution instructors a volumetric Class A (or calibrate	ction followed (handling, ti	me, temperature)?	0	٦	٥
as distilled or deionized water used	d for reconstant and	diffution?	a	٦	¥
as the sample mixed according to t			<u> </u>		4
	ore package insen prior to a	esting"	Ur	٥	٥
the transfer of		Sample Drasses			
		Sample Processir	ig:		
o processed test?	Date of processi	ng			
Bhawna	26 16 120	1			
9			YES	NO	
as the correct sample number tested			1		NA
as the sample at room temperature?				ם כ	۵
as the person running the test current				0	ū
s the affected test run within the st	ability claim listed in the po	ackage insen	.0/	0	<u> </u>
				0	٥
		Deporting Deput			
o reported Results		Reporting Results	S:		
2	Date reported.				
Bhawna	28/6/34				
		Page Lot 4			
sued by Vined Looker Urner					
proved by Dr. Manish Karekar N No. GEN 03	moules.	Issue Date	01 03 2023		





NA

NO

YES

One No GEN 03	vigitish isareka	Versio	n No : 1	- 2	Amend No		Amend D	ate .	
Approved by , Dr. M	Manich Karaba	Lymba	a#6						
	-Las Vinos	1			Issue Date	01.03.2023			
	477	ot	Expi	ration	Page 2 of 4				
ent lot / exp.	•								
					-ay				
				p	eagent:				
uic iast campiatit	on want the n					_			
s the last calibration			recommende	d dating"			۵		•
s the last calibration	on accentable?					3	۵	1	
bration:						YES	NO	. NA	
1-(1)									
	-	-							
th-II				-					
th-I					-				
Z score	BIAS	RMZ							
vious three m	onth EQAS								
					*				
-111			Sent Sent Sent Sent						
1-13									
l-I									
ious month l	IQC SD	CV	Z Score						
				and the state of					
I-III	4								
al-II									
I-I									
on the day on Reading	EQAS sam	ple SD	CV	Z Score					
			4			1700			
here there any shi					un''	. 5		المحا	
as IQC within an	avventable rang	e on the day	that the EOAS	sample was run?		0	0	Jar	
						YES	NO	NA	
				Inte	rnal QC:				
	or the reported	result done v	elleri,						
as the calculation						5	, o		
Vas the decimal sy Vas the reported re	7 3						- -	٥	
as the correct uni	100						0	0	
ve the results bed		recity (match	instrument pri	nt out)7		9	_	۵	
as the test configu							0	<u> </u>	





NΛ

YES

NO

Was the test reagent stored correct	fv?	. 🗸	۵	
Was the test reagent properly prep	ared?	D		
Was the test reagent within manuf	acturer's dating?	ت. ح	_	٥
Instrument:		•	_	11 111 20
		YES	NO	NA
- Was daily maintenance performed	on the day that the EQAS sample was run?		0	~
· Was the person performing mainte	nance current on training?	82=31	8773	
	ectly on the day the sample was tested	٥	٥	4
	e for the instrument (temperature, humidity, electrical, etc.)?		٥	Var
	to the historient (temperature, numidity, electrical, etc.)	9	′ 0	0
	Sample Retest:	×		
Who retested sample?	Date tested			
		YES	NO	NA
Was the EQAS sample retested follows:	lowing receipt of EQAS sample report?			0
If yes, was the result within accepta	able limits for the EQAS sample?	_	2	2
EQAS Evaluation:				•
		YES	NO	NA
Inappropriate peer group or compa	rator?	0	۵	3
- Inappropriate evaluation criteria, e	g narrow limits due to use of a precise method or instrument.		100	775
			a	a

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Approved by Dr. Manish F	Karekar Kula -		
Doc No. GEN 03	Version No. 1	Amend No	Amend Date





P									
11						YES	NO	NA	
as the SOP	followed correctly	7				. 7	0	٥	
						\	780		
aining pe	rformed and i	interpreted co	rrectly?						
YES		O NO		J NA					
terpretat	tion of microso		tion interpre	eted correctly?					
YES		□ . NO		NA					
						_			
ot Verific	eation error ldentific of the proble	ed - Sam	ple deg	en rated	Due to 1	nigh Te	mP		
oot cause	Sat	nple Rec	ived w	ith high	Temp.				
	J-11								
orrective	Action @	IC Don	o Foa	Typhi (0)				
		2							
00	a pambli	2 Result	1 Shall	be con	cordana	? .			
(0	in parabo	(0)	- C-						
ionature	and Name of	Technologist	Section Hea	d					
ignature	and Name of	Technologist	Section Hea	d					
ignature BA	and Name of	Technologist	Section Hea	d					
ignature B	and Name of	Technologist	Section Hea	d					
By	nowny			d					
By	and Name of			d					
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B.A. Review by	NOUNA V QM / HO / T	M: Sign and			age tof ! Issue Date	01.03.2023			
Review by	nowny	M: Sign and	Name		tage t of ± Issue Date	01.03.2023	Amend D		

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Proficiency Testing Outlier Investigation Form

Date	Department	N'agnostic PB Test Analyte Paratybhi(F		1:160		
(ナ)ラ)ユリ Acceptable Results	Senology	Lough Abril.)			
No aggulin	tion					
9	01011	Sample receipt				
- Letter 11 - 1				.775	NA	
			V1.5	NO.		
Was the kit received in good co-	high own			7	<u>۔</u> د	
Was the correct program cycle of	ceesed		~			
Was the kit stored at the proper t	temperature following receipt		W	_	-	
一种						
		Sample Preparation				
Who Prepared sample?	Date Prepared	l .				
Bang	26 6 2	LY			NA .	
			VIS	V()	-3	
Was the obtrect reconstitution his	nuction followed (handling,)	ime_leinp-tatiller	<u>_</u>	7		
Was a volumetric Class A for call	brailed) pipette used for recon-	SCOLO (FE)	J	_		
Was distilled or denoused water to	sed for reconstitution"		٦	ے	1	
Was the sample mixed according to	o the package insert prior to t	esting."	4		u	
		Nec No. (#200) Propriet Neces Add				
		Sample Processing:				
ho processed test?	Date of processi	ing				
Bhowng	26 6 24	1	vice ×	0	NA	
			YES N	()		
as the correct sample number teste	J.		4	J	0	
as the sample at room temperature			~		ū	
as the person running the test curre			~	J	2	
as the affected test ran within the st	tability claim listed in the po-	годе и чеп	1	כ	ū	
Provide.						
1 1000		Reporting Results:				
reported Results	Date reported.					
Bhowng	88/6/24					
		Fasc 1 of 1 Issue Date (i) (1 2021			
and the second s		1 155 100 1100 1100 1100 1100 1100 1100	1 _ 0 _ 3			
uea by Vinod Lonkar - Umacl	farilier:					





NA

NO

1000 See 2000			YES	NO	NAV
			8	0	3
Was the test configuration correct (instrument, met	hod and reagent)				J
Have the results been reported correctly (match inst	trument print out?"		~		
Was the correct unit reported				0)
Was the decimal symbol placed correctly when repo	orted*		~	8)	_
Was the reported result within the instrument's line	ar range [*]		W.	5	a
Was the calculation of the reported result done corre			~	_	
Was the Calculation of the reported tests					
	in .	Internal QC:			
		**	YES	NO.	NA
					V.
Was IQC within an acceptable range on the day that	t the EQAS sample w	INTUR" .	٦		
Where there any shifts of trends in E.N. just before	after the EQAS samp	L was run	2		_
C on the day on EQAS sample Reading MEAN SD	CV / Sco	0.6			
evel-1					
All charges and the second					
evel-II .					
evel-III					
Y ALLEN THE THE PARTY OF THE PA		#I	*		
revious month IQC	and the				
Mean SD CV	/ Score				
evel-l					
evel-II					
escisii					
evel-III					
revious three month EQAS reports					
Z score BIAS RMZ					
tonth-l					
onth-H					
onth-III			ÿ.		
alibration:			YES	NO	NA -
			n	٠	4
Was the last calibration acceptable	7.1355		٦		~ ~
Was the last calibration within the manufacturer's re-	ecommended dampy		J	ت	1
		Reagent:			
eagent lot 'exp.					
Lot	Experation				
		Page 2 of a Issue Date	0.03.2021		
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Approved by Dr Manish Karekar Laule .	W. Francis				
Dec No. GLN 3 Version N	No 1	Amend No		\mend ()	ite





NA

NO

YES

Was the test reagent stored correctly?	1	Ü	0
Was the test reagent properly prepared	Ü	u -	5
Was the test reagent within manufacturer's dating	1	٥	ر
Instrument:			
	YES	NO	NA
Was daily maintenance performed on the day that the FQAS sample was run	۵		1
Was the person performing maintenance current on training?	ם	٥	4
Was the instrument operating correctly on the day the sample was tested		٠	4
Was the lab environment acceptable for the instrument (temperature, humidity, electrical, etc.)	8	, o	3
Sample Retest:	٠		
Who retested sample? Date tested			,
	YES	NO	NA.
Was the EQAS sample retested following receipt of EQAS sample report		ت	-
If ves, was the result within acceptable limits for the EQAS sample."	ū	ū	5
EQAS Evaluation:	YES	NO	NA
Inappropriate peer group or comparator?	0	3	2
- Inappropriate evaluation criteria, e.g. narrow limits due to use of a precise method or instrument	ت	٦	٦
A III. and the state of the sta			





OP

was one SOP followed correctly	ne SOP	A as	as one SOP followed cor	recite
--------------------------------	--------	------	-------------------------	--------

NO NA YES

Staining performed and interpreted correctly?

3 YES

J NO

W

interpretation of microscopic examination interpreted correctly?

J YES

J NO.

Lot Verification

Root cause of the problem. Sample degenerated Due to high Temp. Root cause of the problem

Sample Recived with Aligh Temp.

Corrective Action 9 LC Done For-Typhi [AH]

Comparable Result shall be concordance

Signature and Name of Technologist / Section Head

Bhawre

Review by QM / HO / TM: Sign and Name

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Approved by Dr. Manish Karekar Ly-12-

Doc No. of No.3

Smend No -

Vingno Dale





Proficiency Testing Outlier Investigation Form

late	Reported Results				
(17/7/24)	Sexology	Paratyphi (BH)		1:80	
No Aggulina	tion.				
.00		 Sample receipt 			
起上 [[[]] [] 。			ore A	i()	NA
			YES.	1.00	
Was the kit received in good co	oditioa"				7
Vas the correct program/cycle			3	٦.	7
Was the kit stored at the proper	temperature following received	pt '	4	_	_
		o Desparation:			
		Sample Preparation:			
ho Prepared sample?	Date Prepar	ed			
Bhowng	26/6/	24	YIS ?	NO.	NA
			113		
Was the correct reconstitution in			~	<u> </u>	مان
Was a volumetric Class A (or calibrated) pipette used for reconstitution?			٦	a	~
Was distilled or deionized water			٦.	0	3
Was the sample mixed according	ig to the package insert prior	r to testing	1		-
		Carrie Drossecing			
		Sample Processing:			
ho processed test?	Date of proc	ressing			
Bhawng	26/61	24	****	NO.	NA
			YES	40	
Was the correct sample number	tested*		-	٦.	J
Was the sample at room temper	ature"		4	7	_
Vas the person running the test			W.	٦	
Was the affected test run within	the stability claim listed in	the package ti seff	4		3
		Reporting Results:			
		Reporting Results			
ho reported Results	Date reporte	ed .			
Bhawna	28/6/2	Ŋ			
1 111		Page 1 of 4 Issue Date (i)	103.2024		
	than: I	ISSUE DATE 19			
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DIAGNOSTIC			YES	NO	NA
			8		a
- Was the test configuration correct (in	istrument, method and reagent)		מי	a	٠,
- Have the results been reported correct	aly (match instrument print out				٠ .
- Was the correct unit reported?				J.	7
Was the decimal symbol placed corre	ecily when reported '		52	0	
Was the reported result within the ins			5/	<u> </u>	<u> </u>
Was the calculation of the reported re			3	_	
		100			
		Internal QC:			
			YES	NO	41
	at a street due LOAS comme	nie a stunt	١	٦	4
Was IQC within an acceptable range				ū	W
Where there any shifts or trends in 10	C just before/after the EQAS	Subhis was ten	-		g.
C on the day on EQAS sample	le .				
Reading MEAN	SD CV /	See e			
evel-i					
evel-li					
rvel-III					
revious month IQC Mean SD	CV Z Score				
vel-i		a			
vel-II					
vel-III	-				
14					
revious three month EQAS	reports				
Z score BIAS	RMZ				
onth-l					
onth-H					
onth-III					
llibration:			YES	NO	NA
Sec. 1 . 3			11.3		
vas the last calibration acceptable			9	a a	2
as the last calibration within the man	refretuter's recommended dat	ing.	7		Y
3		Reagent:			
E .		neagent.			
agant lot /avn					
eagent lot / exp.	Expiration	n			
Lon	r-Maranii	Page 2 of 4			
ferend by Vined Links Vined		Issue Date	-0.03.2023		
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Approved by Dr Manish Karekar 1		Amend No		Amend	Dete
Doc No. GEN 03	Version No. 1	Amend (Si)		Amend	Date





	YES	NO	NA
Was the test reagent stored correctly?			<u> </u>
Was the test reagent properly prepared?	4	٥	~
Was the test reagent within manufacturer's dating?	۵.	٥	7
Instrument:	D	٥	
Was daily maintenance performed on the day that the LQAS sample was run	YES	NO	NA
Was the person performing maintenance current on training?			y
Was the instrument operation	0		2
Was the instrument operating correctly on the day the sample was tested)	1
Was the lab environment acceptable for the instrument (temperature, humidity, electrical, etc. if	2	`	٦
Sample Retest	1,50		
ho retested sample? Date tested			
	YES	NO	NA
Was the EQAS sample retested following receipt of EQAS sample report?	1	9	4
I yes, was the result within acceptable limits for the EQAS sample	_ _	2	1
QAS Evaluation:			5/5
	YES	NO	NA
nappropriate peer group or comparator?		0	2
nappropriate evaluation criteria, e.g. narrow limits due to use of a precise method or instrument	ם	٥	2

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Doc No. GEN 03 Version No. 1 Amena No. - Amena Date





OP

Was 'me SOP followed correctly'

YES NO N

J YES	۵	NO	VNA

Staining performed and interpreted correctly?

Interpretation of microscopic examination interpreted correctly?

Lot Verification
Type of error Identified - Sample Degenerated Due to high Temp.
Root cause of the problem

Sample Recived with Augh Temp.

Comparable Regult Shall be concordance

Signature and Name of Technologist / Section Head

Bhawns

THE U

Review by QM / HO / TM: Sign and Name

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Proficiency Testing Outlier Investigation Form

17 10 10 11	Department	Test Analyte	B KabustRala Reported Results				
Acceptable Results	Senology	HIV	Non-Reactive				
Not Given	·						
100		 Sample receipt 					
			YES.	N()	NA		
Was the kill received in good cor				_			
Was the correct program/eyele of			3	5	5		
Was the kit stored at the proper	temperature following receipt			٥	.		
		Sample Preparation:					
Vho Prepared sample?	Date Prepared						
Bhowng	26/6/24						
40/0/27			YIS	501	8.3		
Was the correct reconstitution instruction followed thandling, time temperature?			V	3			
Was a volumetric Class A (or calibrated) pipette used for reconstitution?			_		V		
Was distilled or deionized water used for reconstitution ⁹			٥	5	~		
Was the sample mixed according to the package insert prior to testing?			~	ū	_		
			6.				
		Sample Processing:					
who processed test?	Date of processing	z.					
Blowns	26/6/24						
			YES	N()	1.7		
Was the correct sample number t	ested ²		4	_	J		
Was the sample at room tempera-	ane"		4	ű,	٦		
Was the person running the test of	arrent in their training?		V	O	J		
Was the affected test run within the stability claim based in the package it sen			4	a -	ت		
Was the affected test run within I							
				(0)			
		Reporting Results:		(
		Reporting Results:		140)			
	Date reported .			145			
	Date reported.			*			
Vho reported Results		Page (vi. 1)					
Who reported Results	88/6/24		4 2023				





Vas the test configuration correct (instrument, method and reagent)	~	0	3
lave the results been reported correctly (match instrument print out)	4	0	٥
Nas the correct unit reported	8	0	٥
Vas the decimal symbol placed correctly when reported?	8	0	0
Was the reported result within the instrument's linear range?	4	0	٥
Vis the calculation of the reported result done correctly	4	0	2
Internal QC:			
	YES	NO	NA
Vas IQC within an acceptable range on the day that the EQAS sample was run?		0	-
there there any shifts or trends in IQC just before/after the EQAS sample was run'	. 0	5	-
	9	-	
on the day on EQAS sample Reading MEAN SD CV / Score			
1014			
194-11			
xel-III			
revious month IQC			
Mean SD CV 7 Score			
vel-11			
vel-III			
A Company of the comp			
revious three month EQAS reports			
Z score BIAS RMZ			
xth-l			
nith-II			
TALL IF			
nth-III			
dibration:			
	YES	NO	NA .
/as the last calibration acceptable?	٥	٥	5
fas the last calibration within the manufacturer's recommended dating	٥	0	~
Reagent:			
Expiration			
CAPITATION Page 2 of 4			
	Date 01 03 2023		
Approved by Dr. Manish Karekar			
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A SAME OF THE PROPERTY OF THE PARTY OF THE P	YES	NO.	1465
		0	0
Was the test reagent stored correctly?	1	О	.2
Was the test reagent properly prepared?		_	~
Wasabe test reagent within manufacturer's dating?	J		
Instrument:	YIS	NO	7.7
Was daily maintenance performed on the day that the EQAS sample was run?	٥	0	N N
Was the person performing maintenance current on training?	0		
Was the instrument operating correctly on the day the sample was tested			-
Was the lab environment acceptable for the instrument (temperature humidity electrical, etc.)	W.	_	42
Sample Retest:	٠		
Who retested sample? Date tested			
	YES	NO	NA
Was the EQAS sample retested following receipt of EQAS sample report?		C	8
If yes, was the result within acceptable limits for the EQAS sample?	3)	J
EQAS Evaluation:	YES	NO.	NA
	0	٥	_
Inappropriate peer group or comparator?			2
- Inappropriate evaluation criteria, e.g. narrow limits due to use of a precise method or instrument.	9		

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,OP						
131 130 F			YES	NO.	V.A.	
Was the SOP followed correctly?			-/	0		
			M	J	-	
Staining performed and in	terpreted correctly?					
2 yes	O NO	NA.				
		- 5/4				
Interpretation of microscop	pic examination interp					
J YES C	□ NO	S NA				
Lot Verification						
Type of error Identified	- Qandam	overor				
Deat cause of the problem	HAP III				*	
NIAL S.	halad Base	use Result Not	- Griven	•		
110+ De	Decrea Dece	- C				
Corrective Action _ \ \ \ \ \ \	IC Dama	1 2 1 1 1 2 0	01.047	91		
-/ J	LC Done	(Acceptable R	ورهاي	•		
4-11						
	1					
Signature and Name of Tech	hnologist / Section Head	1				
24		(40)				
Brawns						
Review by QM / HO / TM: S	Sign and Name					
1) problem (1)						
The last						
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4 m c						
in the						
l bearl		Page 1 of 1 Issue Date 1/1 /	13 2023			
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