LifeWell	PT EQAS RESULT REVIEW FORM

Issued by QA:

Department: Immuno assay, Biochemistry, Hematology	**Month / Year:** May - 2023
PT Provider: MHL Eqas	**Distribution / Lot No:**
Analyte(Test): HIV, HCV, HBSAg, LFT, KFT, Lipid Profile, Urine Routine, VDRL, CBC	
Machine used: Mispa CXL Pro Plus, Aspen AD3200, Manual	**Kit used:** Viola
Test done by: Anuj Kumar, Puneet	**Done on:**
Report uploaded by: Abhishek	**Report uploaded on:**
Software used:	
EQAS Report received on 22-05-2023	
Reviewed by: Abhishek **Approved by:** Dr. Parkhedi	
Observations:	

*If results are ungraded, please attach self-assessment.If satisfactory no corrective and preventive action required. But if unsatisfactory, corrective and preventive action is required with optimum evidence.

Self-Assessment Result: ☐ Satisfactory ☒ 5 Unsatisfactory

Attachment: ☑ Yes ☐ No

Please investigate failure for unsatisfactory performance and submit a report to QA and Medical Director in 3 Days.

Approved by

Signature
(Lab Director/Designee)
Dr. Parkhedi
24/5/23

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INVESTIGATION FORM FOR UNACCEPTABLE PT/EQAS RESULTS

Issued by QUA:

Department	Biochemistry		
PT provider	MHL		
Survey Name:			
Date Survey received	3 May 2023	Date Analysis Performed:	08/05/2023
Date Survey Results Submitted	17/5/2023	Date Results received:	25/5/2023

Investigation performed by	Anuj Kumar / Rajeet Gupta		
Lab director	Dr. Pankaj	Date 29/5/23	

Unacceptable Result 1			
Specimen No.	Sample No-1	Analyte	Bilirubin in Direct.
Reported result	0.00	Intended result/range	0.10
Acceptable Lower Limit	0.04	Acceptable Higher Limit	0.16
SD	0.03	CV%	37.35

Unacceptable Result 2			
Specimen No.	Sample No-2	Analyte	Bilirubin D
Reported result	0.00	Intended result/range	0.11
Acceptable Lower Limit	0.038	Acceptable Higher Limit	0.185
SD	0.03	CV%	34.25

Unacceptable Result 3			
Specimen No.		Analyte	
Reported result		Intended result/range	
Acceptable Lower Limit		Acceptable Higher Limit	
SD		CV%	

EVALUATION OF POSSIBLE SOURCES OF ERROR

Clerical	Yes	No	N/A
Incorrect transcription of the result from the instrument read-out or report? (Check the raw data.)			✓
Incorrect instrument/method/reagent reported on the result form (Check instrument log book)			✓
Mis-match of the units of measure between the result form and the instrument results			✓
Incorrect decimal placement			✓
Errors in calculations.			✓
Mis-match between result reported on the 'result form' and on the 'proficiency testing evaluation report'			✓
Mis-match between result reported on the 'result form' and on the 'proficiency testing evaluation report'			✓

Any other clerical problem?			✓

A response of "**Yes**" to any of these questions may indicate a clerical error.

Although reporting of PT results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with PT or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact PT provider.

Procedural	Yes	No	N/A
Written procedure not followed			✓
Improper preparation of reagents			✓
Reagents open stability not within acceptable range			✓
Faulty standards run			✓
Unacceptable IQC results (Run accepted in non-linear range/though controls were out of range)			✓
Incorrect interpretation of microscopic examinations			✓
Incorrect dilution or pipetting error			✓
Incorrect staining or interpretation			✓
Time delay between reconstitution and analysis			✓
Media preparation related			✓
Antibiotic disc potency			✓
Any other procedural problem			✓

A response of "**Yes**" to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method.

A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.

Analytical	Yes	No	N/A
Most recent calibration unacceptable or not within established stability limits at the time of PT			✓
Instrument repaired or replaced recently at time of PT run			✓
Review of past PT results indicate unevenly distributed data or a bias			✓
Intended result not within the measuring range for the instrument			✓
Was instrument maintenance performed on schedule?			✓
Review of records indicate there was related instrument/test problems noted prior to or after the PT was performed			✓
Any other analytical problem?			✓

A response of "**Yes**" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

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INVESTIGATION FORM FOR UNACCEPTABLE PT/EQAS RESULTS

Specimen handling	Yes	No	N/A
Survey specimens not reconstituted as indicated in the Kit Instructions			✓
Survey specimens not stored as indicated in the Kit Instructions not performed as indicated			✓
Special instructions provided in the Kit Instructions not performed as material			✓
Correct tests not performed on the correct vial of proficiency testing			✓
Survey specimen mix-up			✓
Any other problem related to specimen handling?			✓

A response of "**Yes**" to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Surveys materials.

PT Material	Yes	No	N/A
Late shipment			✓
Hemolysed sample			✓
Bacterial contamination			✓
Perceived survey bias			✓
Poor growth in culture			✓
Unstable PT material			✓
Matrix effect incompatible with method			✓
No comparable peer group			✓
Inappropriate peer group based on method reported on result form			✓
Acceptable range too low			✓
Any other problem?			✓

A response of "**Yes**" to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, ensure timely receipt of Surveys after arrival in the institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact PT provider for additional information if needed.

Miscellaneous	Yes	No	N/A
Was analysis performed by technically competent personnel? (Check technical competence records)			✓
Were all patient reports satisfactory on day of run? (i.e. there were no patient complaints)			✓
Were the results of rerun (where possible) the same?			✓
Any other actions (please specify)			✓

SUMMARY REPORT

Root-cause analysis

After Check Maitirance Iqc and calibration, there are found suspected to be Random error.

Corrective Action proposed

Eqas Retained sample rerun result came. Bilirubin D - S21 → 0.07. which is acceptable.
S22 → 0.07

Corrective Action taken (To be filled within 30 days of receipt of EQAS result)

We will guide to our staff to proper maintirance of instrument and after maitirance and qc reports release.

Evidence that problem is solved after corrective action (To be attached)

Rerun data attached.

Preventive Action (if any) proposed:
NA
Conclusion and future plan if no evidence found:
Firstly verification by one technician and second verification by Lab manager.

Recorded by (Sign / Date)	24/11/23
Reviewed by Lab/Medical Director (Sign / Date)	Dr. Pal Ghosh 24/11/23
Reviewed by Head – QA (Sign / Date)	24/11/23

非正式报告单

* * * Hospital

* * CheckerSample Report

Name:		Sex:		Age:	
Spl No.:	2				
Case No.:		Dept.:		Bed No.:	
Dr submission:					
Spl Type:	Serum	Patient Type:		Barcode:	EQAS BC 2
Clinical Diagnosis:				Note:	

Item Abb.	Test Result	Prompt	Unit	Reference
1 DBIL	0.07		mg/dL	0-0.4

* * * Hospital

非正式报告单

* * CheckerSample Report

Name:		Sex:		Age:	Spl No.: 1
Case No.:		Dept.:		Bed No.:	Dr submission:
Spl Type:	Serum	Patient Type:		Barcode:	EQAS BC 1
Clinical Diagnosis:				Note:	

Item Abb.	Test Result	Prompt	Unit	Reference
1 DBIL	0.07		mg/dL	0-0.4

Metropolis Healthcare Ltd., EQAS

LIFEWELL DIAGNOSTICS PVT LTD (LAJPAT NAGAR) (875)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 230104 and Sample No 01 **Report Date :** 19/05/2023

Analyte	Instrument	Result Value	Standard Unit	Z-Score
* Bilirubin Direct	Mispa CXL Pro Plus	0.00	mg/dl	*
! Urea	Mispa CXL Pro Plus	29.36	mg/dl	2.79
! Creatinine	Mispa CXL Pro Plus	1.24	mg/dl	2.12

Legend @ : z score ≤ 2.0 - Acceptable

! : 2.0 < z score < 3.0 - Warning

X : z score ≥3 - Unacceptable

: Not Evaluated

: Delayed Result Entry

* : Not considered for evaluation.

Problem Classification: _____

Corrective Action: _____

Reviewed by: _____ **Dated:** _____

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LIFEWELL DIAGNOSTICS PVT LTD (LAJPAT NAGAR) (875)

Outlier And Analyte Summary Report

Result Details For Cycle No 230104 and Sample No 01

Report Date : 19/05/2023

Instrument : **Mispa CXL Pro Plus**

Analyte	Standard Unit	Result Value	Mean	Z-Score	RMZ
* Bilirubin Direct	mg/dl	0.00	0.08	-3.37 *	0.00
@ Glucose	mg/dl	72.85	71.76	0.32	1.31
! Urea	mg/dl	29.36	24.19	2.79	2.23
! Creatinine	mg/dl	1.24	0.86	2.12	1.60
@ Bilirubin Total	mg/dl	0.15	0.18	-0.60	-0.63
@ Total Protein	g/dL	7.18	6.89	0.39	0.32
@ Albumin	g/dL	4.22	4.02	0.97	0.85
@ Uric Acid	mg/dl	5.61	5.51	0.62	0.64
@ Calcium	mg/dl	9.85	9.98	1.45	1.58
@ Phosphorous Inorganic	mg/dl	5.19	4.87	1.89	1.80
@ Cholesterol	mg/dl	165.09	155.07	0.40	0.41
@ Triglycerides	mg/dl	145.01	126.02	1.02	1.08
@ HDL	mg/dl	35.84	34.49	0.04	-0.11
@ LDL	mg/dl	100.24	94.20	0.66	0.64
@ ALT	U/L	7.74	7.58	0.14	1.42
@ AST	U/L	16.99	16.26	-0.90	-0.78
@ ALP	U/L	60.17	56.37	0.43	0.40
@ GGT	U/L	29.36	26.10	0.81	1.16

Instrument : **Sensa Core ST200 Aqua**

Analyte	Standard Unit	Result Value	Mean	Z-Score	RMZ
@ Chloride	mmol/L	100.80	103.20	0.11	-0.09
@ Sodium	mmol/L	137.60	135.43	0.48	0.48
@ Potassium	mmol/L	4.65	4.34	0.41	0.33

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Outlier And Analyte Summary Report

Result Details For Cycle No 230104 and Sample No 01

Report Date : 19/05/2023

Legend @ : Acceptable

! : 2.0 < z score < 3.0 - Warning

X : z score ≥3 - Unacceptable

: Not Evaluated

: Delayed Result Entry

* : Not considered for evaluation.

Total Parameters	21
Not Evaluated Parameters	0
Evaluated Parameters	21
Outlier Parameters (X)	1
EQAS Score Biochemistry	95.24 %

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

LIFEWELL DIAGNOSTICS PVT LTD (LAJPAT NAGAR) (875)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 230104 and Sample No 02 **Report Date :** 19/05/2023

Analyte	Instrument	Result Value	Standard Unit	Z-Score
* Bilirubin Direct	Mispa CXL Pro Plus	0.00	mg/dl	*
! Glucose	Mispa CXL Pro Plus	86.69	mg/dl	2.3
! ALT	Mispa CXL Pro Plus	12.72	U/L	2.7

Legend @ : z score ≤ 2.0 - Acceptable

! : 2.0 < z score < 3.0 - Warning

X : z score ≥3 - Unacceptable

: Not Evaluated

: Delayed Result Entry

* : Not considered for evaluation.

Problem Classification: _____

Corrective Action: _____

Reviewed by: _____ **Dated:** _____

Metropolis Healthcare Ltd., EQAS

LIFEWELL DIAGNOSTICS PVT LTD (LAJPAT NAGAR) (875)

Outlier And Analyte Summary Report

Result Details For Cycle No 230104 and Sample No 02

Report Date : 19/05/2023

Instrument : **Mispa CXL Pro Plus**

Analyte	Standard Unit	Result Value	Mean	Z-Score	RMZ
* Bilirubin Direct	mg/dl	0.00	0.07	-3.03 *	0.00
! Glucose	mg/dl	86.69	80.48	2.30	1.31
@ Urea	mg/dl	30.48	27.03	1.66	2.23
@ Creatinine	mg/dl	1.09	0.90	1.07	1.60
@ Bilirubin Total	mg/dl	0.15	0.17	-0.65	-0.63
@ Total Protein	g/dL	7.08	6.98	0.24	0.32
@ Albumin	g/dL	4.20	4.03	0.72	0.85
@ Uric Acid	mg/dl	5.90	6.05	0.66	0.64
@ Calcium	mg/dl	9.98	9.94	1.70	1.58
@ Phosphorous Inorganic	mg/dl	5.27	5.12	1.71	1.80
@ Cholesterol	mg/dl	164.35	156.69	0.42	0.41
@ Triglycerides	mg/dl	153.34	140.42	1.14	1.08
@ HDL	mg/dl	33.48	32.55	-0.26	-0.11
@ LDL	mg/dl	100.20	95.72	0.62	0.64
! ALT	U/L	12.72	8.99	2.70	1.42
@ AST	U/L	20.59	19.08	-0.65	-0.78
@ ALP	U/L	62.14	60.61	0.37	0.40
@ GGT	U/L	42.88	41.52	1.51	1.16

Instrument : **Sensa Core ST200 Aqua**

Analyte	Standard Unit	Result Value	Mean	Z-Score	RMZ
@ Chloride	mmol/L	98.50	103.08	-0.28	-0.09
@ Sodium	mmol/L	137.90	136.63	0.48	0.48
@ Potassium	mmol/L	4.65	4.41	0.24	0.33

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LIFEWELL DIAGNOSTICS PVT LTD (LAJPAT NAGAR) (875)

Outlier And Analyte Summary Report

Result Details For Cycle No 230104 and Sample No 02

Report Date : 19/05/2023

Legend @ : Acceptable

! : 2.0 < z score < 3.0 - Warning

X : z score ≥3 - Unacceptable

: Not Evaluated

: Delayed Result Entry

* : Not considered for evaluation.

Total Parameters	21
Not Evaluated Parameters	0
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Outlier Parameters (X)	1
EQAS Score Biochemistry	95.24 %

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