



Issued by QA: June 22/05/2023

Department: <u>Biochemistry</u>	Month / Year: <u>May 2023</u>
PT Provider: <u>Metropolis Healthcare</u>	Distribution / Lot No: <u>230104</u>
Analyte(Test): <u>AST, AIP, GGT, Bil. D, Urea, Creatinine, Glucose, ALT, HbA1c, Bil. T, Total Protein, A1b, Uric Acid, Calcium, Phosphorus, Electrolyte, Tg, HDL, LDL, ALT</u>	
Machine used: <u>AgAPPE Mispa Cx1 pro</u>	Kit used: <u>Agappe</u>
Test done by: <u>Abhishek</u>	Done on: <u>10/05/2023</u>
Report uploaded by: <u>Abhishek</u>	Report uploaded on: <u>12/05/2023</u>
Software used: <u>online web portal</u>	
EQAS Report received on: <u>19/05/2023</u>	
Reviewed by: <u>Abhishek 22/05/2023</u>	Approved by: <u>June 22/05/2023</u>
Observations: <u>Bilirubin Direct urea and creatinine</u>	

\*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  Unsatisfactory

Attachment:  Yes  No

Please investigate failure for unsatisfactory performance and submit a report to QA and Medical Director in 30 Days.

Approved by

Signature (Lab Director/Designee) 

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  $\leq$  2.0 - Acceptable  
 ! : 2.0 < z score < 3.0 - Warning  
 X : z score  $\geq$  3 - Unacceptable  
 # : Not Evaluated  
 ⊙ : Delayed Result Entry  
 \* : Not considered for evaluation.

Problem Classification:

*Bilirubin Direct not consider for evaluation  
 urea and creatinine are in warning*

Corrective Action:

*There is the error in the sample processing after  
 re-run the sample we got the correct value.*

Reviewed by:



Dated: *22/05/2023*

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

Legend @ : Acceptable

! :  $2.0 < z \text{ score} < 3.0$  - Warning

X :  $z \text{ score} \geq 3$  - 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*

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

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  $\leq$  2.0 - Acceptable  
 ! : 2.0 < z score < 3.0 - Warning  
 X : z score  $\geq$  3 - Unacceptable  
 # : Not Evaluated  
 Ⓞ : Delayed Result Entry  
 \* : Not considered for evaluation.

**Problem Classification:**

*Bilirubin Direct not consider for evaluation*

*Glucose and Alt are in warning*

**Corrective Action:**

*then to the error in the sample processing after re-run the sample we get the correct value.*

**Reviewed by:**



**Dated:**

*22/05/2023*

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

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 %

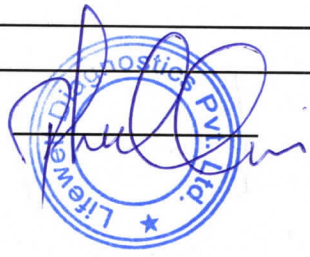
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 Mumbai - 400070

Analyte	Instrument	Result Value	Standard Unit	Z-Score
No Outlier				
Legend @ : z score $\leq$ 2.0 - Acceptable ! : 2.0 < z score < 3.0 - Warning X : z score $\geq$ 3 - Unacceptable # : Not Evaluated Ⓞ : Delayed Result Entry * : Not considered for evaluation.				

Problem Classification: no outlier found Result Satisfactory

Corrective Action: not Required

Reviewed by: 

Dated: 22/05/2023



Instrument : Mispa CXL Pro

Analyte	Standard Unit	Result Value	Mean	Z-Score	RMZ
@ HbA1c	%	8.14	8.92	-0.56	0.10

Legend @ : Acceptable	<table border="1"> <tr> <td>Total Parameters</td> <td>1</td> </tr> <tr> <td>Not Evaluated Parameters</td> <td>0</td> </tr> <tr> <td>Evaluated Parameters</td> <td>1</td> </tr> <tr> <td>Outlier Parameters (X)</td> <td>0</td> </tr> <tr> <td>EQAS Score HbA1c</td> <td>100.00 %</td> </tr> </table>	Total Parameters	1	Not Evaluated Parameters	0	Evaluated Parameters	1	Outlier Parameters (X)	0	EQAS Score HbA1c	100.00 %
Total Parameters		1									
Not Evaluated Parameters		0									
Evaluated Parameters		1									
Outlier Parameters (X)		0									
EQAS Score HbA1c	100.00 %										
! : 2.0 < z score < 3.0 - Warning											
X : z score ≥3 - Unacceptable											
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Analyte	Instrument	Result Value	Standard Unit	Z-Score
No Outlier				
Legend @ : z score $\leq$ 2.0 - Acceptable ! : 2.0 < z score < 3.0 - Warning X : z score $\geq$ 3 - Unacceptable # : Not Evaluated Ⓞ : Delayed Result Entry * : Not considered for evaluation.				

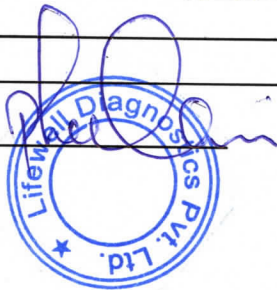
Problem Classification:

*No problem found all Result found  
 Satisfactory*

Corrective Action:

*There is no need of corrective action*

Reviewed by:



Dated:

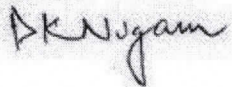
*22/05/2023*

Instrument : Mispa CXL Pro

Analyte	Standard Unit	Result Value	Mean	Z-Score	RMZ
@ HbA1c	%	9.51	10.04	0.75	0.10

Legend @ : Acceptable	<table border="1"> <tr> <td>Total Parameters</td> <td>1</td> </tr> <tr> <td>Not Evaluated Parameters</td> <td>0</td> </tr> <tr> <td>Evaluated Parameters</td> <td>1</td> </tr> <tr> <td>Outlier Parameters (X)</td> <td>0</td> </tr> <tr> <td>EQAS Score HbA1c</td> <td>100.00 %</td> </tr> </table>	Total Parameters	1	Not Evaluated Parameters	0	Evaluated Parameters	1	Outlier Parameters (X)	0	EQAS Score HbA1c	100.00 %
Total Parameters		1									
Not Evaluated Parameters		0									
Evaluated Parameters		1									
Outlier Parameters (X)		0									
EQAS Score HbA1c		100.00 %									
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X : z score ≥3 - Unacceptable											
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Issued by QUA: *22/05/2023*

Department	<i>Biochemistry</i>		
PT provider	<i>MHL</i>		
Survey Name:			
Date Survey received	<i>07 May 2023</i>	Date Analysis Performed:	<i>08/05/2023</i>
Date Survey Results Submitted	<i>17/5/2023</i>	Date Results received:	<i>22/05/2023</i>

Investigation performed by	<i>Amy Kumar / Punit Gupta / Abinida</i>		
Lab director	<i>Dr Paniker</i>	Date	<i>24/05/2023</i>

Unacceptable Result 1			
Specimen No.	<i>Sample No. 1</i>	Analyte	<i>Bilimbin Direct</i>
Reported result	<i>0.00</i>	Intended result/range	<i>0.10</i>
Acceptable Lower Limit	<i>0.04</i>	Acceptable Higher Limit	<i>0.16</i>
SD	<i>0.03</i>	CV%	<i>27.35</i>

Unacceptable Result 2			
Specimen No.	<i>Sample No. 02</i>	Analyte	<i>Bilimbin D</i>
Reported result	<i>0.00</i>	Intended result/range	<i>0.11</i>
Acceptable Lower Limit	<i>0.038</i>	Acceptable Higher Limit	<i>0.135</i>
SD	<i>0.03</i>	CV%	<i>34.25</i>

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.)			<i>/</i>
Incorrect instrument/method/reagent reported on the result form (Check instrument log book)			<i>/</i>
Mis-match of the units of measure between the result form and the instrument results			<i>/</i>
Incorrect decimal placement			<i>/</i>
Errors in calculations.			<i>/</i>
Mis-match between result reported on the 'result form' and on the 'proficiency testing evaluation report'			<i>/</i>
Mis-match between result reported on the 'result form' and on the 'proficiency testing evaluation report'			<i>/</i>

Any other clerical problem?			✓
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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.

<b>Specimen handling</b>	Yes	No	N/A
Survey specimens not reconstituted as indicated in the Kit Instructions			✓
Survey specimens not stored as indicated in the Kit Instructions			✓
Special instructions provided in the Kit Instructions not performed as indicated			✓
Correct tests not performed on the correct vial of proficiency testing material			✓
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.

<b>PT Material</b>	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.

<b>Miscellaneous</b>	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 Maintenance IQC and Calibration.  
There are found Suspected to be Random error

## Corrective Action proposed

Eqas Retained Sample error result come. Bilimbin  
Dhit - sample 1  $\rightarrow$  0.07  
Sample 2  $\rightarrow$  0.07 which is acceptable

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

We have guide to our technical staff to proper  
Maintenance of instrument and after Maintenance  
and QC report released.

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



Review - 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 Director

Recorded by (Sign / Date)	
Reviewed by Lab/Medical Director (Sign / Date)	
Reviewed by Head – QA (Sign / Date)	