INSTRUCTIONS FOR PARTICIPANTS – CLINICAL BIOCHEMISTRY	FORMAT NO.	FB/EQA/FR/009
	D.P NO.	FB/EQA/DP/012
	REV. NO.	03
	DATE	07/01/2025
Ref.: ISO 17043 – 2023 CL. No.: 7.3.5	SHEET	1 of 4

Clinical Biochemistry – CC24061					
Opening Date:	month/date/year	**PT Round No.:**		**Lot No:**	
UPN:		**Result Deadline Date:**	month/date/year (midnight 12:00 IST)	**Report Issue Date:**	

Intended Use:

To provide an independent and confidential Proficiency Testing (PT) of individual laboratory performance to promote a continuous improvement of the quality. The EQAsure Clinical Biochemistry PT scheme is primarily intended for hospitals and clinical laboratories using semiautomated or automated method for clinical biochemistry testing.

Analytes:

Albumin, ALP (Alkaline phosphatase), ALT/SGPT (Alanine aminotransferase), AST/SGOT (Aspartate aminotransferase), Total Amylase, Total Bilirubin, Bicarbonate, Total Cholesterol, HDL Cholesterol, Creatine kinase, Creatinine, Total Calcium, Chloride, Glucose, Lithium, Iron, Magnesium, Potassium, Total Protein, Sodium, Triglycerides, Urea, Uric Acid, Phosphorus.

PT Item:

Lyophilized PT item prepared from human serum added with chemicals, purified bio-chemicals and stabilizers.

Externally Provided Activity:

Preparation of PT items and Homogeneity & Stability testing of PT item.

Storage:

The PT item is shipped with cool bags. Upon arrival of PT item, store it at 2-8°C in vertical position. PT item should be protected from the direct light during storage.

Timing of Assay:

Participants will receive PT item at pre-defined time period**.** Kindly refer to “Calendar of Program Events” to get information about dispatched month of next round of PT item for testing and deadline date of result to be submitted on web portal. Each PT item vial is labeled with lot number, month of PT item use and expiry date. Participants have to use appropriate PT item as per the schedule.

Procedure for Preparation and Analysis:

Preparation:

Remove the vial from the refrigerator and allow it to reach at room temperature (18 to 25°C) for 15 minutes before reconstitution.

Open the vial carefully and reconstitute the lyophilized PT item with deionized water, according to the quantity specified on the vial label.

Allow the reconstituted PT item to stand at room temperature (18 to 25°C) for at least 20 minutes before use. Swirling gently to completely dissolve lyophilized material and ensure homogeneity of the contents. It is recommended to test the PT item as soon as possible after reconstitution.

Make sure that the deionized water used is of good quality: the values of some analytes (Ca, Cl, Na, K) could undergo significant changes depending upon quality of deionized water.

Analysis:

Participants are free to use methods/analyser of their choice. The PT item should be treated and analyzed same as patient sample. Analyze the PT item in accordance with instructions provided in operation manual of the analyzer.

PT item shall not be return back to PT provider unless it is asked for.

PT Results:

Participants have to test PT items by themselves only and are not allowed to utilise external service providers for the same. The participants are advised to keep record of all calculations, graphs and other raw data to demonstrate that PT item testing is done by them in their premises. The failure of participation laboratory to provide above information when asked by EQAsure may lead to results not considered/disqualify participation from PT scheme and decision of EQAsure in this regard shall be final. EQAsure is not seeking this information along with PT reports but may ask for the same if required.

The results of each analyte must be submitted on web portal on or before midnight 12:00 IST on of deadline date of result submission.

Results shall be submitted in the "Result" section on web portal. Refer the "Participant Manual" for initiating request for late result and amendment in results.

Care must be taken to report result of each analyte in the units of measurement available on web portal; the laboratory that uses different units must convert its results using appropriate conversion factor before submitting results.

Performance Evaluation and Reports:

After deadline date of result submission, result received from participants is recorded, analysed and evaluated by valid methods as described in ISO 13528 standard. At the end of each round, participants will get summary report for all analytes as well as report for individual analyte showing their performance along with graphical presentation. All reports are designed as per ISO 17043 requirements.

Bio-safety:

PT item is prepared from human serum and hence it should be considered potentially infectious and should be handled with the same precautions as patient sample.

Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with large volume of water. In case of contact with eyes or if ingested, seek immediate medical attention.

The residual PT item remaining after testing must be decontaminated and disposed of in-compliance with the local regulations of waste disposal.

Factor Affecting Measurement Results:

The PT item should not be used past the expiration date.

It is recommended to store the PT item at recommended temperature as mentioned in "Storage" section.

Participant shall use PT item for analytes mentioned in "Analyte" section.

The performance of this PT item is assured only if it is properly stored and used as described in the Instruction for Participant. Incomplete mixing of PT item before use affects PT item use for testing and remaining PT item.

Confidentiality:

EQAsure is committed to maintain confidentiality for each participant. To protect the privacy of each participant assigned an Unique Participant Number (UPN), which is known only to EQAsure and the participant. Participant results and reports are confidential and only accessible by participant laboratory in their login account. A participant laboratory does not have access to the details of other participants. All details supplied by participants to EQAsure is kept confidential. EQAsure will not disclose the participants identity without the prior permission of the participants to public domain, unless required by regulatory authority and/or accreditation bodies. Participant specific information will not share in public domain if required to share prior permission from participants will be taken. Participant details and performance will be shared to accreditation bodies and regulatory authorities without prior permission of participants, when asked. An authorized person will deal with all communications from participants and reasonable confidentiality will be maintained. For non-disclosure of any information that would breach the confidentiality, staff members have signed the confidentiality agreement.

Collusion between participants is not allowed. To prevent collusion of result, participant should not share or discuss their results with other participants. EQAsure reserves the right to disqualify any participating laboratory from PT scheme if there is evidence of falsification or collusion with another participating laboratory.

Support:

All participants can contact our support team during working hours for administrative, technical, scientific or organizational information at +91 7096119992 and by e-mail at pmt@fugenbiomed.com.

Limited Expressed Warranty Disclosure

FUGEN BIOMED PVT., LTD. limits the warranty to the PT item in as much as the said PT item will function only within the limitations and specification as described in the Instructions for Participants. Any deviation there from by the purchaser or the end user shall not be the liability and/or responsibility of FUGEN BIOMED PVT., LTD. FUGEN BIOMED PVT., LTD. shall not be liable and/or responsible for any misuse of the said PT item after the date of expiry. If any defect is proved in manufacture of the PT item, FUGEN BIOMED PVT., LTD. shall be liable only to the extent of the replacement of the said PT item or refund of its purchase price thereof and shall not be liable for any consequential loss arising there from.

Number of digits before and after decimal point in result entry:

Name of Analyte	Measurement Unit	Reported Unit	Number of Digit to Enter	
			Before Decimal (Maximum)	After Decimal (Maximum)
Albumin	g/dL	g/dL	1	2
	g/L		2	1
ALP	IU/L	IU/L	4	2
	µkat/L		2	2
ALT/SGPT	IU/L	IU/L	4	2
	µkat/L		2	2
AST/SGOT	IU/L	IU/L	4	2
	µkat/L		2	2
Total Amylase	IU/L	IU/L	4	2
	µkat/L		2	2
Total Bilirubin	mg/dL	mg/dL	1	2
	µmol/L		3	1
Bicarbonate	mEq/L	mEq/L	2	2
	mmol/L		2	2
Total Cholesterol	mg/dL	mg/dL	3	1
	mmol/L		2	2
HDL Cholesterol	mg/dL	mg/dL	3	1
	mmol/L		1	2
Creatine kinase	IU/L	IU/L	3	1
	µkat/L		2	2
Creatinine	mg/dL	mg/dL	1	2
	µmol/L		3	1
Total Calcium	mg/dL	mg/dL	2	2
	mmol/L		1	2
Chloride	mEq/L	mEq/L	3	1
	mmol/L		3	1
Glucose	mg/dL	mg/dL	3	2
	mmol/L		2	2
Lithium	mEq/L	mEq/L	1	2
	mmol/L		1	2
Iron	µg/dL	µg/dL	3	2
	µmol/L		2	1
Magnesium	mg/dL	mg/dL	1	2
	mmol/L		1	2
Potassium	mEq/L	mEq/L	1	2
	mmol/L		1	2

Name of Analyte	Measurement Unit	Reported Unit	Number of Digit to Enter	
			Before Decimal (Maximum)	After Decimal (Maximum)
Total Protein	g/dL	g/dL	1	2
	g/L		2	1
Sodium	mEq/L	mEq/L	3	1
	mmol/L		3	1
Triglyceride	mg/dL	mg/dL	4	2
	mmol/L		2	2
Urea	mg/dL	mg/dL	3	2
	mmol/L		2	2
Uric Acid	mg/dL	mg/dL	2	2
	mmol/L		1	2
	µmol/L		3	1
Phosphorus	mg/dL	mg/dL	1	2
	mmol/L		1	2

Next Round Details:

Dispatch Month	Round No.	CC24061	Opening Date	Result Deadline Date	Report Issue Date

Symbol Key:

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol	Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
	Consult instructions for participants		Catalog Number		Temperature Limitation		Biohazard

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