Participant Manual

FB/EQA/PM/001

Author of Version	**Technical Manager**
Review Period	**1 year**
Authorized copy Signatory (For paper copies only)	**PT Coordinator**

DOCUMENT REVISION HISTORY

Revision No.	Effective Date	Section	Details of Change
00	24/11/2022	-	Initial Release
01	18/04/2023	-	The Quality Policy modified in participant manual as per modification done in quality policy in the Quality Manual.
02	31/08/2023	-	Fugen Biomed Logo removed.
03	09/01/2024	-	Name of Fugen Biomed has been changed to Fugen Biomed Pvt. Ltd and also changed address.
04	11/10/2024	-	Participant Manual revised as per ISO 17043:2023 standard requirement.
-	-	-	Appendix 1 is modified.

ACRONYMS AND ABBREVIATION

"@"	Amended Result
EQA	External Quality Assurance
ISO	International Organization of Standardization
IST	Indian Standard Time
"L"	Late Result
PI	Performa Invoice
PT	Proficiency Testing
UPN	Unique Participant Number

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QUALITY POLICY

EQAsure is committed to provide the highest quality proficiency testing (PT) services to its participants, and external stakeholders based on their needs and requirements.

To meet the needs and requirements of users, EQAsure will:

Operate a management system to integrate the organization, procedures, processes, and resources.

Set quality objectives and plans in order to implement this quality policy, continuously monitor, and improve its effectiveness.

Ensure that all operation policies, procedures, and promotional and educational material are maintained and in compliance with the relevant accreditation bodies.

Be committed for timely and effective actions on customer complaints, feedback, non-conformance, and audit findings.

To ensure customer satisfaction and foster a culture of continuous improvement and awareness of staff members for the management system with adequate training.

VISION: To be recognized as most trusted global leader of PT program provider.

MISSION: To provide services, product, data, and technical support for assessing the proficiency of clinical and pathological diagnostic laboratories.

We will achieve our mission by:

- Providing dependable and accredited PT schemes.
- Supplying best-in-class, clinically relevant PT items for effective assessment of laboratory performance.
- Recruitment, training, development, and retention of staff at all level to provide effective support to participants.
- Avail required infrastructure and resources needed for the operation of PT scheme.
- Implement the most advanced system for the PT scheme data analysis.
- Report findings of PT scheme assessment timely, confidential and accurately.
- Continual quality improvement by periodic assessment of user satisfaction, as well as action on finding of internal and external audit.

CORE VALUE: Independent

Collaboration

Affordable

Reliable

Excellence

Signature: _____ Date: _____

1. INTRODUCTION

Fugen Biomed Pvt. Ltd. is an emerging supplier of diagnostic systems and reagents.

The EQAsure program is primarily intended for hospital and clinical laboratories. The EQAsure program is aims to be known for its high-quality PT item, reliability, user-friendliness and affordable prices.

Each participants receives a final report for each PT round that provides an individual performance analysis of submitted results. In the EQAsure reports, statistical processes will be based on ISO 13528 – "Statistical methods for use in proficiency testing by interlaboratory comparison" for calculation of assigned value (robust mean) and standard deviation. At the end of the cycle each laboratory receives a certificate of participation by successfully completed 50 % rounds throughout a program cycle.

2. ACCREDITATION

EQAsure programs accredited for ISO 17043 is listed on web portal – www.eqasure.com along with scope of accreditation and certificate of accreditation.

3. BENEFITS OF EQAsure

- Useful tool for continuous monitoring and improving analytical quality of laboratory test performance.
- Provide early warning of specific problems related to equipment, reagent and/or personnel.
- Help for evaluation of corrective actions initiation.
- Enhance confidence in the quality of results among laboratory, doctor and patients.
- Establish objective evidence of laboratory, doctor and patients.
- Act as a check for efficacy of internal quality control procedure.

4. CONTACT DETAILS

FUGEN BIOMED PVT. LTD.
104, Dharmabhakti Complex,
Khushalwadi, Jamalpore,
Navsari, Post Code: 396 445
Gujarat, India

Tel: +91 709611992
Email: pmt@fugenbiomed.com
Web Portal: www.eqasure.com

5. REGISTRATION PROCEDURE

Participant can register in EQAsure through web portal - www.eqasure.com. By clicking on "Login/New User" button, participant can click on "Sign Up" button.

Participant shall fill up all mandatory registration details; by agreeing terms and conditions and click on "Sign Up" button to confirm registration in EQAsure.

6. TERMS AND CONDITIONS FOR PARTICIPATION

Terms and Conditions are available on web portal - www.eqasure.com.

7. PROGRAM OFFERED

EQAsure offers comprehensive PT programs for hematology basic and clinical biochemistry. Program information is also available on web portal - www.eqasure.com.

EQAsure programs:

1. Hematology Basic (Accredited as per ISO 17043)
2. Clinical Biochemistry

8. PT ITEM FOR TESTING

Different PT program have different composition of the PT item matrix. All PT item must be considered potentially infectious, and handled in accordance with the same safety procedure as for patient samples. For more information participant must refer “PT Item” section in Instructions for Participants.

9. VERIFICATION OF CONTENT OF PT ITEM PACKAGE

PT item package must be checked upon receipt, to ensure it will contain below mentioned points.

- Check that received PT item matches the PT item required for registered program.
- Check that Instructions for Participants is available inside a PT item package.
- Check that vials are properly labeled with program name, month of testing, program code, lot no., expiry date and volume.
- Check PT item is not in any unsatisfactory condition (e.g., broken, leaking, un-labelled, hemolyzed, or clotted).

10. PROCEDURE

Remove the vial/tube from the refrigerator and allow it to reach at room temperature (15 to 30°C) for at least 15 minutes before use.

The PT item should be treated and analyzed the same as patient sample.

11. STORAGE

Store the PT item at 2-8 °C when not in use. For more information participant must refer “Storage” section in Instructions for Participants.

12. DISPOSAL

Remaining residual PT item after testing must be decontaminated and disposed of in compliance with the local regulation of waste disposal. For more information refer “Biosafety” section in Instructions for Participants.

13. SUBMISSION OF RESULTS

EQAsure provides online result entry using web portal - www.eqasure.com, where participant can login to EQAsure using their user’s name and password. For result submission in EQAsure, select “Result” menu.

Result must be submitted in EQAsure on or before midnight 12:00 IST on the deadline date of result submission.

If participant have any query regarding result submission, please contact customer care via e-mail to EQAsure.

14. THE UNITS OF MEASUREMENT REQUESTED BY THE EQAsure

Participants must be used the units of measurement those recommended by the regulatory bodies or guidelines. If participant submits their result in unit other than reporting unit, results will be converted into reporting unit and report will be available in reporting unit.

15. VIEWING THE REPORTS

Participant can view and download their reports online through web portal - www.eqasure.com once reports are uploaded for download.

To view and download report, select “Report” menu.

If participant have any problems/query, please contact customer care via e-mail to EQAsure.

16. GENERAL ADMINISTRATION

16.1 Contact Details (Participant)

The participant must keep their data (in particular billing and shipping address) up to date at all the time in profile menu of EQAsure web portal.

To add a new participant contact (user) by an existing primary contact in the user login, the primary contact typically needs to provide the following information:

- Name of User
- Login Id and Password
- The access profile (full, limited or result entry only) is to be assigned.

For any changes to the details of the primary contact, please contact EQAsure through email ID: pmt@fugenbiomed.com**.**

16.2 Computer System, Web Operation and Communication

All data in EQAsure is held securely and backed up. Participants must enter results using the web portal and reports are also available on web portal in participant login.

The EQAsure records e-mail address for the purpose of notifying participants for dispatch intimation, result submission reminder and report availability. Participant’s e-mails and contact details are not shared with third party without the permission of the participant.

16.3 Data Protection Act

The purpose of the data protection act is to prevent the misuse of personal data held electronically and to ensure that EQAsure holding such data conform to a required standard.

The contact details provided by participants at the time registration are held securely in EQAsure database in order to identify those participants registered for a given activity. Round wise results, evaluation of performance and reports are held securely in EQAsure database.

EQAsure will keep performance analysis data for a minimum of two years; however, responsibility for maintaining historical records of individual laboratory performance lies with the participating laboratory.

16.4 Unique Participant Number (UPN)

Each participant is given a **seven-digit** UPN, which should be used in all communications with the EQAsure.

UPN is printed on your all EQAsure documents like; final report, certificate of registration and certificate of participation.

16.5 Responsibilities of Participants

Participants are always responsible for their own policies, decisions and outcomes.

The participant must keep their data (in particular the shipping and billing address) up to date at all time in profile menu and it is responsibility of each participant to notify the EQAsure regarding change in contact details through e-mail.

The participant must ensure that log in credentials assigned during registration will not be disclosed to any third party.

If PT item is not received within the timeframe, it is the responsibility of the participant to contact EQAsure through e-mail.

Inspect the PT item package on receipt and store it according to Instructions for Participants in the package. Contact EQAsure via e-mail immediately if there is a deficiency identified in the PT item package.

It is responsibility of participant to handle and test PT item in same manner as patient samples.

Role of EQAsure program is not to take responsibility of prevention or detection of any problem in result but to evaluate the performance of laboratory by comparing their result with peer group and providing feedback in the form of report so that participant can make necessary changes or adjustments in their laboratory testing procedure.

Ensure that all configuration (like; analyser, method, analyte and unit) are updated in the EQAsure software before entering and submitting results.

Submit results for each round on or before the deadline date of result submission. If participant have any problem in result submission contact EQAsure through e-mail.

Participants must check their reports as soon as they received. If a report is incorrect or if there are any queries regarding the same contact EQAsure through e-mail.

It is the responsibility of participant to contact EQAsure through e-mail, if report will not receive in due time.

The EQAsure does not make regulation or enforce recommendation but EQAsure hope to share education, interest and knowledge.

The key success of EQAsure as program provider is interaction, effective communication and consistency.

16.6 Participation Fees

Participation fees are program specific. Participation fees include shipping charge within the country although additional carriage will be charged for shipping out of country of origin.

If participant needs extra set of PT item, it is depended on the availability of PT item and additional fees of the PT item shall be paid.

The EQAsure reserves the right to charge the customers additional fees to recover the cost incurred by the EQAsure program in satisfying any special handling, transport or delivery requirements notified or requested by the participant and agreed to by the EQAsure.

16.7 Renewal and Cancellation

Renewal: A participant is required to renew its participation in the EQAsure program cycle at least three months in advance before the completion of running cycle. Participants must complete their renewal process to continue participating. If a participant fails to renew, their participation in the EQAsure will be terminated automatically.

Cancellations: Participant can discontinue the program anytime during cycle. However, participant will not get refund for cancellation in EQAsure. Once participant intimate cancellation of participation, EQAsure will stop sending PT item to them. EQAsure reserves the right to cancel registration of participant if payment will not receive in due time.

16.8 Late and Amended Results

Late Result: Result received after deadline date of result are considered as “Late Result” and will be flagged in report as “L”.

Participant can request to late result only once for particular round and analyser. After that participant cannot request for late result.

Participant can request either late result or amend result at a time in recently closed survey for particular analyser and cannot request for both at same time for particular analyser.

Participant cannot amend the result, flagged as “L” (Late result).

- Late result will be accepted in case of shipping error or administrative error from EQAsure
- Shipping error like delay in PT item delivery.
- Administrative error like sending incorrect PT item, incorrect labeling or any issue in result entry in software for particular participant.
- Participant can request to open window for late result submission from result menu within 48 h after deadline date of result submission.
- Once result window will be re-opened, participant has to submit their late result within 24 h.
- Participant can only enter result which has not previously submitted before deadline date. Result window for already submitted result will not be opened.
- In these case participants has to provide evidence to support the claim.
- Late result will be accepted and updated report will be produced without flag of " L " in case of administrative or shipping error.
- Acceptability of reason for late result submission will be under discretion of PT Coordinator.

Amendment in Results: Correction of previously submitted result with new result after deadline date of result submission is considered as "Amended Result".

Participant can request to amendment in result only once for particular round and analyser. After that participant cannot request for amendment in result.

Amendments up to 2 Days after Deadline Date of Result Submission

- Participant can request to amendment in result from result menu within 48 h after deadline date of result submission.
- Participant may request to open result window from result menu along with reason for amendment as below.
  - Assaying the wrong PT item.
  - Assaying the right PT item in the wrong order.
  - Incorrectly transcribing laboratory results from computer systems or worksheets to results documents or the web entry system.
  - Using incorrect units and/or conversion factors.
  - Technical errors, e.g., incorrect reconstitution, Incomplete mixing after thawing, faulty sampling/pipetting etc.
- Once result window will be re-opened, participant has to submit their amended result within 24 h.
- In these case participants has to provide the evidence that PT item has been analysed before deadline date of result submission and copy of results or screen print of result as evidence.
- Amendments in result request for reason other than above will not be accepted.
- Acceptability of reason will be under discretion of PT Coordinator.

- Result will be amended and updated will be produced with flag of " @ ".

16.9 Certificates of Registration and Certificate of Participation

Certificate of Registration:

Criteria: To receive a "Certificate of Registration" participant has to paid full invoice.

Details Available on Certificate: Name of Participant, Program code, UPN, Program name, Cycle No., Cycle Period, Date and Signature.

Certificate of Participation:

EQAsure will provide "Certificate of Participation" at the end of each program cycle.

Criteria: To receive a "Certificate of Participation" participant has to successfully complete 50% rounds in a cycle, depending upon the type of program.

Details on Certificate: Name of Participant, Program code, UPN, Program name, Cycle No., Cycle Period, Date and Signature of EQAsure.

16.10 Indemnity

The participant will have to compensate EQAsure against any harm and/or loss caused to EQAsure due to inappropriate use of certificate awarded by EQAsure and for any damage to EQAsure's property by participant. The participant has to prevent and hold EQAsure safe from getting damaged by any illegal activity of any third party and in case of such situation; participant has to compensate for the same to EQAsure.

17 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. The EQAsure shall not disclose the participants details in public domain, unless required by regulatory authority and/or accreditation bodies without the prior permission of the participants. Participant specific information will not share in public domain if required to share prior permission from participants will be taken.

18 COMPLAINTS/QUERIES, APPEALS AND FEEDBACK

If a complaint is received, an investigation is conducted in accordance with documented procedure and outcome of analysis will be informed to the participants within 15 days wherever relevant. Complaint/Query and Appeal may be sent to through the email ID: pmt@fugenbiomed.com

Participants shall appeal on their performance evaluation within 5 working days of release report. Any appeals received after 5 working days will not be registered and reviewed.

All complaints/queries and appeals are managed as per documented procedure.

Participants are encouraged to provide feedback for improving any aspect of the PT scheme. Feedback form is sent to participants after completion of cycle for particular PT scheme.

19 TROBLESHOOTING

EQAsure performance report will help participant to understand the quality of their laboratory result and also shows that how comparable is performance of their laboratory to group of peers.

EQAsure asks participant to send their queries via e-mail to EQAsure and EQAsure assists them to troubleshoot EQA result.

20 ALLOWABLE LIMITS

Please refer Appendix 1 for Allowable Limits and Number of digits before and after decimal point in result entry attached to this document.

APPENDIX 1 – Allowable Limits and Number of digits before and after decimal point in result entry

HEMATOLOGY BASIC

Name of Analyte	Measurement Unit	Reported Unit	Number of Digit to Enter		Allowable Limit
			Before Decimal (Maximum)	After Decimal (Maximum)	
WBC (White Blood Cell)	$10^3/\mu L$	$10^3/\mu L$	3	2	± 18%
	$10^9/L$		3	2	
	$10^3/mm^3$		3	2	
RBC (Red Blood Cell)	$10^6/\mu L$	$10^6/\mu L$	1	2	± 10%
	$10^{12}/L$		1	2	
	10^6/mm3		1	2	
HGB (Hemoglobin)	g/dL	g/dL	2	1	± 7%
	g/L		3	1	
	mmol/L		2	2	
HCT (Hematocrit)	%	%	2	1	± 20%
	L/L		1	3	
MCV (Mean Corpuscular Volume)	µm3	fL	3	1	± 10%
	fL		3	1	
MCH (Mean Cell Hemoglobin)	pg	Pg	2	1	-
	fL		1	2	
MCHC (Mean Cell Hemoglobin Concentration)	g/dL	g/dL	2	1	-
	g/L		3	1	
	mmol/L		2	1	
PLT (Platelets)	$10^3/\mu L$	$10^3/\mu L$	3	1	± 25%
	$10^9/L$		3	1	
	$10^3/mm^3$		3	1	
MPV (Mean Platelet Volume)	fL	fL	2	1	-
	μm^3		2	1	
RDW-SD (Red Blood Cells Distribution Width-SD)	fL	fL	2	1	-
RDW-CV (Red Blood Cells Distribution Width-CV)	%	%	2	1	-

APPENDIX 1 – Allowable Limits and Number of digits before and after decimal point in result entry (Continued …….)

CLINICAL BIOCHEMISTRY

Name of Analyte	Measurement Unit	Reported Unit	Number of Digit to Enter		Allowable Performance Limit
			Before Decimal (Maximum)	After Decimal (Maximum)	
Albumin	g/dL	g/dL	1	2	±10%
	g/L		2	1	
ALP (Alkaline phosphatase)	IU/L	IU/L	4	2	± 30%
	µkat/L		2	2	
ALT/SGPT (Alanine aminotransferase)	IU/L	IU/L	4	2	± 20%
	µkat/L		2	2	
AST/SGOT (Aspartate aminotransferase)	IU/L	IU/L	4	2	± 20%
	µkat/L		2	2	
Total Amylase	IU/L	IU/L	4	2	± 30%
	µkat/L		2	2	
Total Bilirubin	mg/dL	mg/dL	1	2	± 20%
	µmol/L		3	1	
Bicarbonate	mEq/L	mEq/L	2	2	10% to 20%
	mmol/L		2	2	
Total Cholesterol	mg/dL	mg/dL	3	1	± 10%
	mmol/L		2	2	
HDL Cholesterol	mg/dL	mg/dL	3	1	± 30%
	mmol/L		1	2	
Creatine Kinase	IU/L	IU/L	3	1	± 30%
	µkat/L		2	2	
Creatinine	mg/dL	mg/dL	1	2	± 15%
	µmol/L		3	1	
Total Calcium	mg/dL	mg/dL	2	2	± 10%
	mmol/L		1	2	
Chloride	mEq/L	mEq/L	3	1	± 5%
	mmol/L		3	1	
Glucose	mg/dL	mg/dL	3	2	± 10%
	mmol/L		2	2	
Lithium	mEq/L	mEq/L	1	2	± 20%
	mmol/L		1	2	

APPENDIX 1 – Allowable Limits and Number of digits before and after decimal point in result entry (Continued …….)

CLINICAL BIOCHEMISTRY

Name of Analyte	Measurement Unit	Reported Unit	Number of Digit to Enter		Allowable Limit
			Before Decimal (Maximum)	After Decimal (Maximum)	
Iron	µg/dL	µg/dL	3	2	± 20%
	µmol/L		2	1	
Magnesium	mg/dL	mg/dL	1	2	± 25%
	mmol/L		1	2	
Potassium	mEq/L	mEq/L	1	2	± 8%
	mmol/L		1	2	
Total Protein	g/dL	g/dL	1	2	± 10%
	g/L		2	1	
Sodium	mEq/L	mEq/L	3	1	± 5%
	mmol/L		3	1	
Triglyceride	mg/dL	mg/dL	4	2	± 25%
	mmol/L		2	2	
Urea	mg/dL	mg/dL	3	2	± 9%
	mmol/L		2	2	
Uric Acid	mg/dL	mg/dL	2	2	± 17%
	mmol/L		1	2	
	µmol/L		3	1	
Phosphorus	mg/dL	mg/dL	1	2	± 16%
	mmol/L		1	2	