Participant Manual

Hematology

FB/EQA/PM/001

Author of Version	**PT Coordinator/Technical Manager**
Document Lead	**Scheme Organizer/Authorized Signatory & Scheme Management Committee**
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Authorized copy Signatory (For paper copies only)	**Scheme Organizer/Authorized Signatory**

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Approved by		**Date**	

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.
-	-	-	Appendix 1 modified.

ACRONYMS AND ABBREVIATION

"@"	Amended Result
EQA	External Quality Assurance
IFU	Instruction for Use
ISO	International Organization of Standardization
IST	Indian Standard Time
"L"	Late Result
PI	Performa Invoice
PT	Proficiency Testing
QMS	Quality Management System
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 of users.

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

Operate a quality management system (QMS) 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 or educational material are maintained and in compliance with the relevant accreditation bodies.

Be committed to 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, staff members for the QMS with adequate training.

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 EQA program
- Supplying best-in-class, clinically relevant EQA material for effective assessment of laboratory practices
- 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 EQA program.
- Implement the most advanced system for the EQA data analysis.
- Report findings of EQA 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

VISION: To be recognized as most trusted global leader of EQA Program provider

CORE VALUE: Independent

Collaboration

Affordable

Reliable

Excellence

Signature: _____ Date: _____

1. INTRODUCTION

Fugen Biomed Pvt. Ltd. is an emerging supplier of diagnostic systems and reagents. Founded by insightful healthcare industry professional, of more than decades of high-performance senior level experience with professional expertise gained in renowned domestic and multinational organisation.

External Quality Assessment (EQA) programs like "EQAsure" are accepted as valuable tools for *in-vitro* diagnostic laboratories to assess the quality of test performance results. EQA programs are developed and maintained following requirements of ISO 17043:2010 QMS.

The EQAsure programs are independently operated, providing participant's confidence and assurance of high-quality samples of measured with stability and homogeneity.

Each laboratory receives a report for each sample that provides the laboratory with an individual performance analysis of submitted results. In the EQAsure reports, statistical processes will be based on ISO 13528:2015 – "Statistical methods for use in proficiency testing by interlaboratory comparison" for calculation of a robust estimation of the consensus mean and standard deviation, which are used to assess the acceptable performance of each participating laboratory. An individual laboratory performance over the entire cycle is compared with other laboratories in terms of bias for all analytes reported. At the end of the cycle each laboratory receives a certificate of participation by submitting a required data throughout a program cycle.

EQAsure offers comprehensive EQA Programs in *in-vitro* Diagnostic laboratories. The EQAsure program is aims to be known for its high-quality samples, reliability, user-friendliness and affordable prices. EQAsure programs offer to maintain and improve the quality of *in-vitro* diagnostics testing, achieving higher patient safety by making healthcare diagnostics more reliable.

2. ACCREDITATION

EQAsure is in the process of getting accreditation for ISO/IEC 17043:2010, "Conformity Assessment- General Requirements for Proficiency Testing" from NABL.

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

Postal Address:
Fugen Biomed Pvt. Ltd.
104, Dharmabhakti Complex,
Khushalwadi, Jamalpore,
Navsari
Post code: 396 445
Gujarat, India

Contact Details:
Tel: +91 909 909 5565
Email: contact@fugenbiomed.com
Website: www.fugenbiomed.com

5. REGISTRATION PROCEDURE

Participant can register in EQAsure through Website - www.eqasure.com. By clicking on log in 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.

On approval of registration in EQAsure will raise proforma invoice (PI) via e-mail to billing contact. On receipt of payment, EQAsure will send confirmation e-mail to participant including their login credential (User Name & Password) and UPN.

6. TERMS AND CONDITIONS FOR PARTICIPATION

Terms and Conditions are available on EQAsure website portal: www.eqasure.com.

7. PROGRAM OFFERED

EQAsure offers comprehensive EQA programs for hematology. Program information is also available on EQAsure website portal: www.eqasure.com.

Available EQAsure programs

1. Hematology Basic (Monthly)
2. Hematology Basic (Quarterly)

8. SAMPLE FOR TESTING

Different EQA program have different composition of the sample matrix. All samples must be considered potentially infectious, and handled in accordance with the same safety procedure as for patient samples. For more information participant must refer "Product Description" section in Instruction for Use (IFU).

9. VERIFICATION OF CONTENT OF TEST SAMPLES PACKAGE

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

- Check that received test samples matches the sample required for registered program.
- Check that IFU is available inside a test sample package.

- Check that vials are properly labeled with program name, month of testing, program code, lot no., expiry date and sample volume.
- Check test samples are 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 samples should be treated and analyzed the same as patient specimens and run-in accordance with the IFU.

11. STORAGE AND STABILITY

Store the sample at 2-8 °C when not in use. The sample will be stable until the expiration. For more information participant must refer “Storage and Stability” section in IFU.

12. DISPOSAL

Remaining residual material after testing must be decontaminated and disposed of in compliance with the local regulation of waste disposal. For more information refer “Biosafety” section in IFU.

13. RETURN RESULTS

EQAsure provides online result entry using EQAsure website 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.

14. THE UNITS OF MEASUREMENT REQUESTED BY THE EQAsure

The units used by the EQAsure are mention in program wise IFU. 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 EQAsure website -www.eqasure.com once reports are uploaded for download.

Report on website is protected by same level of security as used for Result entry. 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.

Primary Contact for the participant laboratory can updates the contact details for their laboratory and notifies the EQAsure via email.

A new participant contact can be added by an existing primary contact by logging a request in the portal and providing the following information:

- New contact's name, e-mail address, phone number and role.
- The participant(s) (include discipline and participant number) to which the contact is to be associated.
- The access profile (full, limited or result entry only) that is to be assigned.
- It is essential that the EQAsure is notified of any contacts that leave an organization/site/laboratory so that the user's profile can be either disassociated or deactivated, depending on the situation.

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 survey distribution and report availability. Participant's e-mails contact details are not shared with other organization without the permission of the individual laboratory on each and every occasion.

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 and also generate address labels the dispatch of test sample or reports. Survey results, analysis performance assessment and report production 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. All participants are entitled to view their personal computer records on request.

16.4 Unique Participant Number (UPN)

On receipt of full payment, EQAsure will assign an UPN to participant.

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; monthly 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 of EQAsure web portal and it is responsibility of each participant to notify the EQAsure regarding change in contact details via e-mail.

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

If material is not received within the timeframe, it is the responsibility of the participant to contact EQAsure customer care for the same.

Inspect the test sample package on receipt and store it according to IFU in the package. Contact EQAsure customer care immediately if there is a deficiency identified in the test sample package.

It is responsibility of participant to handle and test the sample 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; Analyzer, method, analyte and unit) are updated in the EQAsure software before reporting results.

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

It is the responsibility of participant to contact EQAsure via 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 test samples, it is depended on the availability of test sample and additional fees of the test sample 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 customer 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 samples 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 your report as “L”.

Participant can request to late result only once for particular sample and analyzer. 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 analyzer and cannot request for both at same time for particular analyzer.

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 sample delivery.
- Administrative error like sending incorrect sample, incorrect labeling or any issue in result entry in software for particular customer.

- 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.
- Here 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 monthly report will be produced without flag of "Late Result" in case of administrative or shipping error.
- Acceptability of reason for late result submission will be under discretion of Scheme Organizer/Authorized Signatory.

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

Participant can request to amend result only once. After that participant cannot request for amend result.

Amendments up to 2 Days after Deadline Date of Result Submission

- Participant can request to amend 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 selection of reason for amendment as below.
  - Assaying the wrong samples.
  - Assaying the right samples 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 sample has been analyzed before deadline date of result submission and copy of results or screen print of test as evidence.
- Amendments request for reason other than above will not be accepted.
- Acceptability of amendments of reason will be under discretion of Scheme Organizer/Authorized Signatory.
- Result will be amended and updated report will be produced with flag of "Amended Result".

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: Lab Name, Program code, UPN, Program name, Cycle No., Cycle Period, Date, Stamp and signature of EQAsure.

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: Lab Name, Program code, UPN, Program name, Cycle No., Cycle Period, Date, Stamp 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 CONFIDENTIALITIES

EQAsure is committed to maintain confidentiality for each participant. To protect the privacy, each participant is identified by UPN known only to EQAsure and participant.

EQAsure does not disclosed the identity of participant, participant's data, reports, and any other information that reveal identification (name, address) to any third party, unless required by regulatory authority, without prior permission of the participant concerned.

18 COMPLAINTS AND APPEALS/RIGHT TO APPEAL

All participants have right to appeal against the evaluation of their performance in accordance with ISO 17043:2010 standard.

Complaints about any aspect of the service, whether scientific or operational are welcome. If participants have any complaint, query or request, the EQAsure should be contacted immediately, preferably through website or e-mail. The participant should provide to EQAsure with their laboratory code and a clear description of the complaint/query/request.

The Technical Manager/PT Coordinator and/or Scheme Organizer/Authorized Signatory shall follow up on the initial response with a thorough investigation of all aspects of the problem. EQAsure is ultimately responsible for ensuring that appropriate corrective action has been taken.

The EQAsure will respond as soon as possible in timely manner to any complaint or request submitted by participant. If non-compliance cannot be rectified within this period, the participant is informed by EQAsure.

If a participant remains unhappy with the service received, the Technical Manager/PT Coordinator should be contacted directly via e-mail.

19 TROBLESHOOTING

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

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.

20 ALLOWABLE LIMITS OF PERFORMANCE

Please refer Appendix 1 for Allowable Limits of Performance and Decimal Requirement for Result attached to this document.

APPENDIX 1 – ALLOWABLE LIMITS OF PERFORMANCE AND DECIMAL REQUIREMENT FOR RESULT

HEMATOLOGY BASIC

Name of Analyte	Measurement Unit	Reported Unit	Number of Digit to Enter		Allowable Performance Limit
			Before Decimal (Maximum)	After Decimal (Maximum)	
WBC (White Blood Cell)	10^3/µL	10^3/µL	3	2	± 18%
	10^9/L		3	2	
	10^3/mm^3		3	2	
RBC (Red Blood Cell)	10^6/µL	10^6/µL	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	0	
	mmol/L		2	2	
HCT (Hematocrit)	%	%	2	1	± 20%
	L/L		0	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	0	
	mmol/L		2	1	
PLT (Platelets)	10^3/µL	10^3/µL	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	-