QAF-EQAS

PARTICIPANT MANUAL

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Legal Disclaimer & Release Authorization

Amendment Details

Sr. No.	Clause No.	Date of Amendment	Amendment Details	Reasons for Amendment	Approved by

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❖ Introduction

The QAF-EQAS is conducted by the Quality Assurance Forum, Ahmedabad,Gujarat. It is intended to expand understanding regarding quality assurance in the clinical laboratory as part of improving overall diagnostic services rather than any profit-making activity.

The QAF is a standalone independent organization with one clear goal to provide top quality External Quality Assurance Program that will help to raise the quality of the participating diagnostics laboratories

This manual provides a comprehensive overview of how it began, the various contributions to its development, and what is offered to laboratories that participate in the program.

❖ Aims

To provide comprehensive and competent EQA involving all clinical laboratory sections available to all parts of India and the Asian subcontinent to improve and upgrade total clinical laboratory diagnosis standards.

❖ Objectives

- To cater maximum parameters for EQA exercise
- To upgrade and improve quality assurance practice in laboratory medicine
- To prepare and maintain suitable material for analysis
- To manage the packing and transport of material to users in the recommended manner
- To analyze the submitted results in a standard acclaim manner
- To maintain confidentiality

Name of faculty	Responsibility
Dr. Dinesh Rathod	Head of the Organization (Director)
Dr. Bipin Patel	Person responsible for quality management system (Quality Manager)
Dr. Viral Patel	Person responsible for Proficiency Testing Activities (PT Co-ordinator)

❖ Details of Steering/ Advisory Committee

S. N	Name of Person	Qualification with Specialization	Experience in years related to present work	Affiliation	Area of Responsibility
1	Dr Hansa Goswami	MD Pathology	10	ISO 15189:2022 Technical and lead assessor NABL	Planning, advisory
2	Dr Bhavin Kapadia	MD Microbiology	10	ISO 15189:2022 Technical and lead assessor NABL	Planning, advisory
3	Dr Piyush Tailor	MD Biochemistry	07	ISO 15189:2022 Technical and lead	Planning, advisory

Material :

- The PT material for biochemistry and hematology is IQC material. For Serology and thyroid tests retain samples used. The IQC material is procured from a third party. Pooled sera obtained from an outsourced reference laboratory.

Frequency

2 cycles every calendar year

Cycle in February and August

Stability Testing

Stability study is done as per ISO 17043 & ISO 13528 Standard.

Homogeneity Testing -

Stability study is done as per ISO 17043 & ISO 13528 Standard.

Results Submission

Online submission will be available www.qaforum.in Please refer participant user manual for site and QAF EQAS 17043 portal, which is available on-site.

Lab has to enter the results according to test units given in to result submission section. The result should be submitted on or before the last date of submission. Reports submitted after the last requested date will not analyzed.

Number of Participating Labs

To meet the objective of the statistical design, a sufficient number of participants is included in each cycle. It is ensured that at least 12 participants' results requred for robust statistical analysis. Statistical analysis for any deviation from required number will be done as per ISO 13528 and ISO 17043.

Result analysis-Quantitative

Performance evaluated by comparison with other participants. Outliers are removed from analysis by krubbs test. Result analysis is done by robust analysis.

Robust Z – score :- We adopt robust statistical method using participants results to determine assigned values. In the robust Z- score, results are obtained and the z scores are calculated one between within laboratories z score. These are based on the sum and difference of the of results respectively.

A Simple Robust Z score for a laboratory would be as follows:

$$\text{Z score} = \frac{\text{Result} - \text{Median}}{\text{Normalised IQR}}$$

Result analysis- Qualitative

We are using the consensus result of participants as an assigned value. A consensus result is considered when 80 % of participants have similar results.

❖ Result Assessment

Comment	Meaning	Action suggested
Satisfactory	• Z score ≤ ± 2 • Submitted result matching with consensus result	No Action Required
Borderline	• Z score between ± 2 and ± 3	Evaluate IQC performance and quality system
Unsatisfactory	• Z score > ± 3 • Submitted result not matching with consensus result	• Root Cause Analysis and appropriate Corrective andPreventive Action (CAPA) followed by verification of the effectiveness of CAPA. • If required use Alternate method to evaluate performance for that test parameter
NE	Not evaluated May be due to less than 9 number of participant or no consensus among participants' results	• Use Alternate method to evaluate performance for that test parameter
NA	Not Applicable Laboratory has not submitted results	

❖ Evaluation & Release of QAF-EQAS reports:

After one week of the last date of result submission, QAF assigned evaluation to experts. Department-wise analysis is done by an expert in the admin panel via a portal of the QAF EQAS site. On completion of the analysis, results are released under the authority of the coordinator and quality manager.

❖ Procedure for avoiding conflict of interest

During result compilation, result evaluation, and report generation unique ID is used for participant laboratories.

Coding of the Laboratory with unique identification will be done by the coordinator only and the process will be kept confidential during the entire evaluation to take care of conflict of interest.

❖ Feedback/Complaint Handling:

For any issue during the cycle and after the release of reports of a particular cycle feedback/complaints are taken via mail or mobile phone. Feedback form is also available.

On receipt of complaint/ feedback, QAF will give a resolution by phone or mail if urgent. Technical analysis QAF QM assigns tasks for investigation and report of details as per lay down QSP. Final outcome will be communicated to the participant laboratory in 7 working days after receipt of the complaint/ feedback.

❖ QAF provides advisory service on demand regarding performance improvement

Tests included in QAF-EQAS- Programme

Hematology (Two cycles- Aug, Feb per Year)- Whole blood- IQC material- Quantitative				
Hemoglobin (Gm/dl)	Total RBC count (10^6 /µl)	Total WBC count (10^3 /µl)	Total platelet count (10^3 /µl)	Hematocrit (%)
MCV (FL)	MCH (Pg)	MCHC (Gm/dl)	RDW CV (%)	
Biochemistry (Two cycles- Aug, Feb per Year)- Serum- IQC material-Quantitative				
Glucose (mg/dl)	AST (U/L)	ALT (U/L)	Cholesterol (mg/dl)	Triglyceride (mg/dl)
LDL cholesterol (mg/dl)	Creatinine (mg/dl)	Urea (mg/dl)	Total bilirubin (mg/dl)	Direct bilirubin (mg/dl)
Sodium (mEq/L)	Potassium (mEq/L)	Chloride (mEq/L)	Total protein (Gm/dl)	Albumin (Gm/dl)
TSH (pooled sera) (micro IU/ml)	Total T3 (pooled sera) (ng/mL)	Total T4 (pooled sera) (µg%)		
Serology (Two cycles- Aug, Feb per Year)- Serum- Pooled sera-Qualitative				
HIV Antibodies	HbsAg			

❖ Annexure-2 : Registration

Log on to www.qaforum.in for registration and fee payment.

No cash accepted. Online fee payment is available on the portal.

Fee for the first time – Rs 10000

Renewal fee(Annually)- Rs 5000

DECLARATION

I,_____, am an authorized person of our laboratory to enroll of QAF-EQAS and hereby assure that all the above information given by our laboratory is correct. By submitting the above information in the online form, we abide by the rules of QAF- EQAS. We also give the authority to share our data to any authority when it is mandatory.

Signature of Lab Director

GENERAL INSTRUCTION

- The participants are allowed to register anytime during the cycle by paying the Full Registration Fee which will be valid till the end of that cycle.
- The certificate of participation will be issued after the completion of the cycle at the end of the year.
- The certificate will not be issued in the individual's name, but only in the name of the organization/laboratory.
- Please check the status of the sample as soon as you receive it and inform us within 2 days.
- The participants are requested to update the results before the last date of submission.
- The participants are requested to mention the LAB Code in all their correspondence.
- Please do not share or discuss the results with other participants before uploading the results.
- Dispatch of samples, result submission date, and result dispatch date for each round for each field will be done as per the year calendar plan for 2024-2025, which will be shared with you after enrollment and registration.
- The delay of dispatch of samples/results due to unavoidable situations beyond our control will be informed by email provided by participants.
- Sample dispatch tracking details will be shared with participants once the cycle starts and advised to follow that tracking of the sample is the responsibility of the participants.
- If any participant wants to withdraw from the program, then it should be informed in writing and the hard copy should be sent by post. Only email will not be considered as a cancellation request. No refund will be given if any participant wants to withdraw in mid of the cycle.

Steps for participants

1	Registration as a new lab
2	Fill the details
3	Fee payment
4	Verification and approval by QAF
5	Log in and password on registered mail by QAF
6	Log in by lab to select parameters, in parameters select methods, instruments, reagents, etc
7	QAF intimate dispatch of PT material dispatch
8	Participants to receive that and acknowledge that on the portal
9	Analyze as per instructions
10	Enter the report on the portal and submit
11	QAF does analysis and report of cycles that are available on portal
12	Review of results by participant
13	Corrective action and preventive actions if required
14	Feedback to QAF if any
15	Release of certificate by QAF to the participant if eligible
16	Renewal of participation for next year

References

- ✓ ISO/IEC guide- 17043
- ✓ NABL document 162
- ✓ NABL document 163
- ✓ ISO/IEC 13528