



QAF-EQAS 17043

PARTICIPANT MANUAL

Quality Assurance Forum (QAF),

A Unit of Uniqas Healthcare Solution LLP
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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

Following are the objectives of the PT schemes:

(Ref: PT scheme Objectives. Doc. No. QAF71110100)

- 1 To provide the PT scheme with simultaneous & continuous distribution of the PT items for qualitative and quantitative test parameters for medical testing laboratories
- 2 To provide the PT scheme as per the requirements of ISO 17043
- 3 To provide the PT scheme having simultaneous distribution of the PT items to all the participants
- 4 To provide the PT scheme with distribution of the PT items twice a year
- 5 To provide the PT scheme where the assigned value and its' uncertainty is calculated from the results submitted by the participants in the same round for all quantitative test results
- 6 To provide the PT scheme where the assigned value is determined from consensus results of the expert labs for all the qualitative test results.
- 7 To provide the PT scheme where the standard deviation of the PT scheme for the quantitative tests results is determined from the participants results in the same round.
- 8 To evaluate the participant results using z or z' score for the tests with quantitative results.
- 9 To evaluate the participant results by checking agreement of the participant results with that of expert's result for qualitative tests.
- 10 To provide the PT scheme using lyophilized serum for the biochemistry and serology

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tests

- 11 To provide the PT scheme using fixed whole blood for the hematology tests
- 12 To provide the PT scheme for below tests with quantitative results:

Haematology	Clinical Biochemistry
RBC	Albumin
Total WBC	ALT
Hematocrit	AST
Hemoglobin	BUN
Platelet count	Chloride
MCH	Cholesterol
MCHC	Creatinine
MCV	Direct Bilirubin
RDWSD	Glucose
RDWCV*	LDL cholesterol
	Potassium
	Sodium
	Total Bilirubin
	Total Protein
	Triglycerides
	Uric acid*
	Total T3
	Total T4
	TSH

- 13 To provide the PT scheme for below tests with qualitative results:

Serology	Anti HVI 1,2 Antibody HBsAg Anti HCV Antibody
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QAF Structure:

Designated Person name	Responsibility
Dr. Dinesh Rathod	Head of the Organization (Director)
Dr. Bipin Patel	Person responsible for quality management system (Quality Manager)

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Dr. Viral Patel	Person responsible for Proficiency Testing Activities (PT Coordinator)
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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 Shailesh Tailor	MD Biochemistry	07	ISO 15189:2022 Technical and lead assessor NABL	Planning, advisory

Material:

Sr. No.	Section/ Discipline	PT Item Used	PT Item Source	Processing at QAF
1	Clinical Biochemistry	Lyophilized Serum	From Third Party QC Material Manufacturer	Reconstitution in DW
2	Hematology	Whole Blood	From Third Party QC Material Manufacturer	Ready to use
3	Serology	Lyophilized Serum	From Third Party QC Material Manufacturer	Reconstitution in DW

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Frequency

Frequency of PT Item Distribution	Two time in a year
First Cycle	February
Second Cycle	August

PT Operation:

Sr. No.	PT Activity	In-house/ Outsourced
1	PT Design, Planning, Execution, Selection of PT Items, Evaluation of participant results, PT report preparation, review and release, Advise on use of PT report	In-house done by QAF team
2	PT Item material Manufacturing	Third party, commercial QC manufacturer
3	Homogeneity & Stability study of PT Items	Testing of PT items for homogeneity & stability outsourced to NABL accredited laboratory. Evaluation and validation and use of data from homogeneity & stability study on PT items done by QAF team.

Stability Testing

Stability study on PT items is done as per ISO 13528 & ISO 17043 standards.

Homogeneity Testing -

Homogeneity study on PT items is done as per ISO 13528 & ISO 17043 standards

Who can participate in this PT scheme:

To participant in this PT scheme, following requirements must be met: Lab shall

1. Be Medical Testing Laboratory
2. Be Legally identifiable
3. Do in house testing for those tests in which it wants to participant in the PT scheme
4. Do payment as per policy.
5. Participant voluntarily in the PT scheme.
6. Any participants of QAF Interlab Program who want to participant in this QAF-EQAS 17043 program can do by paying fee for the scheme and submitting enrollment form.
7. Any participant of QAF EQAS 17043 can participate in QAF Interlab program after

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submitting enrollment form and fees.

Number of Participating Labs

- To meet the objective of the statistical design, a sufficient number of participants is included in each cycle.
- ISO 13528 standard is applicable to decide minimum number of participants in the PT scheme.
- The PT design will be done for at least minimum 20 participants.
- To use Algorithm A method for assigned value & associated uncertainty from participants result in the same round of PT, minimum 12 participants are required.
- For less than 12 participants, methods described for small number of participants to calculate assigned value and its' uncertainty is use.
- For less than 3 participants, assigned value calculation is not done.

Results Submission

- Online submission will be available on www.qaforum.in Please refer participant user manual for site and QAF EQAS 17043 portal, which is available on-site.
- Lab must enter the results according to test units given in the 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.

Result Analysis-Quantitative

Performance evaluated of the participant labs

- By determining consensus value from participants of same round of the PT scheme and used it to decide/ calculate the assigned value and its' uncertainty.
- By determining Standard deviation of the PT scheme from the results of participants in the same round of the PT scheme.
- Outliers are removed from analysis by grub's test, by using median and algorithm A method.
- Result analysis is done by robust analysis.

Performance scoring: -

- Z- score or Z' score is used for evaluation of the participant results depending upon homogeneity & stability study of the PT items.
- If Z / Z' score is between -2 and +2, performance of the lab is satisfactory.
- If Z / Z' score is less than -3 or more than +3, performance of the lab is not satisfactory.
- If Z / Z' score is between -3 & -2 or +2 & +3, performance of the lab is borderline.

Result analysis- Qualitative

- We are using the consensus result of participants as an assigned value. To determine the consensus result, ISO 13528 standard is used.

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Result Assessment

Comment	Meaning	Action suggested
Satisfactory	<ul style="list-style-type: none"> Z score $\leq \pm 2$ Submitted result matching with consensus result 	No Action Required
Borderline	<ul style="list-style-type: none"> Z score between ± 2 and ± 3 	Evaluate IQC performance and quality system
Unsatisfactory	<ul style="list-style-type: none"> Z score $> \pm 3$ Submitted result not matching with consensus result 	<ul style="list-style-type: none"> Root Cause Analysis and appropriate Corrective and Preventive 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 3 number of participant or no consensus among participants' results	<ul style="list-style-type: none"> 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, Evaluation of the participants' results will be done by the QAF team.
- Department-wise analysis is done 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, quality manager and director.

Procedure for avoiding conflict of interest, impartiality, confidentiality, prevention of falsification/ collusion

- During result compilation, result evaluation, and report generation unique ID is used for participant laboratories.
- During executing the PT scheme, QAF team manages/ avoids conflict of interest as per the documented procedures:

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- Procedure for impartiality & ethical conduct (QAF41000300)
- Procedure for protection of participant's confidential information (QAF42000300)
- Procedure for prevention of collusion and falsification in pt (QAF72130300i)

Feedback/Complaint/Appeals 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. Acknowledgement done by mail/ phone.
- 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.
- Any outcome of this will not lead to any discriminatory action.
- QAF provides advisory service on demand regarding performance improvement
- Refer following procedures for more details:
 - Procedure for handling of complaints (QAF76000300)
 - Procedure for handling of appeals (QAF77000300)

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Annexure 1: PT Scheme Details for QAF-EQAS- 17043 Program

PT Scheme Name:	QAF EQAS 17043			
Target Participants:	Medical laboratories			
Scheme Type:	1: Quantitative, Simultaneous Distribution, Continuous Participation 2: Qualitative, Simultaneous Distribution, Continuous Participation			
Minimum No. of Participants:	At-least 20 participants' requests required to begin additional new cycle of PT scheme.			
Data & Outlier Treatment:	Grub's Test, Median +/- Acceptable Limits, Robust Z Score			
Methods for calculating assigned values with its' uncertainty and standard deviation:				
Consensus values derived from the participants' result is used as the assigned value of the PT scheme.				
1: Robust statistical method – Algorithm A is used to calculate assigned value & it's uncertainty, and standard deviation of PT scheme if more than equal to 12 participants' results available for calculation.				
2: Robust statistical method – Median is used to calculate assigned value & it's uncertainty if less than 12 participants' results available for calculation.				
3: For less than 3 participants, assigned value is not calculated.				
Performance Evaluation:	Quantitative Scheme	Z Score, Z' Score	Qualitative Scheme	Consensus Value
Section/ Discipline:	Hematology	Clinical Biochemistry	Serology	
PT Items:	Whole blood	Serum	PT Item Source:	From third party
External Service used in the PT scheme:	NABL accredited medical laboratory for homogeneity & stability testing			
Frequency of PT Item Distribution:	Two cycles/ Year	Schedule of PT Scheme:	Aug & Feb	
Quantitative Test parameters included:				
From Whole Blood	Hemoglobin (g/dl)	MCV (fl)	RDW CV (%)	
	RBC count (10 ⁶ /µl)	MCH (pg)	WBC count (10 ³ /µl)	
	Hematocrit (%)	MCHC (g/dl)	platelet count (10 ³ /µl)	
From Serum	Glucose (mg/dl)	ALT (U/L)	AST (U/L)	Total bilirubin (mg/dl)
	Cholesterol (mg/dl)	Triglyceride (mg/dl)	LDL cholesterol (mg/dl)	Direct bilirubin (mg/dl)
	Creatinine (mg/dl)	BUN (mg/dl)	Total protein (g/dl)	Albumin (g/dl)
	Sodium (mEq/L)	Potassium (mEq/L)	Chloride (mEq/L)	TSH (micro IU/ml)
	Total T3 (ng/mL)	Total T4 (µg/ml)		
Qualitative Test parameters included:				
From Serum	HIV Antibodies	HbsAg	HCV Antibody	

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Annexure-2: Registration/ Enrolment Form

Accreditation/ Certification	NA	NABL	NABH	CAP	ISO	OTHER
Organization Type	Govt.		Semi Govt.		Private	
Legal ownership	Proprietor	Partnership	LLP	Pvt. Ltd	Public Ltd.	Govt.
Registered Name of organization *						
Unit Name (Lab Name if different from Reg. Name)						
Branch						
Country *						
State *						
City *						
Pincode *						
Lab Address *						
Contact Person's Name *						
Mobile Number *						
E-mail *						
We want to participate for _____ Year in						
QAF-EQAS-ML	Not Accredited	First-Time Registration : Rs 6000/-			Annual Renewal : Rs 4000/-	
QAF-EQAS-ML-Haematology QAF-EQAS-ML-Clinical Pathology QAF-EQAS-ML-Biochemistry QAF-EQAS-ML-Urine chemistry QAF-EQAS-ML-Microbiology QAF-EQAS-ML-Flow Cytometry						
QAF-EQAS-17043	Applied for	Accredited	First-Time Registration : Rs 6000/-			Annual Renewal : Rs 4000/-
Total Payment		Rs 0	(extra 2% online payment charge)			
Your personal data will be used to process your order, support your experience throughout this website, and for other purposes described in our privacy policy.						
I have read and agree to the website terms and conditions*						
						Pay & Register Now

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Annexure-3: 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

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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.

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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

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INSTRUCTIONS TO USERS

- Participants will receive 3 vials, 1 for hematology, 1 for Biochemistry tests, 1 for viral serology and thyroid tests
- The PT material for biochemistry and hematology is IQC material. For Serology and thyroid tests retain samples used.
- Portal allows change in test parameters till you receive the EQAS material and result submission
- Keep RAW data of run in your lab
- After receiving the sample keep it in 2-8 ° Celsius for 30 minutes. Then bring the sample to room temperature when the analysis is done. Before analysis gently mix the vial's contents by inverting 8-10 times. Do not shake. Analysis is to be done within 24 hours of receiving the sample
- After 7 days result entry is not allowed
- If you have not received a sample within 24 hours after mail notification from QAF, inform the coordinator by phone or mail
- Due to any reason if any dates are changed or modified you will informed by mail
- Participants are requested not to discuss or share the results with other labs before the release of reports on the site
- QAF maintains the confidentiality of participants like their demographics, reports, results or other information given by them
- Sample information details for --- cycle -

• Sample receipt date -	
• Sample analysis date-	
• Sample result submission date-	
• Result release date	

- Please acknowledge the receipt of samples – the number of vial and their condition. No breakage, No leakage, properly labeled etc, if Ok write satisfactory

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References

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

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