Introduction

The QAF-EQAS-ML (Quality Assurance Forum External Quality Assessment System for Medical Laboratory) program is provided on behalf of the Quality Assurance Forum, Ahmedabad. It is intended to expand understanding regarding quality assurance in the laboratory as part of improving overall diagnostic services.

The EQAS committee will consist of Chairman, secretary, coordinator, subject experts. Subjects' experts will represent institutes, private practitioner and all major departments of laboratory medicine.

All corresponding for QAF-EQAS-ML should be done to

QAF-EQAS-ML Coordinator
201, Pushpraj archade, Above Axis bank
Near bhuyangdev char rasta
Sola Road, Ahmedbad-61
Gujarat
Qaf2010@gmail.com
Mobile- 9925012686

AIMS –

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

Objectives-

To cater maximum parameter for EQA exercise

To upgrade and improve quality assurance practice in laboratory medicine

To prepare and maintain suitable material for analysis

To manage packing and transport of material to users in recommended manner

To analyze the submitted results by standard acclaim manner

To maintain confidentiality

Samples-

All samples will be derived from pooled human samples. As far as possible, we will attempt to use sample that has been screened for viral diseases. However since there are no tests that can completely screen for all diseases, participants are advised to treat sample with care.

In practice all sample should be treated as patient sample and analysed same as patient. Samples should be an analyzed on the same day of receipt. Please ensure proper mixing of sample before analysis. Please do not analyse /run test by one particular technical person. Please rotate technical staff for performing PT sample analysis.

QAF-EQAS-ML consist of 2 cycle every calendar year (February-last week and August-last week)

The test menu and enrollment form for participant laboratory are available in annexure I & II.

Results submission

The results to be filled in excel sheet provided to you. Please do not do any entry or change in sheet as they read only format except result column, give only desire value or result in provided space. Lab has to enter the results according to test units given to result submission sheet. Result should be submitted before or on the last date of submission. Report received after the requested date will not analysed.

Result should be submitted to official mail IDs.

Result analysis

Assigned or target value are derived by approved statistics. For qualitative tests assigned value is consensus result (80% of participant laboratory) .For quantitative tests assigned value is derived by geographic mean of participant's results ,where extreme outlier (> 3 SD)are excluded.

Performance calculation – for qualitative test not require and for quantitative test Z score is used.

$$\text{Z score} = \frac{\text{Result} - \text{Target result / Target Mean}}{\text{Target SD}}$$

Result Assessment

A laboratory could find its performance in comparison with the other laboratories with the Z score.

Z ≤ I ± 2 I= Satisfactory

I ± 2 I < Z> I ± 3 I = Border line

Z ≥I ± 3 I = Unsatisfactory

The outlier criteria Z > I ± 3 I has confidence level of about 99.73 % i.e. there is< 1 % chance that the result is true member of the population and it is far more likely that there is problem with this result. Laboratories which have a Z score in the region I ± 2 I >Z< I ± 3 I are encouraged to take a close look at their results. A result identified as outlier (Z > I ± 3 I) means that statistically the results is different from the others in the group.

If Z score is I ± 2 I < Z> I ± 3 I, participant laboratory should Evaluate IQC performance and quality system

Your Score	Action Required
Satisfactory (Z ≤ I ± 2 I)	No Action Required
Border line (I ± 2 I < Z> I ± 3 I)	Evaluate IQC performance and quality system
Unsatisfactory (Z> I ± 3 I)	Root Cause Analysis and Appropriate Corrective and Preventive Action (CAPA) followed by verification of effectiveness of CAPA. If require use Alternate method to evaluate Performance for that Test parameter
NE	Not evaluated (may be due to less than three number of participant or may be no consensus among participants' results)
NA	Not Applicable, (as either laboratory has not submitted results or That test is not under scope of Quality Assessment for that laboratory).
NR	Information not reported (given) by Participant Laboratory.

Note: I ± Value I indicate that before using that value convert sign of that value in positive sign

QAF will maintain confidentiality of report generated. Softcopy of report will have password protection which will be unique to cycle and laboratory.

Evaluation & Release of QAF-EQAS-ML reports:

QAF-EQAS-ML Technical Committee will evaluate participants' results and generate report of performance. QAF-EQAS-ML chairman will authorize and release QAF-EQAS-ML report.

Procedure for avoiding conflict of interest

After receipt of results of QAF-EQAS-ML from participants laboratories, laboratory identification number were generated by Quality Coordinator and then during result compilation, result evaluation and report generation same unique ID used for participant laboratories. After finalization of reports by technical committee, all reports of participants were again sent to QAF-EQAS-ML coordinator who again as per record assign correct name of laboratory to that unique identification number.

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

Complaint Handling:

If any participant feels that during submission of results or evaluation, there is either technical error or clerical error, kindly send email to us within 7 working days. After that QAF-EQAS-ML provider will not held responsible.

On receipt of complaint/ feedback, QAF-EQAS-ML provider will put forward matter to technical committee and take appropriate action. Final outcome will be communicated to participant laboratory in 7 working days after receipt of complaint/ feedback.

Improving your QAF-EQAS-ML **program:**

All participating laboratories are encouraged to interact with QAF-EQAS-ML provider and send their suggestion regarding needs of inclusion of new tests or deletion of any existing tests from QAF-EQAS-ML program.

Annexure-1 (scope of QAF-EQAS-ML)

Dept	Parameter	Sample type	Reporting mode	Unit
Immuno-Haematology	ABO Blood Group	EDTA	Qualitative	NA
	Rh Blood Group	EDTA	Qualitative	NA
	DCT	EDTA	Qualitative	NA
	ICT Titre	Serum	Qualitative/ Titre	NA
	ICT Interpretation	Serum	Qualitative	NA
Haematology	Hb Electrophoresis-HBA	EDTA	Quantitative	%
	Hb Electrophoresis-HBA2	EDTA	Quantitative	%
	Hb Electrophoresis-HBF	EDTA	Quantitative	%
	Hb Electrophoresis-HBS	EDTA	Qualitative	NA
	Hb Electrophoresis-HB other	EDTA	Qualitative	NA
	Hb Electrophoresis-Interpretation	EDTA	Qualitative	NA
	G6PD Result		Qualitative	NA
	Sickling Test	EDTA	Qualitative	NA
	Interpretation	EDTA	Qualitative	NA
DIC Markers	D-Dimer	Citrate Plasma	Quantitative	µg/ml
	FDP		Quantitative	µg/ml
Blood Parasite Antigens	Malarial Antigen	EDTA	Qualitative	NA
	Microfilatiral Antigen	EDTA	Qualitative	NA
Biochemistry	ADA	Serum,	Quantitative	U/L
	ADA	Fluid	Quantitative	U/L
	Trop T	Serum	Qualitative	NA
	Apo A1	Serum	Quantitative	mg/dl
	Apo B	Serum	Quantitative	mg/dl
	LDL Cholesterol Direct	Serum	Quantitative	mg/dl
	LP (a)	Serum	Quantitative	mg/dl
	Trop I	Serum	Quantitative	ng/ml
	C3	Serum	Quantitative	g/L
	C4	Serum	Quantitative	g/L
	Ceruloplasmin	Serum	Quantitative	mg/dl
	Angiotensin Converting Enzyme	Serum	Quantitative	U/L
	Cholinesterase	Serum	Quantitative	U/ml
	Protein Electrophoresis -Interpretation	Serum	Qualitative	NA
	IGA	Serum	Quantitative	g/L
	IGG	Serum	Quantitative	g/L

	IGM	Serum	Quantitative	g/L
	IGE	Serum	Quantitative	IU/ml
	Pro-calcitonin	Serum	Qualitative	NA
	Insulin	Serum,	Quantitative	µIU/ml
	Free Testosterone	Serum	Quantitative	pg/ml
	Thyroglobulin	Serum	Quantitative	ng/ml
	25 OH vit D	Serum	Quantitative	ng/ml
	Fluid Protein Fluid	Fluid	Quantitative	g/dl
	Fluid Sugar Fluid	Fluid	Quantitative	mg/dl
	Glyco HB-Average Blood Sugar of Last 2 Month	EDTA	Quantitative	mg/dl
	Glyco HB-Result	EDTA	Quantitative	%
	Urine Calcium	Urine	Quantitative	mg/dl
	Urine Creatinine	Urine	Quantitative	mg/dl
	Urine Microalbumine	Urine	Quantitative	mg/L
	Urine Myoglobin	Urine	Quantitative	ng / ml
	Urine Phosphurus	Urine	Quantitative	mg/dl
	Urine Protein	Urine	Quantitative	mg/dl
	Urine Sodium	Urine	Quantitative	mmol/L
	Urine Uric acid	Urine	Quantitative	mg/dl
Microbiology/Serology	ASO	Serum	Qualitative	NA
	CRP	Serum	Qualitative	NA
	RA factor	Serum	Qualitative	NA
	TPHA		Qualitative	NA
	Widal-O Titre	Serum	Qualitative/ Titre	NA
	Widal-H Titre	Serum	Qualitative/ Titre	NA
	Widal-AH Titre	Serum	Qualitative/ Titre	NA
	Widal-BH Titre	Serum	Qualitative/ Titre	NA
	Widal-Interpretation	Serum	Qualitative/ Titre	NA
	Typhidot IgM		Qualitative	NA
	Typhidot IgG	Serum	Qualitative	NA
	Anti HAV IgM	Serum	Qualitative	NA
	Anti HAV TOTAL	Serum	Quantitative	Index
	HbeAg	Serum	Quantitative	Index
	Anti HBc IgM	Serum	Quantitative	Index
	Anti HBc Total	Serum	Quantitative	Index
	Anti HbeAg	Serum	Quantitative	Index
	Anti Hbs Antibody	Serum	Quantitative	Index
	Anti HEV IgM	Serum	Quantitative	mIU/ml

	Anti HCV Antibody	Serum	Quantitative	Index
	Dengu (ELISA) IgG	Serum	Quantitative	Index
	Dengu (ELISA) IgM	Serum	Quantitative	Pan Bio
	Dengu IgG (Rapid)	Serum	Quantitative	Pan Bio
	Dengu IgM (Rapid)	Serum	Qualitative	NA
	Dengue	Serum	Qualitative	NA
	NS1Antigen(ELISA)	Serum	Quantitative	Pan Bio
	Dengue NS1	Serum	Qualitative	NA
	Antigen(Rapid)	Serum	Quantitative	index
	Toxo IgG	Serum	Quantitative	index
	Toxo IgM	Serum	Quantitative	index
	Rubella IgG	Serum	Quantitative	index
	Rubella IgM	Serum	Quantitative	index
	CMV IgG	Serum	Quantitative	index
	CMV IgM	Serum	Quantitative	index
	HSV I IgG	Serum	Quantitative	index
	HSV I IgM	Serum	Quantitative	index
	HSV IgG	Serum	Quantitative	index
	HSV IgM	Serum	Quantitative	index
	HSV II IgG	Serum	Quantitative	index
	HSV II IgM	Serum	Quantitative	NTU
	Mumps IgG	Serum	Quantitative	NTU
	Mumps IgM	Serum	Quantitative	NTU
	MEASELS IgG	Serum	Quantitative	NTU
	MEASELS IgM	Serum	Qualitative	NA
	Chickungunia Antibody	Serum	Qualitative	NA
	Cryptococcal Antigen	Serum	Qualitative	NA
	Infectious Mononucleosis	Serum	Qualitative	NA
	Leptospirosis IgM	Serum	Quantitative	U/ml
	H. Pylori IgM	Serum	Quantitative	U/ml
	H. Pylori IgG	Serum	Quantitative	U/ml
	H. Pylori Antibody			
Auto Immune	ANA (ELISA)	Serum	Quantitative	Index
	ANA (IF method)	Serum	Qualitative/Titre	NA
	DNA (ELISA)	Serum	Quantitative	IU/ml
	DNA (IF method)	Serum	Qualitative/Titre	NA
	C- ANCA IFA	Serum	Qualitative/Titre	NA
	P- ANCA ELISA	Serum	Quantitative	U/ml
	P- ANCA IFA	Serum	Qualitative/Titre	NA
	Anti Cardiolipin Abs IgG	Serum	Quantitative	GPLU/ml
	Anti Cardiolipin Abs IgM	Serum	Quantitative	MPLU/ml
	Anti Mitochondrial Abs	Serum	Qualitative	NA
	Anti Phospholipid Abs IgG	Serum	Quantitative	GPLU/ml

	Anti Phospholipid Abs IgM	Serum	Quantitative	MPLU/ml
	Anti Smooth Muscle Abs	Serum	Qualitative	NA
	Anti Thyroglobulin Abs	Serum	Quantitative	IU/ml
	Anti TPO antibody Serum	Serum	Quantitative	IU/ml
Flow Cytometry	HLA- B27	EDTA	Qualitative	NA
	Absolute CD3 Count	EDTA	Quantitative	/ul
	Absolute CD4 Count	EDTA	Quantitative	/ul
	Absolute CD8 Count	EDTA	Quantitative	/ul
	%CD4 Count	EDTA	Quantitative	%
	%CD8 Count	EDTA	Quantitative	%
	Ratio of CD4 to CD8	EDTA	Quantitative	NA
Clinical Pathology	UPT	Urine	Qualitative	NA
	Urine Bense Jones Protein	Urine	Qualitative	NA
	Urine Porphobillinogen	Urine	Qualitative	NA
	Urine SG	Urine	Numberical	NA
	Urine pH	Urine	Numberical	NA
	Urine Glucose/Sugar	Urine	Semi-Quantitative	NA
	Urine Albumin/Protein	Urine	Semi-Quantitative	NA
	Urine Acetone/keton	Urine	Semi-Quantitative	NA
	Urine Blirubine/BS-BP	Urine	Semi-Quantitative	NA
	Urine Urobilinigen	Urine	Semi-Quantitative	NA
	Urine Leucocyte Estarage	Urine	Semi-Quantitative	NA
	Urine Nitrate	Urine	Semi-Quantitative	NA
Photographs	Urine Routine	Image	Descriptive	NA
	Microscopic	Image	Descriptive	NA
	PS examination	Image	Descriptive	NA
	ANA PATTERN	Image	Descriptive	NA
	Protein Electrophoresis	Image	Descriptive	NA
	interpretation	Image	Descriptive	NA
	HPLC interpretation	Image	Descriptive	NA
	Microbiology	Image	Descriptive	NA

*** Number of participant in last cycle for this parameter less than 3.**

Annexure-2

Laboratory Details

Name of laboratory :
(Name of Laboratory as mentioned in any license/ registration/ accreditation/ certification body)

Address of laboratory :

Phone :

Email :

Contact person

(1) Name
Mobile
Email

(2) Name
Mobile
Email

Payment Details : Cash/ Cheque/DD -
Amount Rs -
Drawn Bank -
Date -

Remark : Cheque /DD drawn in favour of "**Quality Assurance Forum**" payable at Ahmedabad

I _____ hereby assure you that above all details given by my laboratory are true and in my best knowledge.

Signature of Lab Director

Referance-

1. ISO/IEC guide- 17043
2. WHO Quality Assurance in Hematology
3. NABL document 162
4. NABL document 163
5. ISO/IEC 17025:2005
6. ICMR Guide for transportation of biological samples