USER MANUAL PRQ/PT/23

User Manual of PRE-EQC : An external quality assurance program of *PRE-ANALYTICAL & ANALYTICAL PHASE.*

Dr.Shyamali Pal
PT Coordinator
PRE-EQC

We care for the integrity of the samples received by your laboratory

DBS Specimen: Rejection Criteria

- Insufficient sample volume/incomplete circles
- Clotted sample
- Hemolysis/serum ring
- Abraded/scratched
- Not dry/packed before drying
- Poor humidity control
- No/poody labeled specimen
- Missing sample or lab request form

USER MANUAL PRQ/PT/23

Proficiency Testing Provider: PRE-EQC

PT Coordinator:

Dr. Shyamali Pal, Ph D (Biochemistry)

Director, PRE-EQC

Working Place: Allergimmuno Diagnostics Private Limited

53/1D, Chaulpatty Road, Beliaghata, Kolkata-700010

Testing services is being provided by:

Dr Lal Pathlabs Ltd, Premises no.031-0199, Plot no. CB31/1

Street no.199, Action area-1C, New Town, Kolkata-700156

Email: shy23pal@gmail.com ; M: 91-9874415344

Website: www.pre-eqc.com

Acknowledgements:

Website design and maintenance:

Mr. Arijit Dutta, Mr. Saptarshi Pal, Digital Media Experts Private Limited

Payment for enrolment to be done to the following:

Beneficiary: PRE-EQC

HDFC Bank, CIT Road Branch

A/C No.: 50200039767050

IFSC: HDFC0001224

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ABBREVIATIONS

SL.NO.	NOMENCLATURE	ABBREVIATION
1	Proficiency Testing	PT
2	External Quality Control	EQC
3	External Quality Assurance System	EQAS
4	Median	M
5	Standard Deviation	SD
6	Robust Standard Deviation	RSD
7	Coefficient of variation	CV
8	Standard Error Mean	SEM
9	Confidence Interval	CI
10	Identification	ID
11	International Organization of Standards	ISO
12	International Electro technical Commission	IEC
13	Standard Deviation Index	SDI
14	Clinical Biochemistry	CB
15	Clinical Pathology	CP
16	Assigned Value	AV
17	Standard Deviation of Proficiency Testing	SDPT
18	Turn Around Time	TAT

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Foreword:

The PRE-EQC started in the year 2017 with the aim of monitoring pre-analytical factors only. The previous/existing scheme on pre analytical EQAS consists of sending an erroneous sample and asking customer to find out the root cause. It appears to be more a competence evaluation than External Quality Assurance. Instead, PRE-EQC developed a plan of monitoring environment and TAT through some input of data by the participants. Such data are normally recorded by the medical laboratories as requirements for accreditation. PRE-EQC only accumulated the data and evaluated the findings finally creating a complete external quality control program covering pre-analytical, analytical and post analytical phases.

The program started with comparison of test results of any three analytes from the scope. The participants suggested converting the program into an external quality control program so that all three phases of a medical laboratory can be monitored, The full EQA program started in July 2019 and by November 2020 z-score of pre and post analytical phases are being calculated.

Clinical Pathology is mostly split testing ILC. It has been observed that collection of necessary volume for split testing & TAT management are extremely difficult. So, an EQA for routine urine chemistry has also been developed.

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Introduction

Proficiency testing (PT) involves the use of interlaboratory comparisons for the determination of laboratory performance. The application of comparative analysis adds value to the confidence of the laboratory and helps searching the scope of improvement.

The laboratory services are familiar with EQA which is performance and evaluation of tests in accordance with predetermined conditions. The PRE-EQC is PT/EQA program specially equipped to monitor the Pre analytical &analytical phase of CB and routine urine chemistry (CP).

The pre analytical factors have been selected as per ISO 15189:2012. The Pre analytical PT/ EQA involves assessment and evaluation of temperature management, transport time, preservation time, testing time management and finally evaluation of integrity of the sample. The PRE-EQC survey team offers evaluation of 39 Clinical Biochemistry analytes at every round. The laboratories/ main collection facilities may opt for pre analytical with 3 analytes for only integrity qualification check of the samples. PRE-EQC offers z-scoring of pre-analytical, analytical and post analytical phase.

The PRE-EQC team offers corrective actions to individual participant as part of continual improvement program.

The PRE-EQC is a non-profitable program created for the assistance and improvement of laboratory services. The scheme has been organized as per the requirements of ISO/IEC 17043:2023 and statistical calculations are as per ISO13528:2022&AC 785, IAS, USA.

Aim:

- To provide easy to use external quality assessment service that covers the most commonly performed tests in laboratories.
- To provide a financially viable EQA program.
- To provide data of deviation after replicate analysis, a requirement of ISO15189:2022.
- To help corrective action and troubleshooting.
- Efficient and reliable support to every individual participant.

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***Area of External Service Provider**:*

Working place for sample preparation and dispatch:

Allergimmuno Diagnostics Private Limited

Testing for Homogeneity and Stability of PRE-EQC sample:

Dr LALPATHLABS, Kolkata, New Town.

Area of sole responsibility of Group Head & Director:

Calculations of homogeneity and stability, design of the scheme, calculation of assigned values, interpretations and discussion with the participants.

Scope

- Planning and execution of PRE-EQC in the field of Clinical Biochemistry and Clinical Pathology (chemistry parameters only)
- Inviting medical laboratories to participate in the program
- To create an inexpensive PT program so that small laboratories may participate.
- Dispatching samples within notified time.
- Evaluation of performances as per ISO 13528:2022, ISO 17043:2023, ISO15189:2022

Purpose:

1. To serve the Laboratory medicine Department in an economical manner.
2. To provide pre analytical monitoring and corrective actions.
3. Continual improvement of pre analytical and analytical monitoring.
4. To provide routine urine chemistry EQA.
5. To provide results and interpretations of analytes not under coverage of any External Quality Assurance group.

Confidentiality:

PRE-EQC assures confidentiality of results of the participants and operational integrity. All results and interpretations are confidential subject to disclosure only to the regulatory bodies. To maintain confidentiality unique ID is generated for individual participants.

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Management System Procedure for Handling of Complaints

Policy:

To ensure users a satisfactory service by prompt resolution of complaint.

Scope

The laboratory services.

Responsibility

All personnel involved in PT activities.

Procedure

i)Resolution of complaints maybe related to pre-examination, examination, post examination, procedure, advisory services, dispatch of samples to receipt, testing, data entry and evaluation of reports. Respective personnel take the responsibility. If possible/necessary, immediate action is taken. The addressal is done by the person responsible for communication, the Group Head.

ii) Users are encouraged to fill up the feedback/complaint form in the website though it is optional. Hence, the format of opportunities for improvement is publicly available.

iii) After receiving the complaint PRE-EQC confirms whether laboratory is actually responsible.

iv) All information is gathered to determine whether the complaint is substantiated.

v) A description of the complaint, corrective action, resolution and preventive action is recorded.

vi) Effectivity of implementation is tracked.

vii) Investigation and resolution do not result in any discriminatory action.

viii) The resolution of complaint is reviewed and approved by the Group Head considering the act will fulfil the criteria of impartiality. Any complaint against Group Head herself is reviewed by the Chairperson.

Format of Patient/User Complaint/Feedback

Date	Patient ID	Description of the complaint /Feedback	Investigation	Investigated by	Resolution	Immediate/ Long action	Effectivity	Recurrence

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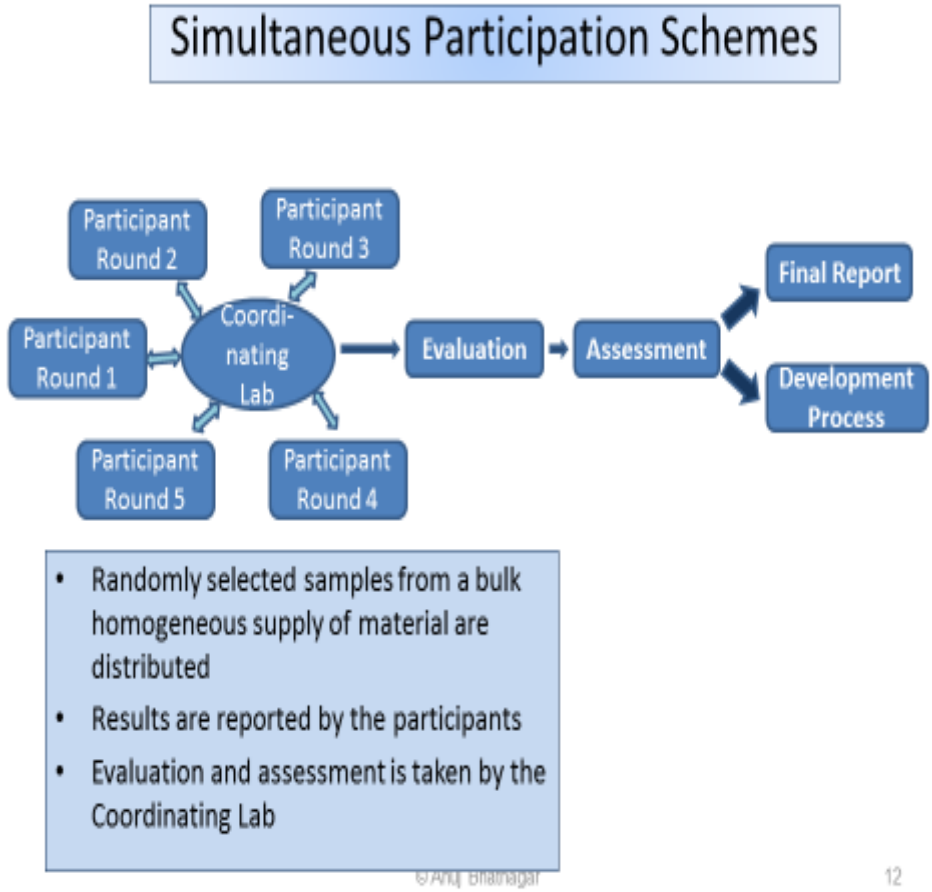
Right to appeal:

The participants possess the right to appeal to the PT Coordinator for any disputed result/ controversy regarding assessment of results or assistance for interpretations or corrective actions.

Design of the scheme:

The PRE-EQC scheme is a simultaneous participation scheme where measurands are quantitative measured analytes. The simultaneous participation proficiency testing scheme involves randomly selected sub samples from a source of material being distributed simultaneously to participants for concurrent testing.



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(Courtesy: NITS, BIS, Mr. Anuj Bhatnagar)

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Procedure for Participation:

- Participation is by enrolment through the web page after payment for one cycle.
- Participation form is provided in the webpage.
- Participation form should be duly filled up.
- Acceptance of enrolment is automated.
- Payment is through “payment gateway”.
- Unique ID is provided to every participant.
- Participation of one year is described as “Cycle”.
- In each cycle number of participations are six for Clinical Biochemistry and four for Clinical Pathology.
- The participations are prescheduled. Samples are being sent to participants in the month of January, March, May, July, September &November.
- The dates of distribution of samples are informed 7 days prior transport in the notice board.
- Formatted result sheets to be obtained by unique password to every participant.
- The samples are transported within scheduled distribution time.
- Test completion time is prescheduled to evaluate Pre analytical criteria.
- Participants are supposed to send the results to the PT-Coordinator within scheduled time.
- The PT-Coordinator retains the sample to dissolve any dispute/difference up to 48 hrs after the last date of report submission. PT Provider is not responsible for loss/ further requirement of sample after 48hrs of result submission.
- All participation results are confidential.
- Confidentiality of participants results are strictly being followed by all members of PRE-EQC team.

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Criteria to be met for participation:

- The participation is voluntary.
- Who will participate: Any medical/clinical laboratory accredited/not accredited.
- Tests for enrolment: As per the "List of tests".
- The participants should perform the test within "Turnaround time".
- Any incidence e.g., damage, loss, misplacement, wrong participant ID etc., to be informed within 48 hrs of the date of result submission.

Selection of measurands:

There are 52 parameters in Clinical Biochemistry with option of selection of methods. Urine chemistry consists of 13 parameters.

Tests are available in "List of tests"(Page 11-14).

The participants may select all available parameters/parameters as per the requirement of the laboratory.

Number of samples will be as per the requirement of the laboratory. The laboratory participating in comprehensive program (CB& CP) will receive one urine sample container (8-10ml), one fluoride plasma vial (1ml), one serum sample vial (1.5ml), and one biological fluid vial (1ml) one K2-EDTA vial for Haemoglobin fractions and one serum sample for HIL index (Haemolysis, Icterus, Lipemia). Samples are master pool of human matrix.

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List of tests: The entire scope is under accreditation except pre analytical parameters

Sl No	Clinical Biochemistry	Analyte/Method/Unit			Periodicity	Decimal places
	Specimen Type	Analyte	Method	Unit	6times in a year/Bimonthly	
1	Fluoride,Plasma	Glucose	Hexokinase/GOD-POD	mg/dL	-do-	2
2	Serum	Urea	Urease-GLDH	mg/dL	-do-	2
3	Serum	Creatinine	Jaffe's,Kinetic	mg/dL	-do-	2
4	Serum	Uric acid	Uricase,End pt	mg/dL	-do-	2
5	Serum	AST	1.IFCC,Without P5P 2.IFCC with P5P	U/L	-do-	2
6	Serum	ALT	1.IFCC,Without P5P 2.IFCC with P5P	U/L	-do-	2
7	Serum	ALP	PNPP,IFCC kinetic	U/L	-do-	2
8	Serum	GGT	SZASZ,IFCC kinetic	U/L	-do-	2
9	Serum	Total Protein	Biuret	g/dL	-do-	2
10	Serum	Albumin	BCG dye binding	g/dL	-do-	2
11	Serum	Globulin	(TP-Albumin)	g/dL	-do-	2
12	Serum	Albumin/ Globulin	Alb/Glob	NA	-do-	2
13	Serum	T Bilirubin	DPD/DMSO	mg/dL	-do-	2
14	Serum	D Bilirubin	DPD/DMSO	mg/dL	-do-	2
15	Serum	I Bilirubin	Calculated (TBil-DBil)	mg/dL	-do-	2
16	Serum	T Cholesterol(TC)	CHOD-PAP	mg/dL	-do-	2
17	Serum	HDL Cholesterol(HDLC)	Direct Enzymatic (Precipitation is not acceptable)	mg/dL	-do-	2

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18	Serum	LDL Cholesterol(LDLC)	Detergent based homogeneous method (Calculated is not acceptable)	mg/dL	-do-	2
19	Serum	VLDL Cholesterol (VLDLC)	Calculated TC- (HDLC+LDLC)	mg/dL	-do-	2
20	Serum	TC/HDLC	Calculated	NA	-do-	2
21	Serum	HDLC/LDLC	Calculated	NA	-do-	2
22	Serum	Triglycerides	GPO-PAP	mg/dL	-do-	2
23	Serum	Total Calcium	OCPC-BAPTA/ ArsenazoIII	mg/dL	-do-	2
24	Serum	Inorganic Phosphorus	UV-Phospho Molybdate	mg/dL	-do-	2
25	Serum	Amylase	GAL-G2-CNP Kinetic	U/L	-do-	2
26	Serum	Lipase	Colorimetric,kinetic using quinonediimine dye	U/L	-do-	2
27	Serum	CK	IFCC,Kinetic using N-Acetyl Cystamine	U/L	-do-	2
28	Serum	LDH	Lactate-Pyruvate, Kinetic	U/L	-do-	2
29	Serum	CKMB	Immunoinhibition	U/L	-do-	2
30	Serum	Carbon di oxide	Phospho enol Pyruvate carboxy kinase	mmol/L	-do-	2
31	Serum	Iron	Ferrozine	µg/dL	-do-	2
32	Serum	TIBC	Calculated (Fe+UIBC)	µg/dL	-do-	2
33	Serum	UIBC	Ferrene without precipitation	µg/dL	-do-	2
34	Serum	Sodium	ISE Direct	mmol/L	-do-	2
35	Serum	Potassium	ISE Direct	mmol/L	-do-	2
36	Serum	Chloride	ISE Direct	mmol/L	-do-	2
37	Serum	FT4	ECLIA/CMIA/ CLIA	ng/dL	-do-	2
38	Serum	T3	ECLIA/ CMIA/	ng/mL	-do-	2

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			CLIA			
39	Serum	T4	ECLIA/ CMIA/ CLIA	µg/dL	-do-	2
40	Serum	TSH	ECLIA/ CMIA/ CLIA	µU/mL	-do-	2
41	Urine	Microalbumin	Immunoturbidimetry	mg/dL	-do-	2
42	Urine	Creatinine	Jaffe Kinetic	mg/dL	-do-	2
43	Urine	Microalbumin Creatinine ratio	Calculated: Microalbumin /Creatinine	---	-do-	2
44	Biological fluid, Other than CSF	Glucose	Hexokinase/GOD-POD		-do-	2
45	Biological fluid, Other than CSF	Total Protein	Biuret		-do-	2
46	Biological fluid, Other than CSF	Albumin	BCG Dye binding		-do-	2
47	Biological fluid, Other than CSF	LDH	Lactate-Pyruvate		-do-	2
48	K2-EDTA, Whole Blood	HbA0	Ion Exchange HPLC D10, TOSOH,VARIANT	%	-do-	2
49	K2-EDTA, Whole Blood	HbA2	Ion Exchange HPLC D10, TOSOH,VARIANT	%	-do-	2
50	K2-EDTA, Whole	HbA1c	Ion Exchange HPLC D10, TOSOH,	%	-do-	2

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	Blood		VARIANT			
51	K2-EDTA, Whole Blood	HbF	Ion Exchange HPLC D10, TOSOH, VARIANT	%	-do-	2
52	K2-EDTA, Whole Blood	Abnormal Hb fractions	Ion Exchange HPLC, D10, TOSOH, VARIANT	%	-do-	2

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Sl No	Clinical Pathology	Analyte/Method/Unit				Decimal Places
	Urine	Analyte	Method	Unit	4times in a year	Up to 2/ May be observation where decimal is not applicable
1	Clinical Pathology	Color	Physical Examination	NA	4times in a year	-do-
2	Clinical Pathology	Appearance	Physical Examination	NA	4times in a year	-do-
3	Clinical Pathology	Deposit	Physical Examination	NA	4times in a year	-do-
4	Clinical Pathology	Protein	Protein –error of indicators	mg/dL	4times in a year	-do-
5	Clinical Pathology	Glucose	Glucose Oxidase	mg/dL	4times in a year	-do-
6	Clinical Pathology	pH	Double Indicator	NA	4times in a year	-do-
7	Clinical Pathology	Blood	Occult blood	mg/dL of Hb	4times in a year	-do-
8	Clinical Pathology	Specific Gravity	pKa, logarithmic decision	NA	4times in a year	-do-
9	Clinical Pathology	Ketone bodies	Rothera's/Legal's	mg/dL	4times in a year	-do-
10	Clinical Pathology	Bilirubin	Dichloroaniline	mg/dL	4times in a year	-do-
11	Clinical Pathology	Urobilinogen	Ehrlich's method	µmol/L	4times in a year	-do-
12	Clinical Pathology	Nitrite	Nitrate reductase	Present/Absent	4times in a year	-do-
13	Clinical Pathology	Phosphate	Heat &acid	Present/Absent	4times in a year	-do-

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Instructions to participants:

Name of the Scheme: PRE-EQC

1. PRE-EQC provides Unique ID to all participants. Enter the webpage by login user ID &Password.
2. Sample1: Serum sample
   Sample2: Fluoride plasma for glucose
   Sample3: Biological fluids
   Sample 4: Urine sample for Clinical Pathology and urine Micro-albumin, Creatinine.
   Sample 5: Serum HIL indices.
   Sample 6: Hb- fractions.

3. Please complete test performance within scheduled time mentioned to you by email before sample transport.

4. Complete pre analytical monitoring and enter the data. Please recheck before submission as wrong entry may affect the "Consensus Data".

5. Please perform the tests twice as the PT-Provider checks inter assay variations.

6. Update any change/changes in the method.

7. For all parameters, please report the exact value. If linearity limit exceeds dilute the sample to the extent suggested by your system manufacturer (Follow the SOP).

8. The sample should be tested like patient sample. No special precaution is necessary.

9. Do not outsource/use the sample as reference or control material of your laboratory.

10. Keep the samples at 2°c-8°c if you are not processing the same immediately.

11. Evaluations are based on "Consensus Data".

12. Please share the information with concerned staff members of your laboratory.

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***PRE-EQC does not enrol the participant whose samples cannot be delivered within 72 hrs.**

Infection markers:

Serum, Fluoride plasma & biological fluids are screened negative for HbSAg, HIV I&II, P24 Antigen and HCV antibody by CLIA before transport.

Instruction for handling the samples:

- Wear gloves and apron.
- Open the pack carefully.
- Take out the samples and place in a sample rack.
- Note the temperature of sample containers immediately after receipt of samples.
- Avoid spillage. If there's spillage follow universal precautions.
- Preserve at 2°c-8°c if the test is not being performed immediately.
- Follow the local/national guideline of sample disposal after completion of test performance.

Potential sources of errors:

- PRE-EQC monitors pre analytical activities. So, it is important to complete the performances of tests within intimated period.

- To observe physical characteristics as it is one of the measurands of pre analytical activities.

- Wrong entry of test results.

- Confusion regarding sample code: 1: Serum, 2: Fluoride plasma, 3: Biological fluids, 4: Urine sample, 5: HIL, 6: K2-EDTA Whole blood.

- Statistical calculations are inbuilt in webpage so except wrong entry there's no major area of non-compliances.

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Sample Preparation:
Samples are prepared from pooled serum/fluoride plasma/biological fluids/urine from routine urine samples. As the Clinical Biochemistry scheme measures pre analytical status the pooled serum/fluoride plasma/biological fluids are without any preservative. The urine sample is not under pre analytical monitoring and preservative added sample.
*Sample is prepared in the afternoon before the day of transport.

Sample preparation for estimation of Haemolysis, Lipemia and Icterus & Clot detection:
Clot Detection:
The sample probes of all automated Biochemistry Analysers are having clot sensor. So, the system will alarm the participant. To prevent damage in the sample probe turbid sample is prepared. Visual characterization is also acceptable.

Sample Transport:
Tri level packing. Samples are kept in airtight primary containers which are separated from each other by cotton layer. Temperature of gel pack kept between 2-8-degree C. Temperature is noted before dispatch. Samples are wrapped with gel pack. The wrapped sample containers are inserted in Specimen Collection Bag with “Biohazard” symbol. Urine is packed in separate specimen collection bag. The containers are placed in insulated thermocol box and tightly sealed. Lab ID, Participants’ & senders address, email, contact number is labelled. Receiving time is tracked from courier services and confirmed from participants.

Result Submission:
The results to be submitted within 7 days from the day of transport. It has been observed the time interval does not affect stability criteria. **The participants are requested to report for missing/damaged samples within 48 hrs after the last day of result submission. Samples are disposed after the deadline/ on day 10.**

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Requirements of production, quality control, storage and distribution:

25% excess sample is prepared for "emergency requirement". The subcontractor laboratory is an accredited laboratory and tests are under the scope of ISO15189:2012. The subcontractor follows the Internal and External quality performance policy.

Storage of sample:

The samples are pooled on the previous working day before sending. As the scheme monitors pre analytical performances the policy of outsourcing is followed. The Clinical Biochemistry sample is pooled and thoroughly mixed fluoride plasma, serum samples and biological fluids without preservative. The urine samples for Clinical Pathology and Micro albumin & creatinine are "preservative added" samples. The samples are distributed within 72 hrs and result submission is instructed to be completed within next 7 days. The samples are stored for maximum 10 days at 2°c-8°c.

Distribution:

The samples are distributed within 72hrs by courier services. The PT Coordinator assures that participants receive the sample within scheduled time. **Samples are preserved two more days to take action in the case of lost/damaged PT items.**

Precautions to prevent collusion/falsification:

Every set of test item is freshly pooled samples. The PT Provider tests the homogeneity and stability on the day of sample dispatch. The results are validated by comparing with assigned mean of participants. So, the situation of collusion/falsification would never arise.

Procedures for the test methods to be used for homogeneity and stability testing:

As per ISO13528:2022.

Stability:

As per ISO13528:2022, stability to be done twice. One subset on day1 and another subset on the last day of submission of results by participants. PRE-EQC obtained difference of two results within 0.3*SDPT. But ISO 13528:2022 has provided option that if deviation is obtained >0.5SDPT in a round then number of repeat tests may be increased (e.g., Subset 1 &2 4 times each to minimise the deviation). Though PRE-EQC never had to take the option but the recommendation is accepted as policy.

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Homogeneity:

CP& CB: In every round till November 2021. After obtaining satisfactory homogeneity for consecutive 12 rounds (6rounds/year) only stability is being tested from January 2022. Moreover, it is established that human blood components like serum, plasma, biological fluids are homogeneous in nature. K2-EDTA mixing in whole blood makes the sample homogeneous. Human urine is basically homogeneous.

The samples are called off if stability results are not satisfactory and 2nd time samples are send by next 7-10 days to the participants.

N.B. ***The delivery may be delayed due to unavoidable circumstantial situations which PT Provider is unable to overcome.***

Report of homogeneity & stability:

The "Admin" reports as: **Homogeneity and Stability reports are adequate".**

Homogeneity: Passed/not passed

Stability: Passed/not passed

****Results of homogeneity and stability may be disclosed to the regulatory body.***

Responsibility of participants:

- Allow adequate time for delivery of the PT items by enrolling in the program in timely manner.
- Inspect the PT items package on receipt and store/analyze it according to instructions.
- Contact PT Coordinator immediately if there is a deficiency identified in the specimen package or with individual PT items.
- Ensure "Universal Precautions" protocol during use of PT item. Handle and test the PT item as you would a routine patient sample following the routine procedures used in your laboratory.
- Submit the results within instructed time. Your delayed result entry may affect the process of evaluation.

Results not within the range of consensus data: As per ISO13528:2022, policy of blunder removal is followed.

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Feedback, Complaints and appeals:

PRE-EQC requests all participants to provide feedback through software, mail or phone.

Feedback/complain tab is available in the webpage.

Suggestions to participants:

PRE-EQC team encourages discussion with individual participant regarding the performances for continual improvement within the limit of confidentiality and operational integrity.

Annual summary sheet:

May be downloaded from website

Certificate of Participants: -do

Previous results: -do-

Time limit for display of previous results: 2years.

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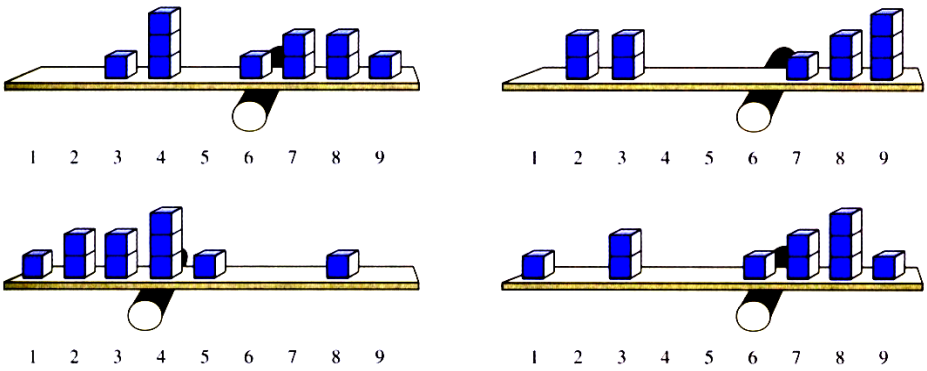
Statistical design:

Based on robust calculations.

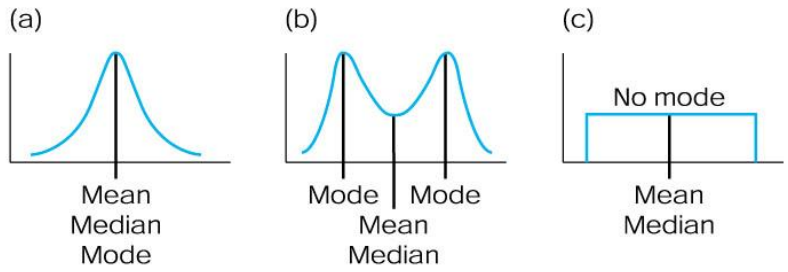


Median:

- The median is the middle value when observations are ordered. To find the middle, count in (N+1)/2 scores when observations are ordered lowest to highest.

Mode:

- The most frequent score.



Measures of dispersion:

- Standard Deviation

  Measure of the average amount by which observations deviate from the mean.

- Range

  Difference between the smallest and largest observations.

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Evaluation of results:

Assigned value:

Median derived from set of results submitted by participants. Assigned value is ideally specific for peer group but if participation is less then all method mean of comparator may be used as assigned value.

%Deviation:

The percent deviation of laboratory result from the assigned value, or deviation from 1st result when intra assay deviation is measured. % Deviation is used when number of participants is less than 5.

Standard Deviation Index (SDI)/z-score:

The measurement of bias and closeness to the target value. Target value may be an assigned value of peer group value. In PRE-EQC the results expressed in z-score

Z-Score= Lab result- Assigned mean/ RSD

Standard Error Mean (SEM):

Standard deviation of sampling distribution of the sample mean.

SEM= SD/√n

n= Number of laboratories

SEM is equivalent to SDI and used when deviation is wide. SEM is also expressed as SDI/z-score.

Hence, Mean±2SEM = Range within 2SD / 95% Confidence Interval.

Mean±3SEM = Range within 2SD / 99% Confidence Interval.

The application of SEM is useful when number of laboratories/participants is ≥30.

For convenience PRE-EQC team supplements both z-score & Confidence Interval range.

Utility of SEM:

Continual Improvement; Optional for the participants.

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Evaluation of results:

Pre-Analytical Monitoring:

1. Time interval between preparations to receipt by the participant: Sample preparation time is recorded by the PT Provider. Generally, the afternoon before sample transport. PT Coordinator enters time through "Admin" column.

2. Time interval from core lab to participant: Sample transport time; The dispatch time is entered by "Admin." Time of receipt is entered by the participant.

3. Time of receipt by the participant: Sample receipt time.

4. Temperature when received: The temperature of the sample immediately after receipt.

5. Temperature during analysis: Room temperature of the laboratory.

6. Preservation temperature: Optional; if the participant starts testing the sample immediately preservation temperature may be omitted.

7. Time lag between two performances: PRE-EQC instructs the participants to perform replicate testing. The time lag between two performances to be entered.

8. Physical characteristics: Haemolysis, Lipemia, Icterus index & clot detection:

Measurands	Haemolysis Index (g/L)	Lipemia Index (mg/dL)	Icterus Index (mg/dL)
No	0.16	71	0.8
Within Limit	0.51	124	1.3
Not appropriate	1.66	1044	8.7
To be rejected	5--6	1327	29

Clot detection: The probe sensors of the automated systems detect invisible clots. Visible clots are detected by visual observation.

Visual characterisation is also possible as all automated systems do not possess estimation facility.

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Analytical Monitoring:

The evaluations are simple. Assigned value is based on consensus data. Robust mean, SD, Z-score is calculated. Up to ±2 z-score results are acceptable. 2-3Z-score is in warning range. > 3 z-score is beyond the acceptable range.

The evaluations are method specific. The number of participants is small. So, peer group evaluation is not possible.

CP:

Routine urine analysis consensus data are Ordinale results.

Example:

Glucose: Negative/+/++/+++/++++

Inter assay deviation:

PRE-EQC designed performances of tests in duplicate. The time lag between two sets of performances is variable. The % deviation between two performances is calculated.

- Inter-assay % Deviation of less than 15 are generally acceptable.
- Intra-assay % Deviation should be less than 10.
- These scores reflect the performance of the assay ***in the hands of the user***; such performance score is useful for measurands with high SDPT.

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Result Summary Sheet:

Pre-Analytical Result:

Analyte	Assigned Value(mins)	Participant's Result(mins)	Result
1. Time interval between Preparations to receipt by the participant	1080- 10080----		z-score
2. Time interval from core lab to participant	60- 8640	----	z-score
3. Time interval between receipt to analysis	60-8640	----	z-score
4. Temperature when received	Consensus data	Result	z-score
5.Temperature during analysis	Consensus data	Result	z-score
6.Preservation temperature	2°c-8°c	Result	z-score
7.Time lag between two performances	Consensus data	Result	z-score

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CB:

Analyte	Result	Unit	Median	Participant's z-Score	Inter assay Deviation (%)
Glucose	110	mg/dL	116	-2	5

CP:

Analyte	Assigned Value	Participant's Result	Comment
Glucose	++++	+++	Passed/Not Passed

----------End of report ----------

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Scientific Coordinator
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Only for CP (*/**)

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USER MANUAL PRQ/PT/23

TEMPLATE FOR REGISTRATION

Visit at www.pre-eqc.com

Register

↓

Salutation

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First name

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Last name

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E-mail

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Phone

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Password

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Confirm Password

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Address

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Register& enter to the homepage

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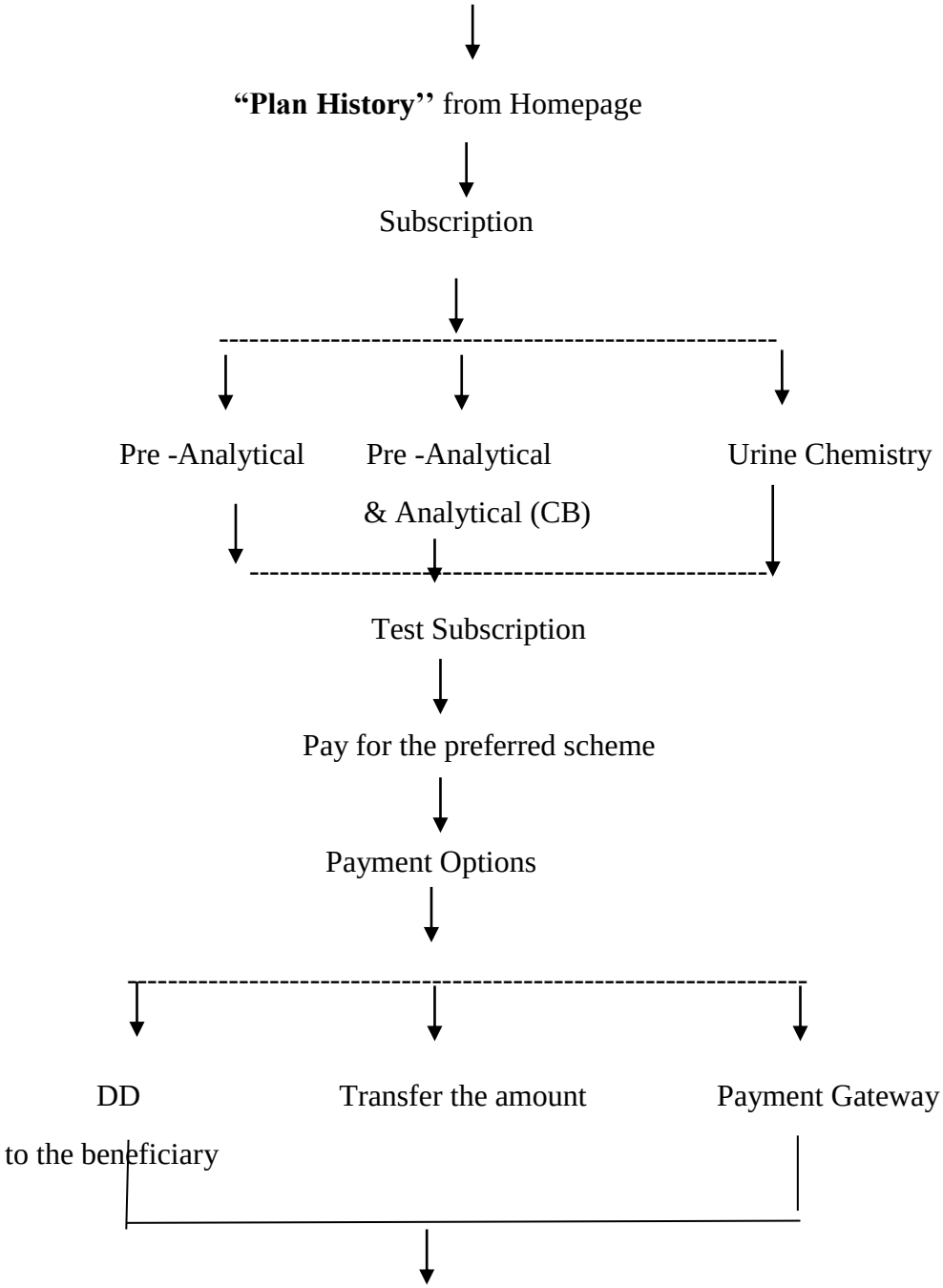
Choice of Scheme and test subscription

Registration



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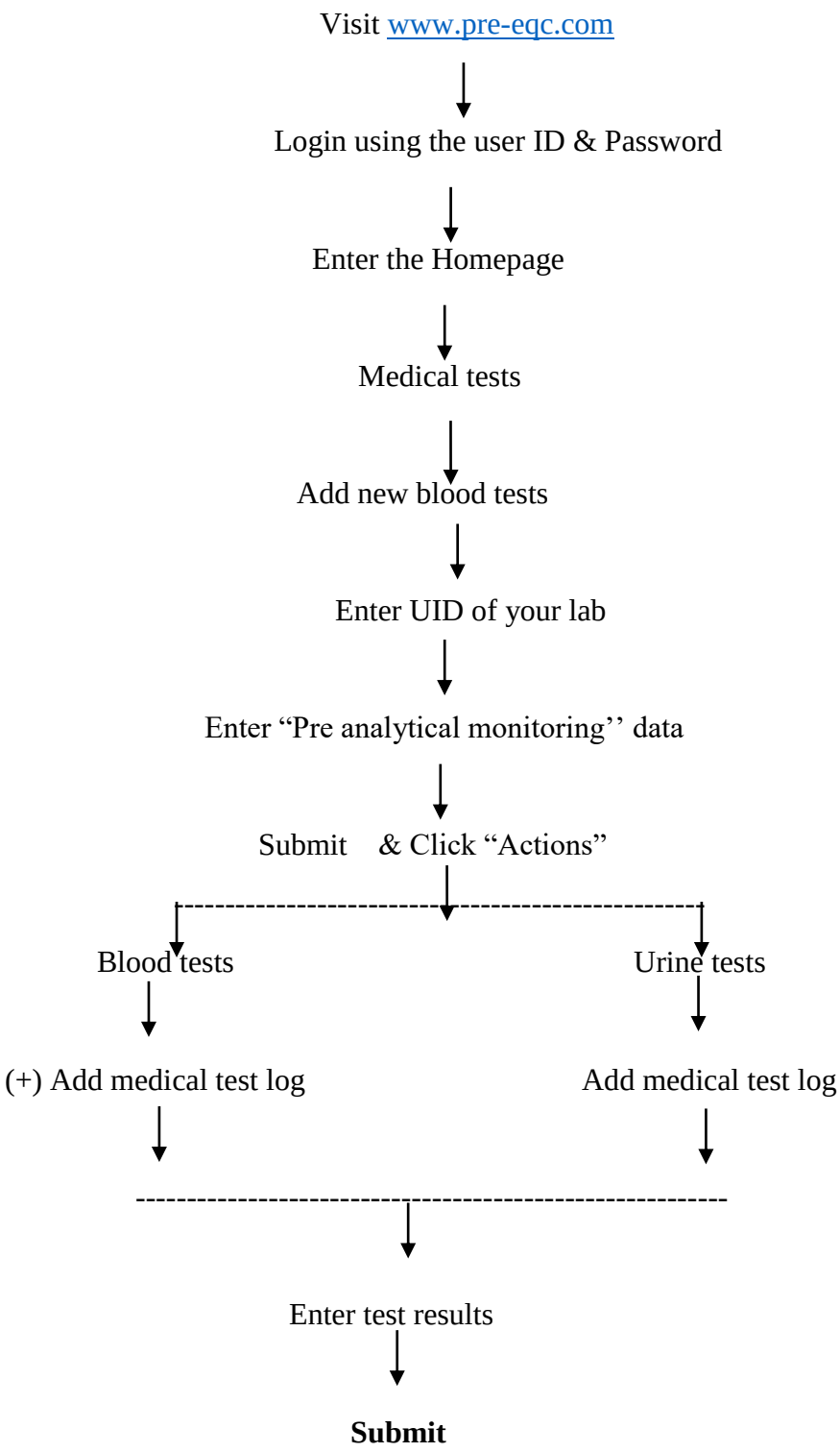
RESULT ENTRY



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EVALUATION OF RESULTS

Visit www.pre-eqc.com

↓

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Medical tests

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Add new blood tests

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Enter UID of your lab

↓

Find pre analytical monitoring results. At the right-hand side there are two options. “Actions” and “column curves”

↓

Click “Column curve” sign

↓

Get the results

The results are stored in virtual clouds. So, the data are auto stored data.

No need to take print outs.

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