INDIAN SOCIETY OF HAEMATOLOGY & BLOOD TRANSFUSION

Christian Medical College Vellore

External Quality Assessment Scheme

Haemostasis Module

2023

Organized by

Departments of Hematology and Transfusion Medicine &Immunohaematology
Christian Medical College
Vellore 632 004, Tamil Nadu
India

Contents

1.0 Introduction

1.1 The EQAS program is being provided on behalf of the Indian Society of Haematology &Blood Transfusion, by Christian Medical College Vellore

1.2 This program is intended to develop awareness regarding quality assurance in the laboratory as part of improving overall patient related diagnostic services.

1.3 An EQAS Committee will plan the activities of the EQAS.

Chair	Dr. Alok Srivastava
Program Coordinator& Quality manager	Dr. Joy Mammen
Scientific Coordinator	Dr. Sukesh Nair Dr. Tulasi Geevar
Associate Program Coordinator	Ms. Sowmiya Bala
Technical Coordinators	Mr. Stanley John Mr. Joel Thamburaj
Bio-statistician	Ms.ML Kavitha
Dy Quality Manager	Mr. G Ajay Sam

1.4 The EQAS Committee will be responsible to the ISHBT.

1.5 All correspondence should be addressed to:

The Program Coordinator
ISHBT – CMC EQAS
Department of Transfusion Medicine
Christian Medical College
Vellore, Tamil Nadu- 632 004. India
Tel: 91 – 416 – 228 3618.

Email: haemeqa@cmcvellore.ac.in

Website: http://www.cmceqas.org

2.0 Aims and Objectives

This section outlines and discusses the aims and objectives of the program.

2.1 Aim:

This program is intended to provide competent external proficiency testing to all levels of laboratories in India so as to improve the existing standards of diagnostic services in hemostasis.

2.2 Objectives:

To increase awareness regarding issues of quality control and proficiency testing in the field of hemostasis.

2.2.1 To produce quality control material for hemostasis testing following recommended procedures.

2.2.2 To arrange for suitable packaging and forwarding services so as to cater to all laboratories wishing to participate in the program.

2.2.3 To analyze the results received and provide reports in a confidential manner to the participating laboratories.

2.2.4 To make available suitable intervention if so requested by the participant laboratories – these will be at the discretion of the organizer.

2.3 Participation in this program is voluntary

2.4 Analysis will be confidential. Intervention will only be at the written request of the participating laboratory.

2.5 This is not to monitor the services offered by the lab. There will be no punitive action on laboratories that are found to consistently produce unacceptable results.

3.0 Scope of the Program

3.1 The program is intended to give the participating lab an objective impression of their accuracy and precision with reference to the other laboratories in the program.

3.2 All participants will have to register on the **Registration Form** provided by the Program Coordinator or downloaded at the website (www.cmceqas.org)

3.3 The participant will also have to complete a **Methodology Survey Form** with details of procedures used, reagents and methods.

3.4 Analysis will be dependent on the data provided – since hemostasis is a method and reagent dependent process. It is mandatory to fill in the details requested.

3.5 If there is any change of any component of the testing procedure it should be update in your profile page.

3.6 On registration, a four digit Participant Identification Number (PIN #) will be assigned. Eg: PIN # 1001

3.7 In all future correspondence, the PIN Number should be quoted.

3.8 The program will be strictly confidential regarding analysis of results and these will only be communicated to the address of the person provided at registration.

3.9 The program is not punitive.

3.10 The organizers only on specific written request of the participant may extend technical and practical assistance.

3.11 Participation in the EQAS does not automatically validate routine performance of the lab. This program does not replace internal quality control practices.

4.0 Survey related details

4.1 Samples

4.1.1 All samples will be derived from human plasma. As far as possible, we will attempt to use plasma 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 plasma with care.

4.1.2 All QC samples are to be treated and processed in a manner similar to routine patient samples.

4.2 Frequency:

4.2.1 There will be three surveys in a calendar year. A schedule will be provided to participants at the time of enrollment or at the beginning of the year.

4.2.2 Each survey will include a paired sample for each test.

4.3 Parameters:

4.3.1 Each survey will include the following tests for those labs appropriately registered.

	Prothrombin Time
	Activated Partial Thromboplastin Time
	Thrombin Time
	Factor VIII:C Assay
	Factor IX:C Assay
	Fibrinogen Assay
	Von Willebrand Factor Antigen Assay
	Ristocetin Co-factor assay/ Collagen binding assay

4.4 Other parameters may be added on at the discretion of the organizers in response to the needs of the participants.

4.5 The sample sent will suffice to perform the test in duplicate.

4.6 The mean result of the duplicate should be reported as would be the routine practice in the laboratory.

5.0 Results

The results obtained should be entered into the online before the closing date.

5.1 Appropriate codes should be used where necessary referring to specific sections in the material provided.

5.2 As reports depend on the results of the participant labs, if results are delayed, they may not be included.

5.3 If a test methodology is changed or if a new reagent is used, you can edit in your member area. If this information is not provided, the report may not reflect the true situation.

5.4 The website is activated , participants may enter their results in the website using your member login profile.

6.0 Assessment of Results

6.1 The overall aim of assessing results will be threefold:

6.1.1 To provide an overall summary of the correct and incorrect results

6.1.2 To provide for each individual laboratory an analysis of its performance in the current and previous surveys.

6.1.3 To assist in root cause analysis – help differentiate random errors from systematic errors

6.2 The results will be analyzed by the method described in Section 7 (Analysis).

7.0 Analysis

7.1 The target value and the limits of acceptable performance are based on statistical and clinical justifications

7.2 Target value is assigned in accordance with standard procedures specified in ISO documents.

7.3 Standard statistics for parametric distributions are performed. Standard Deviation for Proficiency Assessment (SDPA) is calculated based on Algorithm A.

7.4 We have changed the assessment system for Factor assays from the aA-eE grading system to a percentage deviation system with limits of acceptable performance based on the assigned value.

7.5 To overcome the matrix effect, peer groups based on reagents will be considered for evaluation purposes. A minimum of 10 participants are required for the formation of a peer group.

8.0 Participant Action

8.1 The participant (Lab In-Charge) is expected to review the QC report received with the Lab supervisor and the concerned technologist.

8.2 There should be a process of feedback so as to ensure that good results are acknowledged and results that are outwith consensus are reviewed to identify the possible source of error – random or systematic.

8.3 If the participant has any queries, these should be addressed to the Coordinator at the address specified above.

8.4 The participant may request for technical assistance if results show consistent error.

8.5 This should be made in writing to the Coordinator at the address specified above.

8.6 All such correspondence will be confidential.

8.7 The Coordinator will make all attempts to provide such assistance as requested, if feasible.

8.8 The Coordinator is however not under any compulsion to provide assistance if it is not feasible.

9.0 **Force Majeure clause:** We as a Proficiency Testing provider shall not be responsible for cancellation or delay in delivery of EQA consignment resulting from one or more of the force majeure events beyond our reasonable control, such as but not limited to: Acts of God, Earthquakes, Strike(s), Lockout(s), or other labour disturbances, Civil Commotion, War, Acts of terrorism, Riots, Epidemics, Fires, Floods or unusually severe weather conditions, Accidents or other contingencies, Nation/State- imposed restrictions etc, the non-occurrence of which was a basic assumption on which the contract to provide PT services was made for the year. If the force majeure conditions continue beyond six (6) months, the parties shall then mutually decide the future course of action.

10.0 CALENDAR:

Activity	Month	Comment
Start of New cycle Renewal	January	Renewal of subscription for the coming year
Survey 1	March	Samples dispatched Reports provided
Survey 2	July	Samples dispatched Reports provided
Survey 3	November	Samples dispatched Reports provided

11.0 Appendix

Parameter	Option Code	Option Text
Method	A01	Manual
	A02	Semi Automated
	A03	Automated
End point detection	B01	Optical Nephelometry
	B02	Optical Transmittance
	B03	Optical Turbidometry
	B04	Optical Absorbance
	B05	Mechanical
	B06	Electromechanical
	B07	Optomechanical
	B08	Aggregometry
	B09	Immuno-turbidometry
	B10	Enzyme Linked Immuno Sorbent Assay (ELISA)
	B11	Line Immuno Assay (LIA)
	B12	Latex Assay
	B13	Light Scatter
Factor Assay Principle	C01	Clot based
	C02	Chromogenic
	C03	von Clauss Technique

	C04	PT fibrinogen
Source of plasma	D01	Geometric Mean of 20 plasmas
	D02	Arithmetic mean of > 20 normal plasmas
	D03	Commercial plasma
	D04	Freeze dried plasma pool
	D05	Pooled plasma (Not specified)
Thromboplastin reagent	E01	Other (Specify)
	E02	Local (in-house)
	E03	BiopoolThromboplastin
	E05	Dade (Baxter) Thromboplastin IS
	E06	Dade (Behring) Thromborel R
	E07	Dade (Behring) Thromborel S
	E08	Dade Innovin
	E09	Diagen Freeze dried thromboplastin
	E10	DiamedDiaplastin
	E11	ImmunoImmunoplastin
	E12	Instrumentation Labroatory PT Fib HS
	E13	Instrumentation Laboratory PT Fib Recombinant
	E15	Sigma Thromboplastin
	E16	Pacific Haemostasis (not specified)
	E17	Coagpia PT - S (Sekisui)
	E18	Stago Neoplastin CI Plus
	E20	TCoag (Trinity biotech)
	E21	Tulip Uniplastin
	E22	Tulip Liquiplastin
	E23	Helena PT Reagent
	E24	StagoTriniclot PT reagent
	E26	Haemosilrecombiplastin
	E27	Quickcoag PT reagent
	E28	Neoplastine R
	E30	Proieclot's PT HS
	E31	Phophoplastin RL
	E32	Diagnosthrombo
	E33	Dialab Thromboplastin Liquid
	E34	Technoclone Technoloplastin
	E35	Erba Protime LS
	E36	Stago Neoptimal
	E37	Tulip Lyoplastin
	E38	Medirox MRX Owren's PT
APTT reagent	F01	Other (Specify)
	F02	Local (in-house)

	F03	Amax Alexin
	F04	BiomerieuxPlatelin LS
	F05	Biopool APTT reagent
	F06	Dade (Behring) cephaloplastin
	F07	Dade (Behring) Pathromtin SL
	F08	Dade Actin
	F09	Dade Actin FSL
	F10	DiamedDiacelin
	F11	Helena APTT Reagent
	F12	Instrumentation Laboratory APTT SP
	F13	Instrumentation Laboratory Synthafax
	F14	Instrumentation Laboratory Synthasil
	F15	NycomedCephotest
	F16	Sigma APTT reagent
	F17	Stago CK Prest
	F18	Tulip Liquicelin
	F19	Tcoag APTT Reagent
	F20	Dade Actin FS
	F21	STA PTT Automate
	F22	Quickcoag APTT reagent
	F23	STA Cephascreen
	F24	Prieclot's APTT reagent
	F25	Phospholin ES
	F26	Diagnos APTT
	F28	Technoclone Dapttin
	F29	Technoclone Siron LS
	F30	Erba Actime
TT reagent	G01	Other (Specify)
	G02	Local (Inhouse)
	G03	BiomerieuxThromboquik
	G04	Helena Thrombin Time Reagent
	G05	Instrumentation Laboratory Test Thrombin
	G06	Merck Thrombin Time
	G07	Pacific Haemostasis Thrombin Time reagent
	G08	Dade (Siemens) Test Thrombin
	G09	Sigma Thrombin Reagent
	G10	Stago Thrombin reagent
	G11	Tcoag (Trinity Biotech) Thrombin time reagent
	G12	Tulip Fibroscreen
	G13	Technoclone Thrombin Reagent

	G14	Erba Thrombin Time
Source of buffer	H01	Local (in-house)
	H02	Commercial
Interpretation	J01	Normal
	J02	Borderline
	J03	Abnormal
	J04	INR Above Therapeutic Interval
	J05	INR Within therapeutic interval
	J06	INR Below therapeutic interval
	J07	Correction study: Probable factor deficiency
	J08	Correction Study: Probable inhibitor
Analyzer	K01	Other (Specify)
	K02	Amax Destiny
	K03	Amelung KC Series
	K04	BBL Fibrosystem
	K05	BenkhThrombolyser
	K06	BiobasCoagulomnater Clot 1
	K07	BiomerieuxCoag A Mate series
	K08	ERBA Uno
	K09	Hemostar XF
	K10	Humaclot Junior
	K11	Instrumentation Laboratory ACL series100/1000/Eli
	K12	Instrumentation Laboratory Elite Pro
	K13	Instrumentation Laboratory Futura/Advance/Pro
	K14	Labor Coadata 2001
	K15	Labor Fibrintimer
	K16	Pacific HaemostasisHaemoscreen
	K17	Stago Automate STA
	K18	Stago STA Compact
	K19	Stago STA Satellite
	K20	Sysmex CA 50
	K21	Sysmex CA 500
	K22	Sysmex CA 1500
	K23	Sysmex CS 2000i
	K24	Trinity Biotech
	K25	Tulip CoaLab 6000
	K26	Axiom Coadata 501
	K27	Behnk CLP
	K28	Behnk Coagulator

	K29	Biomerieux OPTION series
	K30	Diamed CD2
	K31	Diamed CD4
	K32	ERBA Coag 2
	K33	Grifols Q
	K34	Instrumentation Laboratory CL Analyzer
	K38	RAL Technica Clot SP
	K39	Ceveron Alpha
	K40	Erba ECL 105
	K41	Erba ECL 412
	K42	Erba ECL 760
Source of factor deficient plasma	L01	Local (in-house)
	L02	Commercial

END OF DOCUMENT