Christian Medical College Vellore

External Quality Assessment Scheme

Transfusion Module

2025

Organized by

Department of Transfusion Medicine & Immunohaematology

Department of Clinical Virology

Christian Medical College

Vellore 632 004, Tamil Nadu

India

Contents

1. Introduction

1.1. The EQAS program is being provided by the Christian Medical College External Quality Assessment Scheme (CMCEQAS), Vellore.

1.2. This program intends to develop awareness regarding quality assurance in the blood bank to improve overall patient-related diagnostic services.

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

Chair	Dr. Alok Srivastava
Program Coordinator	Dr. Joy Mammen
Scientific Coordinators	Dr. Dolly Daniel Dr. Rajesh Kannangai Dr. John Jude Anthony
Associate Program Coordinators	Mrs. Sowmiya Bala
Technical Coordinators	Mr. Amal Raj Mr. Gurushave Mr. Joel Thamburaj
Quality Manager	Mr. Stanley John
Biostatistician	Ms. M Kavitha

1.4. All correspondence should be addressed to

The Program Coordinator
CMC EQAS – TRANSFUSION MODULE
Department of Transfusion Medicine
Christian Medical College
Vellore 632 004
Tamil Nadu, India

Tel: 91 – 416 – 228 3618
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2. Aims and Objectives

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

2.1. Aim:

2.2. This program is intended to provide appropriate proficiency testing to all levels of blood banks in India to improve the existing standards of Laboratory Testing in all aspects of Transfusion practice.

2.3. Objectives:

2.4. To increase awareness regarding quality control and proficiency testing issues in the field of Transfusion medicine.

2.5. To produce quality control material for Transfusion medicine testing following recommended procedures.

2.6. To arrange suitable packaging and forwarding services to cater to all laboratories wishing to participate in the program.

2.7. To analyze the results received and confidentially provide reports to the participating laboratories.

2.8. To make available suitable interventions if requested by the participant laboratories – these will be at the discretion of the organizer and subject to the availability of appropriate resources.

2.9. Note:

2.10. Participation in this program is voluntary

2.11. CMCEQAS will conduct the analysis; all results and data will be confidential. The results and reports will not be divulged to any other participant or organization except under appropriate legal requirements. Data management is not subcontracted.

2.12. The intervention will only be at the written request of the participating blood bank.

2.13. This program is not intended to monitor the services offered by the lab. Blood banks that are producing persistently defective results

Will be alerted to the situation and encouraged to take necessary root cause analysis and corrective action.

2.14. COLLUSION: Blood bank staff are requested NOT to collaborate to analyze materials or discuss the results of tests on EQAS material with friends or other blood banks before submitting results to the EQAS provider. This will constitute collusion and lead to disqualification, which will be recorded on the certificate.

3. 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. The following parameters will be offered

<table>
<tr><th></th><th>Program</th><th>Parameters
(You should tick only the parameters you performand wish to be evaluated for)</th><th>Tick (√) to Indicate Participation</th><th>Pricing</th></tr>
<tr><td rowspan="5">Laboratories</td><td>Program A</td><td>Blood Grouping and Typing</td><td rowspan="12" colspan="2">Subscription fees are subject to periodic revision.</td></tr>
<tr><td>OR</td><td></td></tr>
<tr><td rowspan="2">Program B</td><td>Blood Grouping and Typing</td></tr>
<tr><td>Direct Coombs and Indirect Coombs test</td></tr>
<tr><td colspan="3">OR</td></tr>
<tr><td rowspan="7">Blood Centers</td><td rowspan="4">Program C</td><td>1. Blood Grouping and typing</td></tr>
<tr><td>2. Direct Coombs and Indirect Coombs test</td></tr>
<tr><td>3. Compatibility test</td></tr>
<tr><td>4. Antibody Screening</td></tr>
<tr><td rowspan="2">Program D</td><td>5. Antibody Identification</td></tr>
<tr><td>Transfusion Transmissible Infections Screen Module (serology – HIV, HBV, HCV, Syphilis and malaria –smear)</td></tr>
<tr><td>TOTAL</td><td>Donor Haemoglobin Screen
Total Charge for Blood centers (C +D)</td></tr>
</table>

3.3. All participants will have to register on the **Registration Form** provided.

3.4. The details of procedures used, reagents, and methods must be provided on the methodology form and will be confidential.

3.5. It is essential to provide methodology data as analysis will depend on it. It is mandatory to fill in the details requested.

3.6. Qualitative results are compared to the results from the reference laboratory. Quantitative results are analyzed using standard statistical methods as per acceptable international standards.

3.7. If there is any change in any component of the testing procedure, it should be included in the space provided in the result entry sheets.

3.8. A four-digit Transfusion Participant Identification Number (TPIN) will be assigned upon registration. E.g., TPIN # T0001

3.9. In all future correspondence, the TPIN Number should be quoted.

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

3.11. An annual de-identified summary will be provided to the NBTC for all DGHS-supported blood centers.

3.12. The program is not punitive.

3.13. The organizers, only on specific written requests of the participant, may extend technical and practical assistance.

3.14. Participation in the EQAS does not automatically validate the lab's routine performance. This program does not replace internal quality control (IQC) practices and emphasizes the need for routine, daily IQC.

3.15. SAMPLES

3.16. All samples will be derived from human donors. As far as possible, we will attempt to use immunohematology samples that have been

Screened for viral diseases. However, since no tests can thoroughly screen all diseases, participants are advised to treat the samples with care as they would for potentially infected samples. (Universal precautions).

3.17. The samples sent for TTI screening were prepared by patients and donors and have been highly characterized as the respective markers. These potentially infectious samples need to be handled with appropriate universal precautions. The EQAS provider is not liable for any issues arising from the mishandling of EQAS specimens by participant Blood Bank staff.

3.18. All QC samples are to be treated and processed like routine patient samples. No special attention must be provided to the analysis of the EQAS samples.

3.19. SURVEY FREQUENCY

3.20. There will be three surveys in a calendar year. The three surveys and their reports comprise a Cycle. The usual survey schedule is in March, July, and November. Unique challenges may be conducted occasionally at the discretion of the Organizer. The end-of-cycle report will be provided 60 days after the last survey.

3.21. CALENDAR:

Activity	Month	Comment
Start of New Cycle	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
Renewal	January	
	February (following)	End-of-cycle report

3.22. PARAMETERS

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

3.23.1 Blood Grouping and Type

3.23.2 Compatibility testing

3.23.3 Direct and indirect Antiglobulin (Coombs) test,

3.23.4 Antibody screening

3.23.5 Antibody Identification

3.23.6 TTI Screening: Antibodies to HIV I and II, Hepatitis B surface antigen, Anti-HCV antibodies, Syphilis, and malaria screening.

3.23.7 Donor Haemoglobin Testing.

3.24. More than one blood/serum/plasma sample may be sent for a test parameter.

3.25. The program will provide at least two samples for grouping exercises and three challenges for compatibility testing. DAT/IAT will be based on the clinical requirements based on the case scenario provided. Antibody screening and identification will be based on compatibility testing results.

3.26. TTI screening: At least five lyophilized samples will be providedfor serological testing for HIV (antibodies), HBsAg, HCV (antibodies), and Syphilis. For Malaria, slides will be provided for those who perform microscopy routinely and lyophilized whole blood for those using Rapid testing. Please use your routine methods to test the samples and report the results. Adequate sample will be provided for performing the test ONE time only.

3.27. Liquid stable samples will be provided for donor haemoglobin testing. Please test using your usual method. The sample will be adequate only for a single test.

3.28. RESULTS

3.28.1 Results should be entered online from your member login. Entering your results online is mandatory. Hard copies of results sent by post or courier will not be accepted.

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

3.28.3 Interim reports will be provided to the participants. We will NOT accept the results submitted after the publication of the Interim report.

3.28.4 Please maintain a scanned copy of your worksheet (internal lab document), which will have to be submitted if required for troubleshooting or verification.

3.29. CONTACT

3.29.1 The Program Coordinator,

CMC EQAS – TRANSFUSION MODULE,

Department of Transfusion Medicine,

Asha Building, 7th Floor

Christian Medical College,

Vellore – 632 004, Tamil Nadu,

3.30. Web address: http://www.cmceqas.org

3.31. Email inquiries may be made to tegas@cmcvellore.ac.in

3.32. Web-based portal www.cmceqas.org Transfusion module member area is active. You may also view/edit your participant profile details and download past survey reports and certificates of participation from previous years using your login credentials.

4. Analysis

4.1. **Target value for Immunohaematology Exercises**:

4.1.1 The organizer establishes the target (desirable) result by performing an adequate number of replicate tests in an NABL-accredited laboratory.

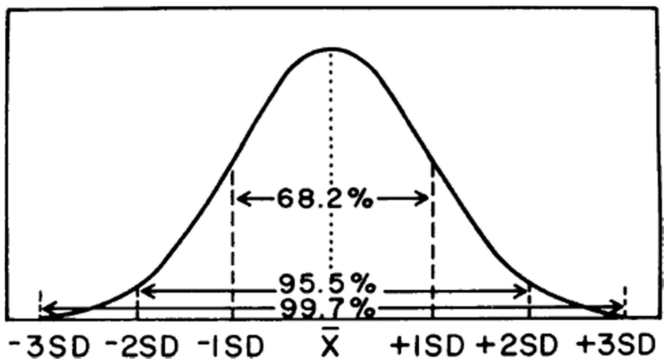
4.1.2 The participant's result will be compared to the target results.

4.1.3 Where required, the analysis of quantitative results will include standard statistical methods.

4.1.4 **Target Value for Transfusion Transmissible Infections**: the result of the Organizing Lab is taken as the target value. The target (desirable) organizer establishes results by performing an adequate number of replicate tests in an NABL-accredited laboratory. All participant results will be evaluated to see if the expected target (Negative/positive) has been achieved. Samples are adequately characterized on multiple platforms before dispatch.

Target Value for Haemoglobin: This is meant for EQA for blood donor screening. A participating laboratory should not utilize this program to offer EQA for diagnostic services. The target value will be arrived at using standard statistics after excluding outliers.

The mean value that arrives after trimming outliers will be the target value. The Standard Deviation will be calculated. The difference between your test results and the overall average is often expressed by a **standard deviation index**, or SDI, representing the difference in standard deviations from the overall mean.



For example, an SDI of 1.0 would indicate your result fell one **standard deviation** from the mean.

Results falling within 3 SDI are termed "Acceptable." Results outside 3 SDI are "Unacceptable." Participants who receive an assessment of SDI between 2-3 must review their procedures.

5. Assessment of Results

5.1. The overall aim of assessing results will be threefold:

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

5.1.2 To provide each laboratory with an analysis of its performance in the current and previous surveys.

5.2. To assist in identifying the cause of deviating results.

5.3. Results should be entered online in the appropriate places in the result entry form available in your member area.

5.4. Care must be taken to complete the results entry correctly since prevention of transcription error forms part of post-analytical quality assurance.

5.5. If a test methodology is changed or a new reagent is used, the appropriate indication should be made in the space provided on the result entry sheet.

5.6. The report may not reflect the true situation if this information is not provided.

5.7. It is recommended that the Participants retain a photocopy of all results returned to the EQAS Center.

5.8. Result entry forms and codes used are provided in the Appendix.

5.9. The method described in Section 4 (Analysis) will analyze the results.

5.10. Scoring System

5.10.1 Scoring will be based on the modules opted for.

5.10.2 Each test will be scored as per the details below

Performance Scoring System

	Per test result	No of tests/samples	Total
Blood Group			
Patient/Donor Identification	10 points	5	50
Blood Group	40 points	5	200
Compatibility Test			
Donor Identification	10	3	30
Compatibility testing	30	3	90
Comment/Interpretation	10	3	30
Other tests			
Direct Antiglobulin test (DCT)	50	1	50
Indirect Antiglobulin test (ICT)	50	1	50
Antibody screening	50	1	50
Antibody identification	50	1	50

		Maximum Achievable Score by Program		
S. No.	**Parameters**	**Program**	**Parameters**	**Maximum**
1	Immunohematology parameters	Program A	Grouping, Typing,	200
2	Immunohematology parameters	Program B	Grouping, Typing, DCT/ICT	350
3	Immunohematology parameters	Program C	Grouping, Typing, Compatibility, DCT/ICT	500
			Grouping, Typing, Compatibility, DCT/ICT, Antibody screening, Antibody identification	600
2	Transfusion TransmittedInfection	Program D	Virology	30
			Syphilis	10
			Malaria	10
	Donor Haemoglobin	Hb	Qualitative	20
			Quantitative	20
			Donor Acceptance	20

6. Participant Action

The participant (Blood Bank medical officer) is expected to review the Report sent by the EQAS organizer and the Lab supervisor.

6.1. There is a feedback process to ensure that good results are acknowledged and results that are not acceptable are reviewed to identify the possible source of error – random or systematic.

6.2. Participants must conduct root cause analysis to understand the nature of the defect detected during EQAS. It is the responsibility of the participants to conduct appropriate analysis and implement corrective action.

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

6.4. The participant may request technical assistance if the results show consistent error.

6.5. This should be done by writing to the coordinator at the above address.

6.6. All such correspondence will be confidential.

6.7. The coordinator will make all attempts to provide such assistance as requested, if feasible.

6.8. The coordinator is, however, not under any compulsion to assist if it is not feasible.

6.9. The participants should not discuss results among themselves before submission of results. This will be considered collusion, and it will then be incumbent on the organizer to take necessary action.

7. 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 labor 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.

END OF DOCUMENT