Christian Medical College Vellore

External Quality Assessment Scheme

Transfusion Module

2024

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 Christian Medical College External Quality Assessment Scheme (CMCEQAS), Vellore.

1.2. This program is intended to develop awareness regarding quality assurance in the blood bank 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	Dr. Joy Mammen
Scientific Coordinators	Dr. Dolly Daniel
	Dr. Rajesh Kannangai
	Dr. John Jude Anthony
Associate Program Coordinator	Mrs. Sowmiya Bala
Technical Coordinators	Mr. Amal Raj Mr. Stanley John Mr. Gurushave Mr. Joel Thamburaj
Quality Manager	Mr. Gift Ajay Sam
Bio-statistician	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
Fax: 91 – 416 – 223 2035
Email: teqas@cmcvellore.ac.in
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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 so as to improve the existing standards of Laboratory Testing in all aspects of Transfusion practice.

2.3. Objectives:

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

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

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

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

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

2.9. Note:

2.10. Participation in this program is voluntary

2.11. Analysis will be conducted by CMCEQAS and all results and data will be treated as being confidential. The results and reports will not be divulged to any other participant or organization except under appropriate legal requirement. Data management is not subcontracted.

2.12. 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 for analysis of materials or discuss the results of tests on EQAS material with friends or other blood banks prior to submission of results to the EQAS provider. This will constitute collusion and will then lead to disqualification that 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 actually perform and wish to be evaluated for)</th><th>Tick (√) to Indicate Participation</th><th>Pricing</th></tr>
<tr><td rowspan="4">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="8">Blood Banks</td><td rowspan="5">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>5. Antibody Identification</td></tr>
<tr><td rowspan="2">Program D</td><td>Transfusion Transmissible Infections Screen Module (serology – HIV, HBV, HCV, Syphilis and malaria –smear)</td></tr>
<tr><td>Donor Haemoglobin Screen</td></tr>
<tr><td>TOTAL</td><td>Total Charge for blood Banks (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 be dependent on this data. 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 of any component of the testing procedure it should be intimated in the space provided in the result entry sheets.

3.8. On registration, a four digit Transfusion Participant Identification Number (TPIN #) will be assigned. Eg: TPIN # T0001

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

3.10. 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.

3.11. For all NACO supported blood banks and annual de-identified summary will be provided to the NBTC.

3.12. The program is not punitive.

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

3.14. Participation in the EQAS does not automatically validate routine performance of the lab. This program does not replace internal quality control (IQC) practices and in fact 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 there are no tests that can completely screen for all diseases participants are advised to treat the samples with care as they would for potentially infected samples. (Universal precautions).

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

3.18. All QC samples are to be treated and processed in a manner similar to 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 with their reports comprises a Cycle.The usual schedule for the surveys is in March, July and November months. Special challenges may be conducted from time to time at the discretion of the Organizer. End of cycle report will be provided by 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 or 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 a minimum of 2 samples for grouping exercise and 3 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 the results of the compatibility testing.

3.26. TTI screening: A minimum of 5 lyophilized samples will be provided for 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 tests 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. Sample will be adequate only for a single test.

3.28. RESULTS

3.28.1 Results should be entered online from your member login. It is mandatory to enter your results online. Hard copy of results send 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 results submitted after the publication of the Interim report.

3.28.4 Please make sure to 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 enquiries may be made to:
teqas@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, download past survey reports and certificate of participation of previous years using your login credentials.

4. Analysis

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

4.1.1 The target (desirable) result is established by the organizer by performing adequate number of replicate testing in an NABL accredited laboratory.

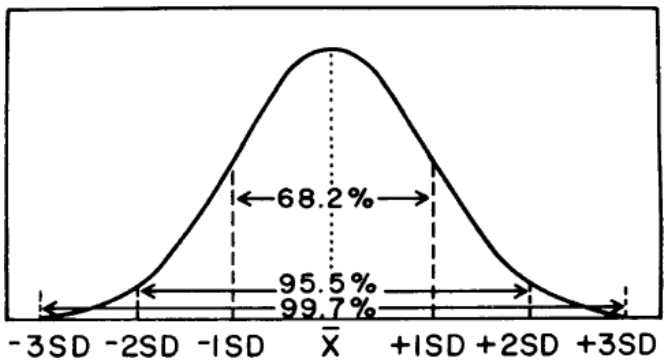
4.1.2 The participant's result will be assessed in comparison with the target results.

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 results of the Organizing Lab is taken as the target value. The target (desirable) result is established by the organizer by performing adequate number of replicate testing 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 prior to dispatch.

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

The Mean value arrived at after trimming of 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, which expresses the difference in terms of the number of 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 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 for each individual laboratory 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 if a new reagent is used, the appropriate indication should be made in the space provided on the result entry sheet.

5.6. If this information is not provided, the report may not reflect the true situation.

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

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

5.9. The results will be analyzed by the method described in Section 4 (Analysis).

5.10. Scoring System

5.10.1 Scoring will be based on the modules opted for.

5.10.2 Each individual test will be scored as per details below

Performance Scoring System

	Per test result	No of tests/sampl es	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 Transmitted Infection	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 medial officer) is expected to review the Report sent by the EQAS organizer along with the Lab supervisor.

6.1. There is a process of feedback so as 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 implementation of 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 for technical assistance if results show consistent error.

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

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 provide assistance if it is not feasible.

6.9. The participants should not discuss results among themselves prior to 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 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.

END OF DOCUMENT