



ALBERTA LABORATORY **QUALITY** ENHANCEMENT PROGRAM

College of Physicians and Surgeons of Alberta

Transfusion Medicine Program Guide

College of Physicians and Surgeons of
Alberta

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Introduction

Mandate

To monitor individual laboratory performance to ensure the highest standard of laboratory service in the interest of patient care.

The Alberta Laboratory Quality Enhancement Program (ALQEP) is operated under the auspices of the College of Physicians and Surgeons. The long term objective of the ALQEP is to ensure that laboratories can produce precise, accurate and timely test results in accordance with standard practice and in the interest of accomplishing quality patient care.

Our short-term goals are to:

- monitor laboratory performance by proficiency testing, and
- assist laboratories experiencing difficulty in attaining good performance.

ALQEP's goals are achieved by:

- the presentation of standardized specimens relevant to clinical practice, for analysis and reporting by laboratories on a prescribed schedule,
- the tabulation and evaluation of results by ALQEP Committees and the reporting of assessments to participants,
- professional assistance, where appropriate, to promote the performance of the laboratory to an acceptable standard, and
- providing educational resources to assist laboratories in enhancing quality of laboratory services.

The intent of a survey is to assess the laboratory's overall performance, not the proficiency of individual laboratory technologists/technicians. Therefore, it is essential that proficiency specimens received from the ALQEP be processed at the receiving laboratory as if they were routine patient samples. Proficiency samples must not be sent to another laboratory and results must not be compared with those obtained in other laboratories. The quality control methods employed in producing results from proficiency samples should be the same for patient samples. Repeat testing should be performed only in accordance with in-house criteria for patient results.

This program guide provides a general overview of the ALQEP and more specifically, information related to the Transfusion Medicine Program.

Terms of Reference

The ALQEP Committee functions in parallel with the Advisory Committee on Laboratory Accreditation and Quality Control. It liaises with the Advisory Committee on matters relating to the level of proficiency in public and independent medical diagnostic facilities within the province of Alberta.

The ALQEP Committee performs functions and considers issues related to quality assurance which may include, but are not restricted to, the following:

1. Selection of quality control material and programs for proficiency testing
2. Monitoring the proficiency level of laboratories through assessment of survey testing results
3. Communication with laboratories regarding non-proficient performance
4. Recommendations to the Advisory Committee regarding the suspension of testing
5. Review of scope of activities versus needs
6. Participation in promoting a national quality assurance program

Out of province participants will continue to liaise with their accrediting agency regarding performance.

Committee Structure

Dr. J. L. Hannon
Director

Ms. S. Hanington
Manager, Quality of Care

Ms. E. McBride
Program Manager

Ms. E. Behr
Technical Analyst

CONSULTANTS

CHEMISTRY:	Dr. F. Bamforth
CYTOLOGY:	Dr. G. Johnson
HEMATOLOGY:	Dr. G. Clarke
MICROBIOLOGY:	Dr. D. Church
TRANSFUSION MEDICINE:	Dr. J.L. Hannon Ms. B. Padget

Objectives of the Transfusion Medicine Program

The objective of the ALQEP Transfusion Medicine program is to ensure that participating laboratories follow appropriate testing protocols and perform accurate testing on a consistent basis. The survey cases are carefully selected to address all aspects of serologic testing encountered by transfusion laboratories. The degree of difficulty is appropriate to the scope of testing performed by each individual facility.

Registration

Laboratory and Method Registration

The registering laboratory records its shipping address, contact name, telephone number, FAX number, and e-mail address on the *Transfusion Medicine Profile* (Appendix A).

Address/Contact - determines where and to whom the samples are shipped.

The laboratory also completes the Transfusion Medicine Profile, using the *Method/Reagent/Code Sheet*. This information is utilized when assessing results to determine if a specific method, reagent type or reagent source is common among facilities with unexpected results. This analysis is shared with participants in the *Survey Report*.

Laboratory Classification

Laboratories are classified based on their scope of testing.

- ◆ **Level A:** Facilities that perform ABO & Rh(D) typing, antibody screen, crossmatch (if performed at facility) and complex serologic investigation including antigen typing, as required, and specialized investigation techniques (e.g. elution, absorption, neutralization)
- ◆ **Level B1:** Facilities that perform ABO & Rh(D) typing, antibody screen, crossmatch (if performed at facility) and basic serologic investigation including possible antigen typing
- ◆ **Level B2:** Facilities that perform ABO & Rh(D) typing, antibody screen and crossmatch (if performed at facility)
- ◆ **Level C:** Facilities that perform ABO typing and / or Rh(D) typing
- ◆ **Level D:** Dispensary only facilities that receive, store and transfuse blood components but do not perform transfusion medicine testing

Surveys

Frequency of Surveys

Levels A, B1, B2, C:

Bimonthly

- ♦ January, March, May, July, September, November

Level D:

Three per year

- ♦ February, June, October

Composition of Surveys

Levels A, B1, B2:

Each survey consists of **two challenges**. Each challenge has one simulated patient plasma / red cell set and two donor red cell samples. The red cells are suspended in preservative and should be treated as unwashed red cell suspensions.

In order to vary the degree of difficulty for Level A and B laboratories, different materials are distributed as reflected in the labeling of samples and accompanying documentation.

Level C:

Each survey consists of **four challenges**. Each challenge consists of a simulated patient plasma / red cell set for laboratories performing ABO and Rh typing and simulated patient red cells only for those laboratories performing Rh typing only. The red cells are suspended in preservative and should be treated as unwashed red cell suspensions.

As correct specimen identification is a critical aspect of blood transfusion procedures, deliberate labeling errors are periodically included in Level A, B and C survey challenges. Participants are expected to ensure that patient identifying information on the samples and requisitions is consistent and should not perform testing if a labeling error is identified.

Level D:

Each survey consists of a paper challenge with questions that may require short answer or multiple choice responses.

Shipments

Levels A, B1, B2, C:

All shipments are sent by courier service with a guaranteed maximum delivery of 2 – 3 days. The shipments are sent in the afternoon of the dates indicated on the annual shipping schedule (refer to the ALQEP website for exact shipping dates:

- ♦ www.cpsa.ab.ca
 - >> Programs and Services
 - >> Accreditation / Quality of Care
 - >> Diagnostic Laboratory Testing – ALQEP
 - >> Transfusion Medicine

If you do not receive the package when expected, contact ALQEP immediately so the shipment can be traced.

Survey samples are contained in packaging type TC125-1B which meets the requirements of the National Standard of Canada CAN/CGSB-43, 125-M90, *Packaging of Infectious Substances and Diagnostic Specimens*, November 1990.

Level D:

Surveys are sent by email or by regular mail, as requested by the participant.

Calendar of Events

Levels A, B1, B2, C:

Week	Monday	Tuesday	Wednesday	Thursday	Friday
1	Samples shipped from ALQEP		Samples received by laboratories		
2					Results due date
3	Results assessed				
4			Final report sent to laboratories		

Level D:

Week	Monday	Tuesday	Wednesday	Thursday	Friday
1	Surveys sent from ALQEP; Emailed surveys received by laboratories			Mailed surveys received by laboratories	
2					
3					
4					Results due date
5	Results assessed				
6			Final report sent to laboratories		

Instructions for Analysis

Each Survey Challenge will be accompanied by an *Instructions for Analysis* sheet which will give detailed instructions for completing the survey and submitting results.

General Instructions:

All survey samples have been tested and are negative for HBsAg, anti-HBC, HCV, anti-HCV, HIV, anti-HIV, anti-HTLV and WNV; however, no test method can offer absolute assurance that infectious agents are absent. The samples should be handled with universal precautions at all times.

Levels A, B1, B2:

Confirm correct identification of samples and requisitions.

Perform the following tests, using routine testing protocols:

- ◆ Type and screen on patient sample
- ◆ Compatibility determination between patient sample and donor cells
- ◆ Any additional testing routinely performed by your laboratory (e.g. confirmation of donor ABO/Rh, antibody identification, serologic investigation)

Record your results on your routine laboratory worksheets.

Complete the enclosed Report Form for each challenge.

Level C:

Confirm correct identification of samples and requisitions.

Perform the following tests, using routine testing protocols:

- ◆ ABO and/or Rh(D) typing on each patient red cell/plasma set

Record your results on your routine laboratory worksheets. Complete the enclosed Report Form.

Level D:

Responses to the challenge should be completed by personnel who routinely perform the task.

Complete the enclosed Survey Response Sheet for the challenge.

Submission of Results

Completing the *Report Form*

The laboratory must complete one *Report Form* (Levels A, B1, B2) for each challenge in the shipment. Level C laboratories complete one *Report Form* for the shipment. Level D laboratories are to complete the *Survey Response Sheet*.

Be sure to include all information requested on the *Report Form* or *Survey Response Sheet*.

Submit by fax or scan and email the Report Forms, testing worksheets and antigen profiles of all screening cells and panels used. Document date submitted and retain copies of submitted information.

Note: For Level A, B1, B2, C surveys: In order for results to be assessed, copies of testing worksheets and antigen profiles of all screening cells and panel cells used **must** be faxed with the *Report Form*.

Assessment of Results

Evaluation Criteria

Levels A, B1, B2, C:

The program grading system is analyte specific. Participants receive a grade for each analyte tested. The analytes graded are dependent on the survey content and may vary for each challenge. Graded Analytes include:

- ◆ Pre-analytic analysis — patient and donor samples
- ◆ ABO typing — patient samples
- ◆ ABO typing confirmation — donor samples (if testing is performed)
- ◆ Rh(D) typing — patient samples
- ◆ Rh(D) typing confirmation — donor samples (if testing is performed)
- ◆ Antibody detection
- ◆ Compatibility testing
- ◆ Donor transfusion suitability determination
- ◆ Phenotyping (Level A / B1 laboratories)
- ◆ Antibody identification (Level A / B1 laboratories)

Participant responses are evaluated on the basis of:

- ◆ test results
- ◆ interpretation of results
- ◆ use of appropriate procedures
- ◆ clerical accuracy

Results from six referee laboratories are assessed prior to evaluation of participant responses in order to ensure that quality of the testing material did not deteriorate during the shipping process and test results are consistent with expected results.

Confirmation of the test result is required by 80% (5 / 6) of referees OR 95% of participants to grade testing of analytes. The ALQEP Transfusion Medicine Committee will review minor errors to determine if they should be considered in the determination of consensus. Participant errors that do not reflect discrepancies in actual testing are not included in consensus determination (e.g., interpretation errors, clerical / transcription errors, incorrect processes). Assessment of non-testing analytes (e.g., pre-analytic and post-analytic processes) will not require consensus if based on a requirement of standards.

The grading key outlines criteria for “Acceptable” (A), “Acceptable, with Recommendation” (A-R), and “Unacceptable” (U) performance. A significant error is assigned where test performance or interpretation would result in an adverse patient outcome. Minor errors indicate a decreased level of performance within the laboratory without a negative consequence for the patient. Errors are further categorized as testing, interpretation, procedural, clerical or other.

Laboratories are notified of both significant and minor errors. In the case of a significant error, the ALQEP program requires Alberta laboratories to submit a reply outlining corrective action within two weeks.

Assessment Grades

Acceptable Results	
Grade	Description
A	Acceptable result
A-R	Acceptable result, with recommendation (refer to comment included on report)

Unacceptable Results	
Grade	Description
U-S	Significant (major) error
U-M	Minor error

Error Categories	
Grade	Description
1	Testing error
2	Interpretation error
3	Procedural error
4	Clerical error
5	Other error

Other Grades	
NT	Not tested
NA	Not applicable
NG	Not graded
NR	No response

Level D:

The Level D program has been developed with an educational focus and while results are reviewed upon submission, a performance grade is not assigned.

Participant responses are evaluated on the basis of:

- ♦ acceptable evaluation and follow-up of situations presented
- ♦ use of appropriate process and procedures
- ♦ appropriate documentation
- ♦ clerical accuracy

If a facility response indicates practice that may impact patient or staff safety, or if a series of responses indicates a trend of suboptimal performance, notification is sent to the laboratory director (Alberta participants) or the provincial accrediting organization (out-of-province participants). The ALQEP program requires Alberta laboratories to submit a reply outlining corrective action within two weeks.

Survey Report

Levels A, B1, B2, C:

The assessed *Report Forms*, as well as a copy of the *Survey Report*, are distributed to each facility within four weeks of the shipment date.

The *Survey Report* includes the following:

- ◆ The number of respondents for the survey
- ◆ Expected results for the analytes in the survey
- ◆ The number of acceptable and unacceptable results for each analyte
- ◆ Method specific analysis of antibody reactivity
- ◆ Description of errors assigned
- ◆ Educational materials or references

A sample survey report is included in Appendix B.

Level D:

The paper challenge survey report is a summary of laboratory responses and is distributed to each laboratory within six weeks of the shipment date.

The *Survey Report* includes the following:

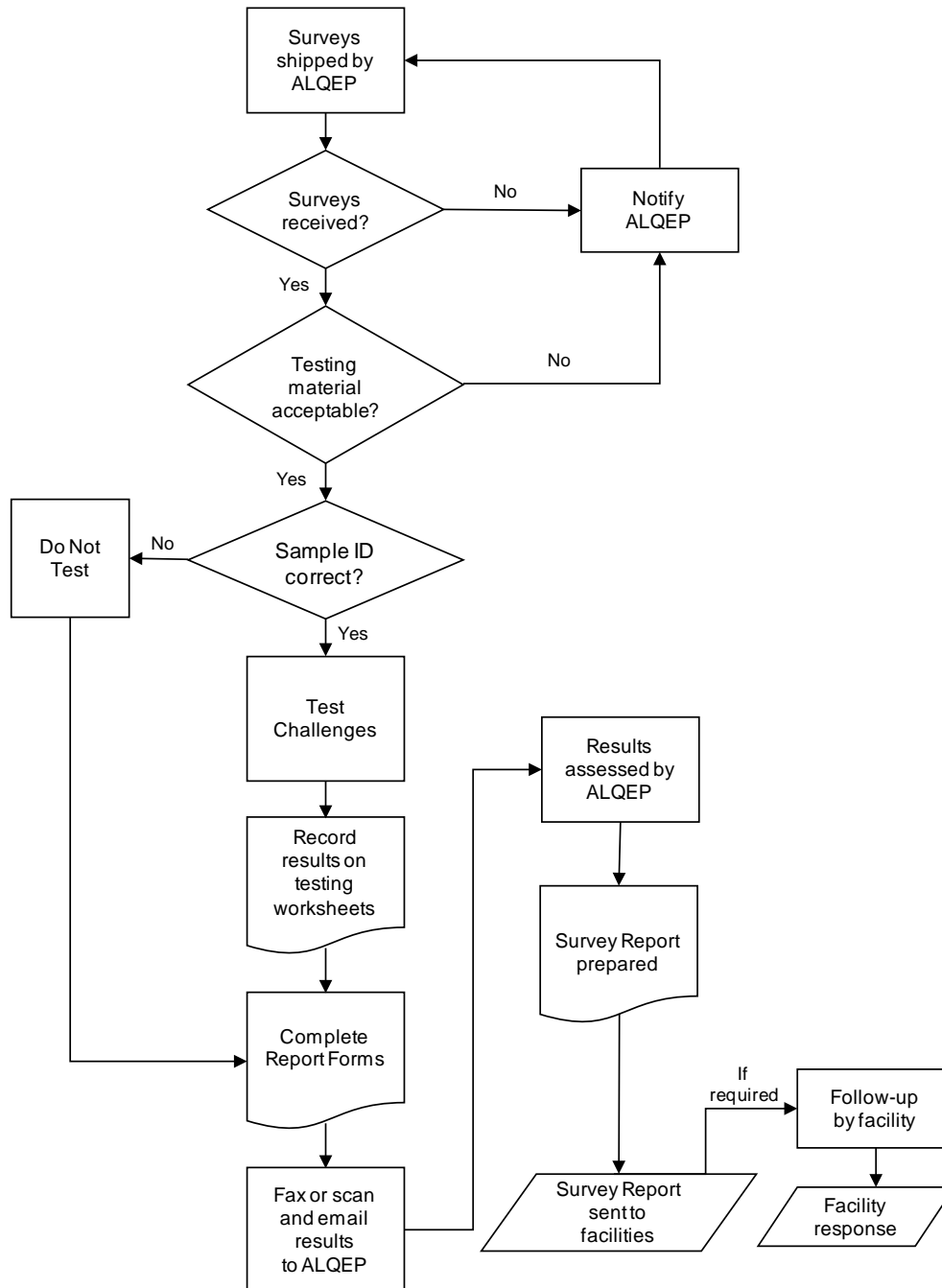
- ◆ The number of respondents for the survey
- ◆ Expected responses to the questions in the survey
- ◆ Educational materials or references

The *Survey Report* is distributed in the following manner:

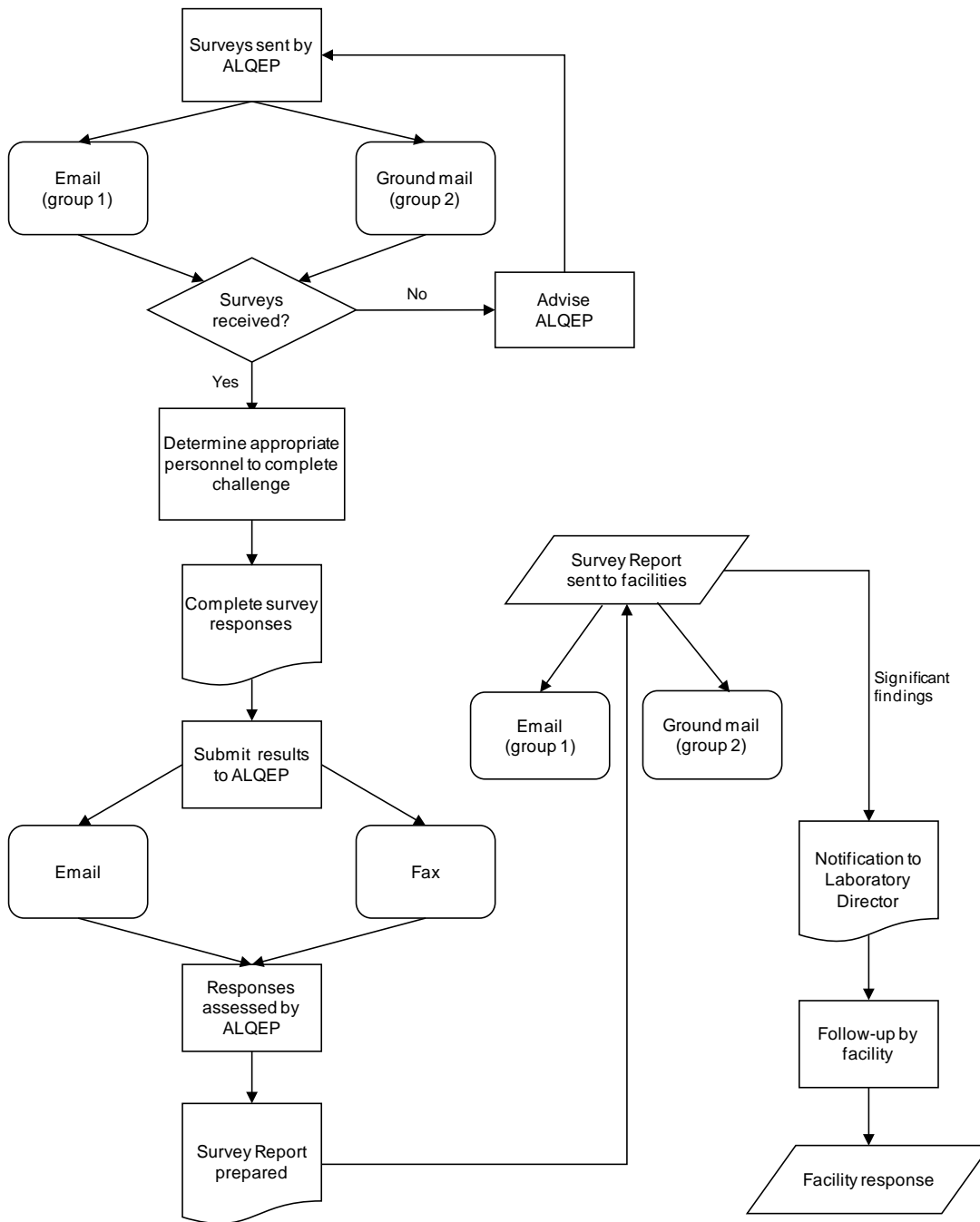
- ◆ Participants who have requested that the survey challenges be sent by email receive an email with the *Survey Report* as an attachment.
- ◆ Participants who have requested that the survey challenges be sent by regular mail will receive a hard copy by mail.

Process Flow

Level A, B1, B2, C



Level D



Appendix A

For a copy of the Transfusion Medicine Profile, please visit the Forms & Codes Listing of the website at http://www.cpsa.ab.ca/Services/Quality_of_Care_Main/ALQEP/ALQEP_Transfusion_Medicine.aspx.

Appendix B

Example Survey Report



ALBERTA LABORATORY QUALITY ENHANCEMENT PROGRAM
College of Physicians and Surgeons of Alberta

Transfusion Medicine – Survey Report 07-01 & 07-02

Surveys were distributed to 155 laboratories:

Level A:	Alberta:	11	Level B2:	Alberta:	22
	British Columbia:	16		British Columbia:	45
	Manitoba:	2		Manitoba:	5
	Saskatchewan:	4		Saskatchewan:	24
	Voluntary:	1		Voluntary:	3
Level B1:	Alberta:	0	Level C:	British Columbia:	7
	British Columbia:	10			
	Manitoba:	1			
	Saskatchewan:	3			
	Voluntary:	1			

Results were not submitted by one Level C facility.

Survey 07-01 A

Summary of Responses

Analyte	Sample	Acceptable Result	# of participants	# with acceptable results	# with unacceptable results
Preanalytic analysis	07-01 A	Acceptable labeling	34	34	0
ABO	07-01 A PC/PP	O	34	34	0
ABO	07-01 A DC-1	O	32	32	0
ABO	07-01 A DC-2	O	32	32	0
Rh(D)	07-01 A PC	Negative	34	34	0
Rh(D)	07-01 A DC-1	Negative	33	33	0
Rh(D)	07-01 A DC-2	Negative	33	33	0
Phenotype	07-01 A PC	C-	32	32	0
Phenotype	07-01 A DC-1	C-	32	32	0
Phenotype	07-01 A DC-2	C-	32	32	0
Antibody screen	07-01 A PP	Positive	34	33	1
Antibody identification	07-01 A PP	Anti-D Anti-C	34	34	0
Compatibility	07-01 A DC-1	Yes	33	33	0
Compatibility	07-01 A DC-2	Yes	33	33	0
Transfusion suitability	07-01 A DC-1	Yes	33	33	0
Transfusion suitability	07-01 A DC-2	Yes	33	33	0

Unacceptable Responses

Significant error:

- 1 – testing
 - 1 - failed to detect anti-D and anti-C

Discussion

One facility confirmed the presence of anti-G as well as anti-D and anti-C in the patient plasma.

The majority of facilities indicated that they would investigate the patient history to determine if the anti-D may be passively acquired from Rh(D) Immune Globulin.

A number of facilities performed additional phenotyping on the patient and/or donor red cells as required by their facility policy or to confirm compatibility of units with antibodies that they were unable to exclude in antibody identification; however, only the C phenotyping was graded.

Antibody Reactivity – 07-01 A PP

Strength of reaction	# of respondents: reactions with D+C- panel cell		
	Gel	Peg IAT	Solid Phase
negative	0	0	0
weak +	0	0	0
1+	0	0	0
2+	10	7	0
3+	5	5	0
4+	0	4	2

Strength of reaction	# of respondents: reactions with C+D- panel cell		
	Gel	Peg IAT	Solid Phase
negative	0	0	0
weak +	0	0	0
1+	0	0	0
2+	5	6	0
3+	10	5	0
4+	0	5	2

Note : 1 participant reported a negative antibody screen by Peg IAT.

Survey 07-02 A

Summary of Responses

Analyte	Sample	Acceptable Result	# of participants	# with acceptable results	# with unacceptable results
Preanalytic analysis	07-02 A	Acceptable labeling	34	34	0
ABO	07-02 A PC/PP	A	34	34	0
ABO	07-02 A DC-1	A	29	29	0
ABO	07-02 A DC-2	O	29	29	0
Rh(D)	07-02 A PC	Positive	34	34	0
Rh(D)	07-02 A DC-1	Positive	24	24	0
Rh(D)	07-02 A DC-2	Negative	26	26	0
Phenotype	07-02 A PC	Jk ^a -	28	28	0
Phenotype	07-02 A DC-1	Jk ^a +	30	30	0
Phenotype	07-02 A DC-2	Jk ^a +	28	28	0
Antibody screen	07-02 A PP	Positive	34	31	3
Antibody identification	07-02 A PP	Anti-Jk ^a	31	31	0
Compatibility	07-02 A DC-1	No	20	18	2
Compatibility	07-02 A DC-2	No	20	18	2
Transfusion suitability	07-02 A DC-1	No	31	31	0
Transfusion suitability	07-02 A DC-2	No	31	31	0

Unacceptable Responses

Significant errors:

- 3 – testing
 - 3 – failed to detect anti-Jk^a in antibody screen
- 4 – testing
 - 4 - failed to detect anti-Jk^a in crossmatch

Discussion

Donor cell 2 (DC-2) was listed as type A Rh(D) Positive on the Instructions for Analysis Sheet. Twelve facilities commented that they would return the donor unit to the blood supplier for investigation. This is the required process when a discrepancy is discovered with unit labeling.

A number of facilities performed additional phenotyping on the patient and/or donor red cells as required by their facility policy or to confirm compatibility of units with antibodies that they were unable to exclude in antibody identification; however, only the Jk^a phenotyping was graded. A number of facilities also commented that they would not report the phenotype, or do so with caution, until it was determined if the patient had been recently transfused.

Antibody Reactivity – 07-02 A PP

Strength of reaction	# of respondents: reactions with Jk(a+b-) cell		
	Gel	Peg IAT	Solid Phase
negative	0	1	0
weak +	0	0	0
1+	10	5	0
2+	4	9	0
3+	1	0	0
4+	0	0	3
Not tested: 1			

Strength of reaction	# of respondents: reactions with Jk(a+b+) cell		
	Gel	Peg IAT	Solid Phase
negative	1	2	0
weak +	4	1	0
1+	6	7	0
2+	2	6	1
3+	1	0	0
4+	0	0	2

Survey 07-01 B

Summary of Responses

Analyte	Sample	Acceptable Result	# of participants	# with acceptable results	# with unacceptable results
Preanalytic analysis	07-01 B	Acceptable labeling	114	114	0
ABO	07-01 B PC/PP	O	111	111	0
ABO	07-01 B DC-1	O	106	106	0
ABO	07-01 B DC-2	O	105	105	0
Rh(D)	07-01 B PC	Negative	111	111	0
Rh(D)	07-01 B DC-1	Negative	106	106	0
Rh(D)	07-01 B DC-2	Negative	105	105	0
Antibody screen	07-01 B PP	Positive	114	114	0
Antibody identification	07-01 B PP	Anti-D	15	15	0
Compatibility	07-01 B DC-1	Yes	106	105	1
Compatibility	07-01 B DC-2	Yes	105	104	1
Transfusion suitability	07-01 B DC-1	B1: yes B2: no	112	110	2
Transfusion suitability	07-01 B DC-2	B1: yes B2: no	112	110	2

Unacceptable Responses

Minor errors:

- 2 – testing
 - 2 – unexpected positive reaction in crossmatch
- 4 – interpretation
 - 4 – donor units reported as suitable for transfusion without appropriate investigation

Discussion

A number of facilities indicated that they would investigate the patient history to determine if the anti-D may be passively acquired from Rh(D) Immune Globulin.

A number of Level B1 facilities performed phenotyping on the patient and/or donor red cells as required by their facility policy or to confirm compatibility of units with antibodies that they were unable to exclude in antibody identification; however, no phenotyping was graded.

Antibody Reactivity – 07-01 B PP

Strength of reaction	# of respondents: reactions with D+ screening cell					
	Gel	Peg IAT	LISS IAT	Sal. IAT	Alb. IAT	Solid Phase
negative	0	0	0	0	0	0
weak +	0	0	0	1	0	0
1+	2	2	1	7	0	0
2+	34	20	3	5	1	0
3+	20	8	0	0	0	0
4+	0	0	0	0	0	5
Positive – strength not recorded	1	2	0	0	0	2

Survey 07-02 B

Expected Responses

Analyte	Sample	Acceptable Result	# of participants	# with acceptable results	# with unacceptable results
Preanalytic analysis	07-02 B	Acceptable labeling	114	114	0
ABO	07-02 B PC/PP	A	114	114	0
ABO	07-02 B DC-1	A	102	102	0
ABO	07-02 B DC-2	A	102	102	0
Rh(D)	07-02 B PC	Positive	114	114	0
Rh(D)	07-02 B DC-1	Positive	96	96	0
Rh(D)	07-02 B DC-2	Positive	96	95	1
Phenotype	07-02 B PC	E-	15	15	0
Phenotype	07-02 B DC-1	E-	15	15	0
Phenotype	07-02 B DC-2	E-	15	15	0
Antibody screen	07-02 B PP	Positive	114	107	7
Antibody identification	07-02 B PP	Anti-E	15	15	0
Compatibility	07-02 B DC-1	Yes	104	103	1
Compatibility	07-02 B DC-2	Yes	104	103	1
Transfusion suitability	07-02 B DC-1	B1: yes B2: no	110	110	0
Transfusion suitability	07-02 B DC-2	B1: yes B2: no	110	110	0

Unacceptable Responses

Significant errors:

- 5 – testing errors
 - 4 – failed to detect anti-E
 - 1 - incorrect Rh(D) typing (D positive unit typed as D negative)

Minor errors:

- 5 – testing errors
 - 3 – unexpected positive reaction with E- screening cells
 - 2 – unexpected positive reactions in crossmatch

Antibody Reactivity – 07-01 B PP

Strength of reaction	# of respondents: reactions with E+ screening cell					
	Gel	Peg IAT	LISS IAT	Sal. IAT	Alb. IAT	Solid Phase
negative	0	0	2	2	0	0
weak +	0	0	0	4	0	0
1+	1	3	1	7	0	0
2+	29	18	1	0	1	0
3+	27	9	0	0	0	0
4+	0	0	0	0	0	6
Positive – strength not recorded	0	2	0	0	0	1

Survey 07-01 C**Summary of Responses**

Analyte	Sample	Acceptable Result	# of participants	# with acceptable results	# with unacceptable results
Preanalytic analysis	07-01 C-1	Acceptable labeling	7	7	0
Preanalytic analysis	07-01 C-2	Acceptable labeling	7	7	0
Preanalytic analysis	07-01 C-3	Acceptable labeling	7	7	0
Preanalytic analysis	07-01 C-4	Acceptable labeling	7	7	0
ABO	07-01 C-1 PC/PP	O	2	2	0
ABO	07-01 C-2 PC/PP	A	2	2	0
ABO	07-01 C-3 PC/PP	B	2	2	0
ABO	07-01 C-4 PC/PP	B	2	2	0
Rh(D)	07-01 C-1 PC	Negative	7	7	0
Rh(D)	07-01 C-2 PC	Positive	7	7	0
Rh(D)	07-01 C-3 PC	Positive	7	7	0
Rh(D)	07-01 C-4 PC	Negative	7	7	0

There were no unacceptable responses for Survey 07-01 C.

**Alberta Laboratory Quality Enhancement Program
Transfusion Medicine Program
Proficiency Testing Assessment Grades**

Acceptable Results	
Grade	Description
A	Acceptable result
A-R	Acceptable result, with recommendation (refer to comment included on report)

Unacceptable Results	
Grade	Description
U-S	Significant (major) error
U-M	Minor error

Error Categories	
Grade	Description
1	Testing error
2	Interpretation error
3	Procedural error
4	Clerical error
5	Other error

Other Grades	
Grade	Description
NT	Not tested
NA	Not applicable
NG	Not graded