



Canadian Blood Services
Soci t  canadienne du sang

**DIAGNOSTIC SERVICES
MANITOBA**

**YEAR IN REVIEW
JANUARY – DECEMBER 2013**

CANADIAN BLOOD SERVICES – MANITOBA DIAGNOSTIC SERVICES

SENIOR STAFF AND CONTACT INFORMATION

**Red Cell Serology Medical Officer
Debra Lane MD, FRCPC**

**(204) 789-1079
debra.lane@blood.ca**

**Platelet Immunology Medical Director
Peter Nickerson MD, FRCPC**

**(204) 789-1125
peter.nickerson@med.umanitoba.ca**

**Diagnostic Services Manager
Lee Grabner MLT, ART**

**(204) 789-1128
lee.grabner@blood.ca**

**Assistant Manager, Diagnostic Services
Lynne Meilleur, MLT**

**(204) 789-1149
lynne.meilleur@blood.ca**

**Red Cell Serology – Charge Technologists
Perinatal Laboratory
Dora Lopes-Carvalho, MLT**

**(204) 789-1090
dora.lopes-carvalho@blood.ca**

**Crossmatch Laboratory
Henri Beaubien, MLT**

**(204) 789-1093
henri.beaubien@blood.ca**

**Platelet Immunology Charge Technologist
Lynnette Beaudin, MLT**

**(204) 789-1109
lynnette.beaudin@blood.ca**

**Perinatal Laboratory
Telephone
Fax**

**(204) 789-1088
(204) 789-1006**

**Crossmatch / Accession Laboratory
Telephone
Fax**

**(204) 789-1085
(204) 779-8593**

**Platelet Immunology Laboratory
Telephone
Fax**

**(204) 789-1152
(204) 789-1186**

Website

<http://www.blood.ca/diagnosticservices>

TABLE OF CONTENTS

| | Page |
|--|------|
| SENIOR STAFF and CONTACT INFORMATION..... | 2 |
| TABLE OF CONTENTS..... | 3 |
| TABLES and FIGURES..... | 4 |
| A. PERINATAL LABORATORY..... | 5 |
| Testing Performed..... | 5 |
| Testing Frequency..... | 5 |
| Specimens Tested..... | 6 |
| Antibodies Identified..... | 7 |
| B. CROSSMATCH LABORATORY..... | 8 |
| Testing Performed..... | 8 |
| Specimens Tested..... | 9 |
| Antibodies Identified..... | 10 |
| C. PLATELET IMMUNOLOGY LABORATORY..... | 11 |
| Testing Performed..... | 11 |
| Specimens Tested..... | 12 |
| D. QUALITY INDICATORS..... | 13 |
| Turn-Around-Time..... | 13 |
| Rejected Specimens..... | 15 |
| E. ACCOMPLISHMENTS in 2013..... | 18 |
| Automated Testing Instrument Upgrade..... | 18 |
| ABLE Study..... | 18 |
| Business Continuity Planning..... | 18 |
| College of American Pathologists (CAP) Laboratory Accreditation..... | 18 |
| Genotyping..... | 19 |
| Massive Transfusion Protocol Development..... | 19 |
| Perinatal Advisory Committee..... | 19 |
| Platelet Donor Selection (PDS) Software Stabilization..... | 19 |
| Provision of Red Cell Aliquots to Hospital Customers..... | 19 |
| Trace Line [®] Laboratory Information System (LIS)..... | 20 |
| F. GOALS for 2014..... | 20 |
| Automated Antibody Screen Investigation Algorithm..... | 20 |
| Automated Testing Instrument Upgrade..... | 20 |
| International Platelet Workshop..... | 20 |
| National Blood Shortages Plan..... | 20 |
| Trace Line [®] Laboratory Information System (LIS)..... | 20 |
| Frequency of Kell Antibodies..... | 20 |

TABLES

| | Page |
|--|------|
| Table 1: Perinatal Specimens Tested..... | 6 |
| Table 2: Total Number of Perinatal Antibodies Detected..... | 7 |
| Table 3: Perinatal Patient Antibody Titres..... | 7 |
| Table 4: Crossmatch Specimens Tested..... | 9 |
| Table 5: Total Number of Crossmatch Antibodies Detected..... | 10 |
| Table 6: Platelet Immunology Specimens Tested..... | 12 |
| Table 7: Turn-Around-Time – Routine Criteria by Specimen Type..... | 14 |
| Table 8: Turn-Around-Time – Routine Perinatal Specimens | 14 |
| Table 9: Turn-Around-Time – Routine Crossmatch Specimens..... | 14 |
| Table 10: Quarterly Rejection Rates – Perinatal..... | 16 |
| Table 11: Quarterly Rejection Rates – Crossmatch..... | 17 |
| Table 12: Quarterly Rejection Rates – Platelet Immunology..... | 17 |

FIGURES

| | Page |
|---|------|
| Figure 1: Total Perinatal Specimens Tested..... | 6 |
| Figure 2: Total Number of Perinatal Antibodies 2012-2013..... | 8 |
| Figure 3: Total Crossmatch Specimens Tested..... | 9 |
| Figure 4: Total Numbers of Crossmatch Antibodies 2012-2013..... | 11 |
| Figure 5: Total Platelet Immunology Donor Specimens Tested..... | 13 |
| Figure 6: Total Platelet Immunology Patient Specimens Tested..... | 13 |
| Figure 7: Perinatal Routine TAT..... | 14 |
| Figure 8: Crossmatch Routine TAT..... | 15 |
| Figure 9: Perinatal Rejection Reasons..... | 16 |
| Figure 10: Crossmatch Rejection Reasons..... | 17 |
| Figure 11: Platelet Immunology Rejection Reasons..... | 18 |

A. Perinatal Laboratory

The Perinatal Laboratory within Diagnostic Services at Canadian Blood Services provides diagnostic testing of pregnant women for blood type and red blood cell antibodies. Results from this screening assist physicians, midwives and nurse practitioners in ensuring the appropriate management of a pregnancy for both the mother and baby. Testing is provided for Manitoba, Northwest Ontario, eastern Nunavut and some Saskatchewan residents close to the Manitoba-Saskatchewan border.

Testing Performed

Canadian Blood Services Perinatal Laboratory routinely performs the following tests:

- ABO/Rh blood type
- Screen for red blood cell antibodies
- Antibody Identification, if antibodies are detected
- Antibody Identification referrals from facilities in Manitoba and Northwest Ontario
- Antibody Titre, if a clinically significant antibody is identified
- Phenotyping
- Fetal Bleed Screening Test
- Kleihauer-Betke Test for quantitation of fetal-maternal hemorrhage
- Direct Antiglobulin Test for detection of HDFN (Hemolytic Disease of the Fetus/Newborn)
- Bedside testing during fetal cordocentesis

Testing Frequency

Mothers – Initial Testing All women should be tested upon their first prenatal visit.

Mothers – 26-28 Weeks Gestation All Rh negative women should be retested at 26-28 weeks gestation. Rh positive women should also be retested at 26-28 weeks gestation when there is only one blood group result available (usually first pregnancy) or if patient is at increased risk of allo-immunization (e.g. previous transfusion, fetal trauma or procedure, IV drug use).

Mothers – Antibody Present If the antibody is known to cause HDFN, it is recommended that specimens be submitted every three to four weeks for the duration of the pregnancy dependant on the specificity of the antibody and the strength of the antibody titre. More frequent testing may be indicated if the antibody titre rises rapidly or if clinical monitoring mandates that additional sampling would provide helpful information.

Mothers – Postnatal Following delivery, specimens from the mother and her baby should be tested if the Rh of the mother is unknown, the mother is Rh negative, the mother has a clinically significant antibody or if the baby shows signs of HDFN (i.e. anemia or jaundice). Midwives or hospitals that do not perform transfusion medicine testing should submit specimens to Canadian Blood Services. A fetal bleed screening test is performed if an Rh negative woman delivers an Rh positive baby. The Kleihauer-Betke assay is performed when the mother has a positive fetal bleed screening test.

Newborns (Cords) Cord blood or neonate specimens must be submitted with the mother's specimen as noted above. ABO/Rh testing is performed on cord or neonatal specimens submitted to Canadian Blood Services. The direct antiglobulin test is performed if the mother has a clinically significant antibody or on request if the baby shows signs of HDFN (i.e. anemia or jaundice).

Partners When a woman has an antibody capable of causing HDFN, specimens from the partner will be requested for ABO/Rh and antigen phenotyping. This will assist in assessing the probability of the baby being affected by the antibody. Partners' specimens may also be tested to assess Rh Immune Globulin (RhIG) eligibility of Rh negative mothers.

Specimens Tested

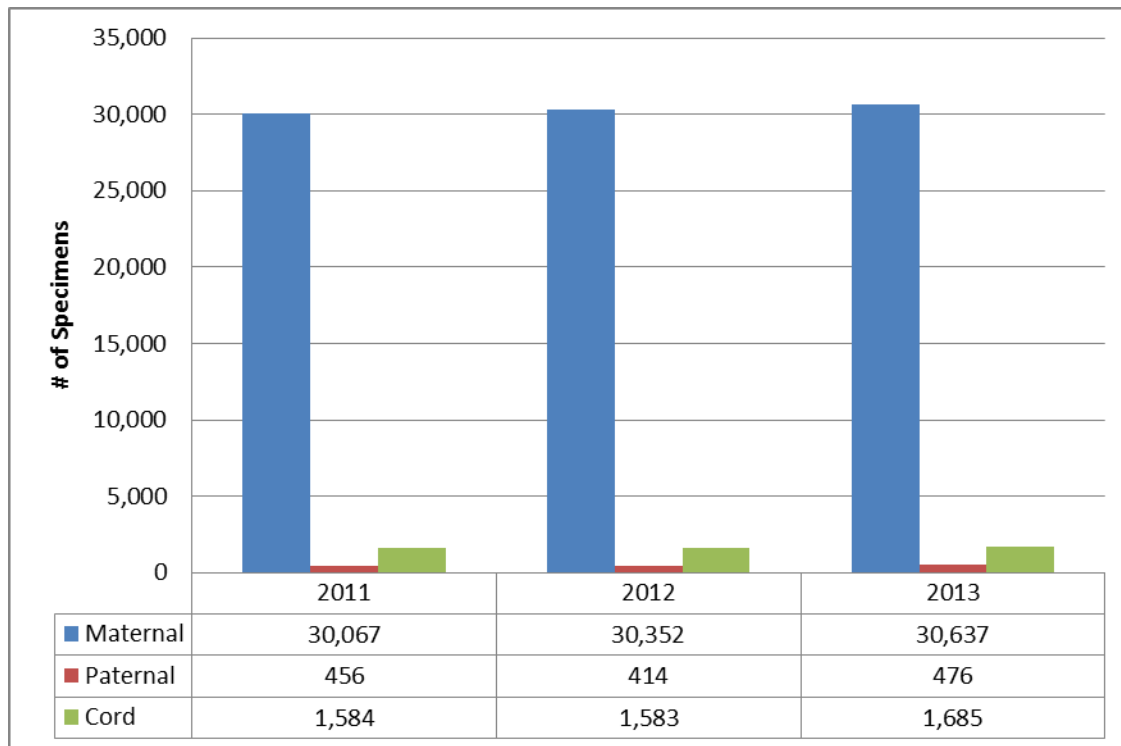
The data in this report reflects the calendar year period to enable better correlation to other government statistical data such as birth rates.

The data includes all women tested, including referral patients from Ontario, Saskatchewan and Nunavut. The total number of specimens tested has risen slightly between 2011 and 2013 as seen in *Table 1* below.

Table 1: Perinatal Specimens Tested

| Specimen Type | Test Type | 2011 | 2012 | 2013 |
|-------------------------------|-----------------|---------------|---------------|---------------|
| Maternal | Type and Screen | 30,067 | 30,352 | 30,637 |
| Paternal | ABO/Rh | 456 | 414 | 476 |
| Cord | ABO/Rh | 1,584 | 1,583 | 1,685 |
| Total Specimens Tested | | 32,107 | 32,349 | 32,798 |
| Patients Tested | | N/Av | 23,357 | 23,481 |

Figure 1: Total Perinatal Specimens Tested



Antibodies Identified

In 2013, a total of 278 antibodies were reported (see *Table 2*). This is moderately higher than 2012. Two hundred and seventy-four women had antibodies identified during their pregnancies (increased from 236 women in 2012), of these; forty-two women had multiple antibodies.

Antibodies identified were considered to be clinically significant if they have been reported to cause HDFN. The most common clinically significant antibodies identified were: anti-K, anti-E, anti-c, anti-Jk^a, anti-C and anti-D (see *Figure 2*) which together represented 69% of the total antibodies identified.

Titres for 13 of the clinically significant antibodies increased from non-critical to critical levels during the pregnancy with a total of 51 antibody titres at critical levels (see *Table 3*). Recommendations were made for all patients with a critical titre level (current or previous pregnancy) and all Kell system antibodies to be referred to a High Risk Fetal Assessment Clinic for further follow-up and monitoring during pregnancy.

Table 2: Total Number of Perinatal Antibodies Detected

| Antibody | Number Detected 2012 | Number Detected 2013 |
|----------------------|----------------------|----------------------|
| Anti-D | 12 | 11 |
| Anti-C | 10 | 13 |
| Anti-C ^w | 0 | 0 |
| Anti-Ce | 1 | 0 |
| Anti-c | 28 | 21 |
| Anti-E | 63 | 63 |
| Anti-e | 4 | 5 |
| Anti-f | 1 | 1 |
| Anti-G | 0 | 1 |
| Anti-K | 45 | 64 |
| Anti-M | 19 | 18 |
| Anti-N | 2 | 3 |
| Anti-S | 4 | 5 |
| Anti-s | 0 | 0 |
| Anti-Fy ^a | 2 | 5 |
| Anti-Fy ^b | 2 | 2 |
| Anti-Jk ^a | 11 | 19 |
| Anti-Jk ^b | 6 | 9 |
| Anti-Le ^a | 16 | 24 |
| Anti-Le ^b | 5 | 4 |
| Anti-Lu ^a | 1 | 1 |
| Anti-Lu ^b | 1 | 1 |
| Anti-Di ^a | 2 | 0 |
| Anti-Di ^b | 0 | 0 |
| Anti-Kp ^a | 1 | 1 |
| Anti-Kp ^b | 0 | 1 |
| Anti-P ₁ | 1 | 0 |
| Anti-Wr ^a | 2 | 3 |
| Anti-A ₁ | 2 | 3 |
| Anti-JMH | 1 | 0 |
| Anti-Ge3 | 0 | 0 |
| Total | 242 | 278 |

Table 3: Perinatal Patient Antibody Titres

| Antibody | Critical Level | Non-Critical Level | Non-Critical to Critical |
|--------------|----------------|--------------------|--------------------------|
| Anti-C | | 8 | |
| Anti-c | 3 | 11 | 2 |
| Anti-Ce | 1 | 1 | 1 |
| Anti-D | 7 | 6 | 2 |
| Anti-DC | | | |
| Anti-DE | | | |
| Anti-e | 1 | 1 | |
| Anti-E | 7 | 45 | 4 |
| Anti-Ec | 2 | | |
| Anti-Fya | | 3 | |
| Anti-Fyb | | 1 | |
| Anti-G | | | |
| Anti-Jka | | 12 | |
| Anti-Jkb | | 4 | |
| Anti-K | 29 | 30 | 4 |
| Anti-M | | 1 | |
| Anti-S | 1 | 1 | |
| Total | 51 | 124 | 13 |

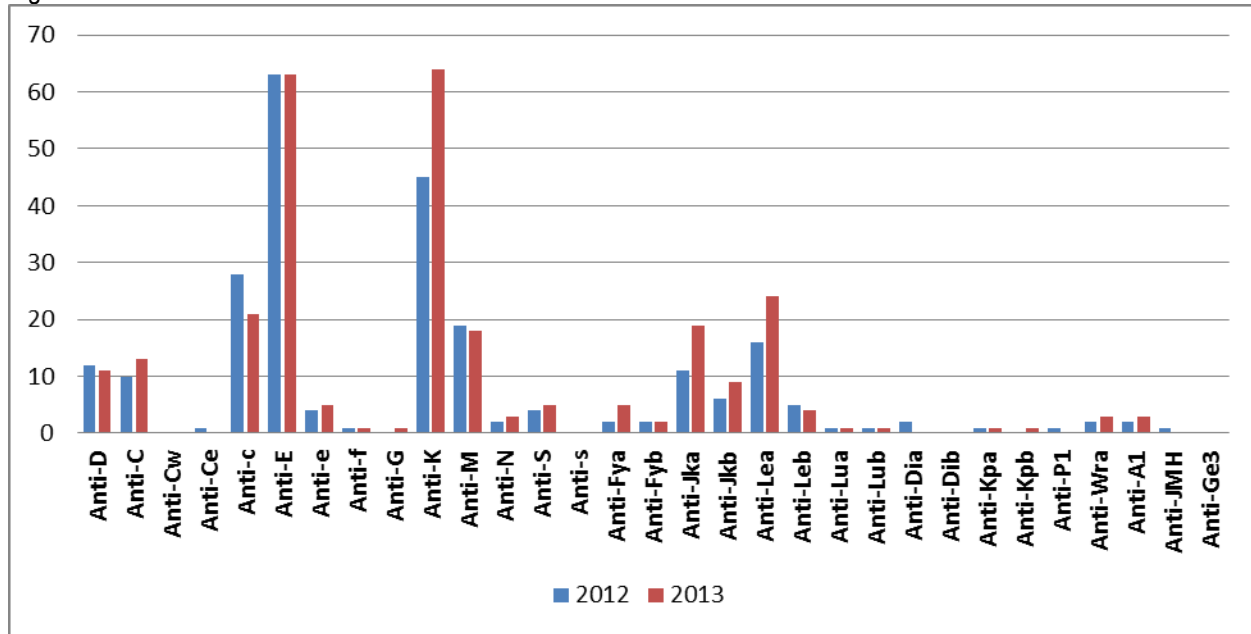
Notes:

¹ Antibody titres for Kell system antibodies continue to be performed in Manitoba at the request of the High Risk Fetal Assessment obstetricians.

² Total antibodies include antibodies detected in combination with other antibodies.

³ May include multiple pregnancies in a year.

Figure 2: Total Number of Perinatal Antibodies 2012 – 2013



Note: Antibody titres for Kell system antibodies are still performed in Manitoba at the request of the High Risk Fetal Assessment obstetricians.

B. Crossmatch Laboratory

The Crossmatch Laboratory within Diagnostic Services at Canadian Blood Services provides centralized transfusion medicine services for 70 hospitals in Manitoba and eastern Nunavut that do not perform these tests. Reference services are provided for 5 rural hospitals with crossmatching laboratories in Manitoba and hospitals in Northwest Ontario.

Testing Performed

The Crossmatch Laboratory routinely performs the following tests:

- ABO/Rh blood type
- Screen for red blood cell antibodies
- Antibody Identification, if antibodies are detected
- Crossmatch, electronic and serological
- Isohemagglutinin Titre
- Phenotyping (patient and donor units)
- Transfusion Reaction Investigation
- Direct Antiglobulin Test
- Elutions and Absorption
- Cold Agglutinin Screen
- Thermal Amplitude

Antibody screening is routinely performed by solid phase testing. A combination of solid phase testing and indirect antiglobulin tube testing using PEG for enhancement is the primary antibody identification methods. PEG IAT is also the manual back-up method for antibody screening.

The Crossmatch Laboratory distributes both stock and crossmatched red cell and platelet components to those hospitals which receive all of their transfusion medicine services from Canadian Blood

Services. Component manipulation such as plasma reduced platelets and red cells for exchange transfusion and IVT are also prepared as necessary.

As a Reference Laboratory, the Crossmatch Laboratory provides performs complex antibody investigations and distributes crossmatch compatible (or least incompatible) red cell units.

Specimens Tested

The data in this report reflects a calendar year period to enable better correlation to other government statistical data.

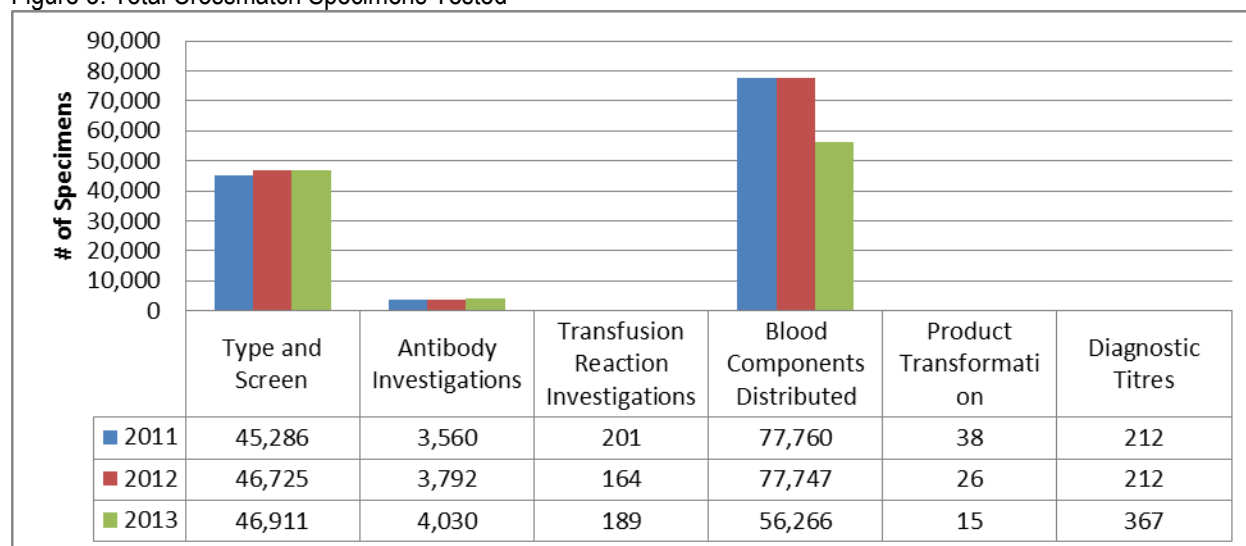
The total number of crossmatch specimens tested has shown a steady increase over the past 3 years as illustrated in *Table 4* below. With the implementation of the Trace Line LIS at two tertiary hospitals in Winnipeg, the number of red cell components distributed has decreased. These hospitals now hold a stock inventory of red cell components and perform electronic crossmatch on demand thus reducing the number of red cells issued and reserved for specific patients on hand in the hospital Blood Bank.

Table 4: Crossmatch Specimens Tested

| Specimen Type | Test Type | 2011 | 2012 | 2013 |
|---|---|---------------|---------------|---------------|
| Crossmatch | Type and Screen | 45,286 | 46,725 | 46,911 |
| | Antibody Investigations | 3,560 | 3,792 | 4,030 |
| | Transfusion Reaction Investigations | 201 | 164 | 189 |
| | Blood Components Distributed | 77,760 | 77,747 | 56,266 |
| | Product Transformation | 38 | 26 | 15 |
| | Diagnostic Titres (Cold agglutinin, Isohemagglutinins) | 212 | 212 | 367* |
| Test Totals (excluding components distributed) | | 46,821 | 50,919 | 51,512 |
| Patients Tested | | N/Av | 28,085 | 28,498 |

*Increase is due to a change in data collection method implemented in 2013.

Figure 3: Total Crossmatch Specimens Tested



Antibodies Identified

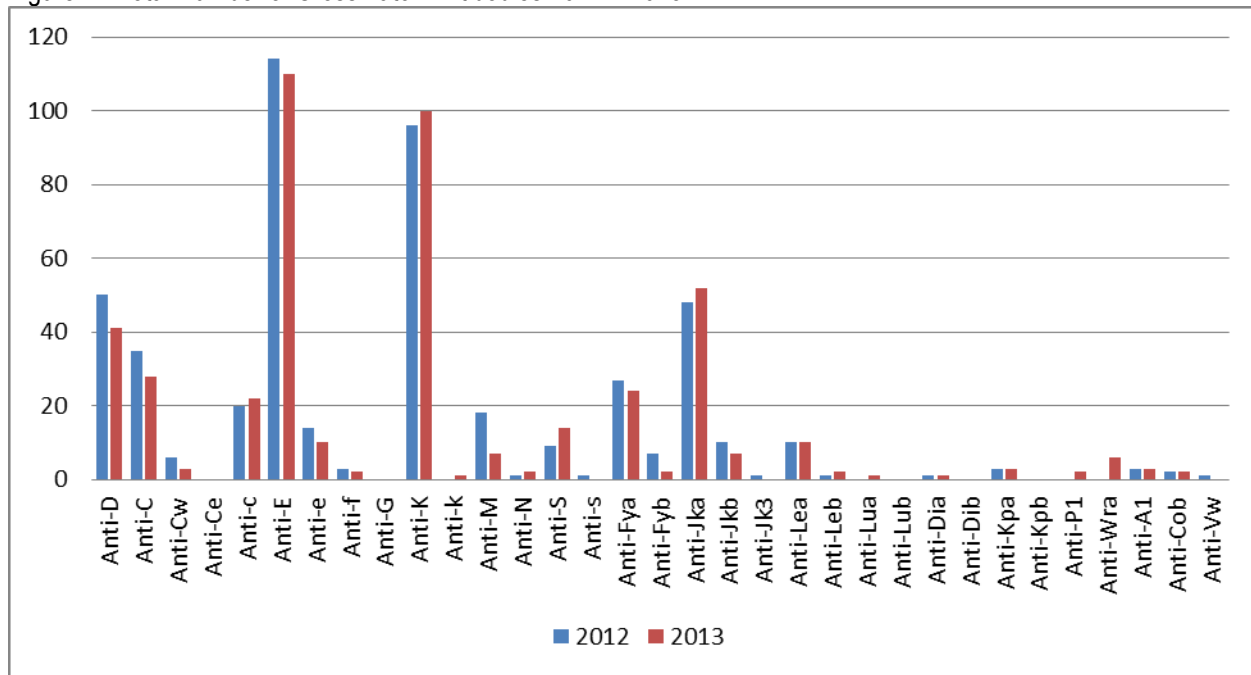
In 2013, a total of 455 antibodies were reported (see *Table 5*). The total number of antibodies detected is slightly lower than in 2012, but the distribution of the most common antibodies remains consistent. Three hundred and eighty-four patients had antibodies identified, of these; sixty patients had multiple antibodies.

Antibodies identified were considered to be clinically significant if they have been reported to cause acute or delayed hemolytic transfusion reactions. The most common clinically significant antibodies identified were: anti-E, anti-K, anti-Jk^a, anti-D and anti-C (see *Figure 4*) which together represented 72.5% of the total antibodies identified.

Table 5: Total Number of Crossmatch Antibodies Detected

| Antibody | Number Detected 2012 | Number Detected 2013 |
|----------------------|----------------------|----------------------|
| Anti-D | 50 | 41 |
| Anti-C | 35 | 28 |
| Anti-C ^w | 6 | 3 |
| Anti-Ce | 0 | 0 |
| Anti-c | 20 | 22 |
| Anti-E | 114 | 110 |
| Anti-e | 14 | 10 |
| Anti-f | 3 | 2 |
| Anti-G | 0 | 0 |
| Anti-K | 96 | 100 |
| Anti-k | 0 | 1 |
| Anti-M | 18 | 7 |
| Anti-N | 1 | 2 |
| Anti-S | 9 | 14 |
| Anti-s | 1 | 0 |
| Anti-Fy ^a | 27 | 24 |
| Anti-Fy ^b | 7 | 2 |
| Anti-Jk ^a | 48 | 52 |
| Anti-Jk ^b | 10 | 7 |
| Anti-Jk ³ | 1 | 0 |
| Anti-Le ^a | 10 | 10 |
| Anti-Le ^b | 1 | 2 |
| Anti-Lu ^a | 0 | 1 |
| Anti-Lu ^b | 0 | 0 |
| Anti-Di ^a | 1 | 1 |
| Anti-Di ^b | 0 | 0 |
| Anti-Kp ^a | 3 | 3 |
| Anti-Kp ^b | 0 | 0 |
| Anti-P ₁ | 0 | 2 |
| Anti-Wr ^a | 0 | 6 |
| Anti-A ₁ | 3 | 3 |
| Anti-Co ^b | 2 | 2 |
| Anti-Vw | 1 | 0 |
| Total | 481 | 455 |

Figure 4: Total Number of Crossmatch Antibodies 2012 – 2013



C. Platelet Immunology Laboratory

The Platelet Immunology Laboratory within Diagnostic Services at Canadian Blood Services provides human leukocyte (HLA) and platelet specific (HPA) antigen typing and antibody investigation testing to assist health care providers in the management of thrombocytopenic patients who have become refractory to vital platelet transfusions, patients affected by neonatal alloimmune thrombocytopenia and autoimmune disorders and patients suspected to be affected by platelet function disorders (PTP). The Laboratory also performs testing on patients and donors for the investigation of Transfusion Related Acute Lung Injury (TRALI). The Laboratory provides service to all Manitoba hospitals and is a national reference lab for any hospital in Canada requiring these testing services.

In addition, the Laboratory also performs HLA and HPA typing on blood donors prior to being placed onto a national platelet donor registry. The registry is used to conduct searches to identify suitably compatible donors who can be used for patients that show no benefit from conventional platelet components.

Testing Performed

The Platelet Immunology Laboratory routinely performs the following tests:

- HLA Antigen Typing
- HLA Antibody Screen
- HLA Antibody Identification, if antibodies are detected
- HLA Antigen Typing for disease association
- HPA Antigen Typing
- HPA Antibody Screen
- HPA Antibody Identification, if antibodies are detected
- Platelet Crossmatch
- Selection of HLA/HPA Compatible Donors for Platelet Transfusion

HLA antibody screening and identification is performed using Luminex bead technology. Whereas HPA antibody screening, identification and crossmatching are performed using a solid phase platform for both the commercial ELISA kits and the MAIPA method.

A combination of Luminex bead technology and MicroSSP are the primary HLA and HPA genotyping methods utilized for typing both patients and donors.

Selection lists of HLA/HPA compatible donors for patients' requiring platelet transfusion support are generated by the Platelet Immunology Lab using the national platelet donor database.

Specimens Tested

The data in this report reflects a calendar year period to enable better correlation to other government statistical data.

Table 6 below illustrates the total number of Platelet Immunology specimens tested. The total number of donor specimens has remained stable over the past 2 years compared to 2011. In 2011 new HPA antigen typing methodology was being developed and donor samples were stored until testing could be performed resulting in a higher test volume than usual that year. The total number of patient specimens has remained relatively stable over the past 3 years.

Table 6: Platelet Immunology Specimens Tested

| Specimen Type | Test Type | 2011 | 2012 | 2013 |
|--------------------|--|--------------|--------------|--------------|
| Donor | HLA Antigen Typing | 1752 | 1382 | 1329 |
| | HLA Antibody Screen/Identification | 130 | 81 | 72 |
| | HPA Antigen Typing | 2010 | 708 | 684 |
| | HPA Antibody Screen/Identification | 26 | 17 | 6 |
| Patient | HLA Antigen Typing | 1003 | 1038 | 1129 |
| | HLA Antibody Screen/Identification | 94 | 97 | 89 |
| | HPA Antigen Typing | 97 | 130 | 132 |
| | HPA Antibody Screen/Identification | 184 | 178 | 165 |
| | Selection of HLA/HPA Matched Platelet Donors | 241 | 271 | 323 |
| Test Totals | | 5,537 | 3,902 | 3,929 |

Figure 5: Total Platelet Immunology Donor Specimens Tested

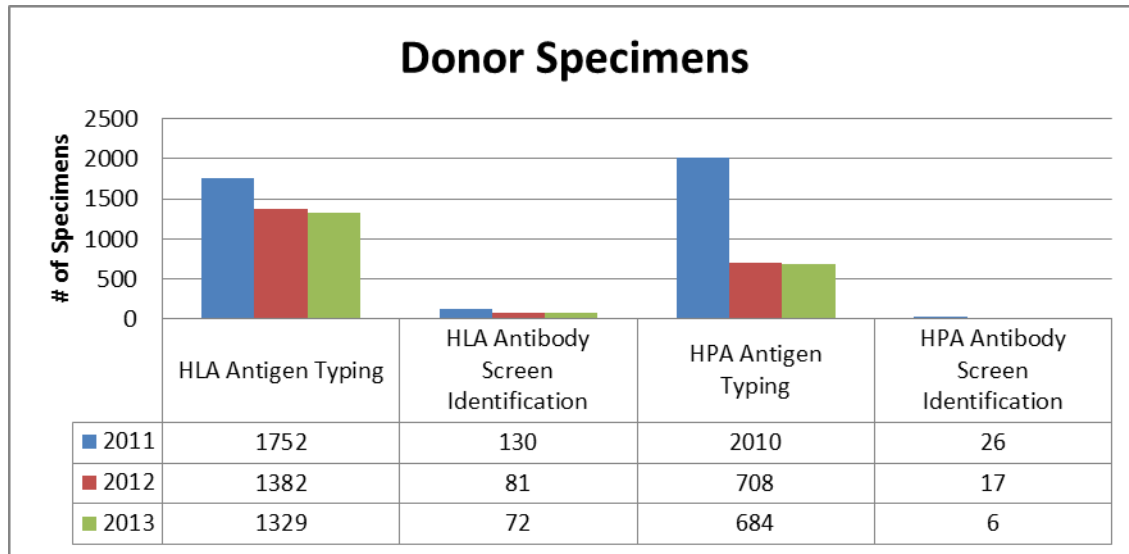
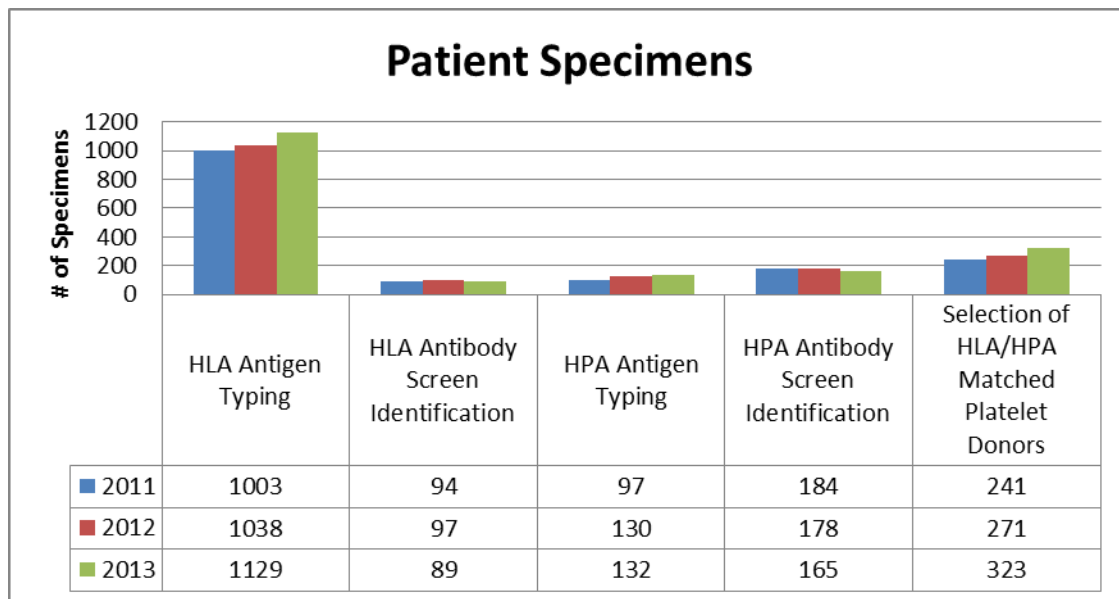


Figure 6: Total Platelet Immunology Patient Specimens Tested



D. Quality Indicators

The laboratories monitor many quality indicators and the two which are most relevant to this document are turn-around-time and rejected specimens which are presented below.

Turn-Around-Times

To ensure timely reporting of patient test results, Canadian Blood Services monitors turn-around time (TAT) from when the specimen is received at Canadian Blood Services in Winnipeg to the time when the results are available. Since monitoring of this quality indicator began in 2008, the percentage of specimens has consistently exceeded the predefined TAT threshold. Samples whose testing exceeds the expected TAT are usually those where clinically significant antibodies are detected or where

difficulty in finding compatible blood is encountered. TAT data for Platelet Immunology will be available commencing in 2014.

Table 7: Turn-Around Time – Routine Criteria by Specimen Type

| Specimen Type | Expected Turn-Around Time | Expected % of Specimens Which Meet or Exceed Expected TAT |
|-------------------------------------|---------------------------|---|
| Routine Perinatal Specimens | 72 hours | 85% |
| Perinatal Specimens with Antibodies | 72 hours | 85% |
| Routine Crossmatch Specimens | 24 hours | 85% |

Table 8: Turn Around Time – Routine Perinatal Specimens

| Turn Around Time (TAT) | 2011 | 2012 | 2013 |
|---------------------------------------|-------|-------|-------|
| % of Specimens Tested within 72 hours | 85.2% | 88.9% | 88.3% |
| % of Specimens Tested > 72 hours | 14.8% | 11.1% | 11.7% |

Figure 7: Perinatal Routine TAT

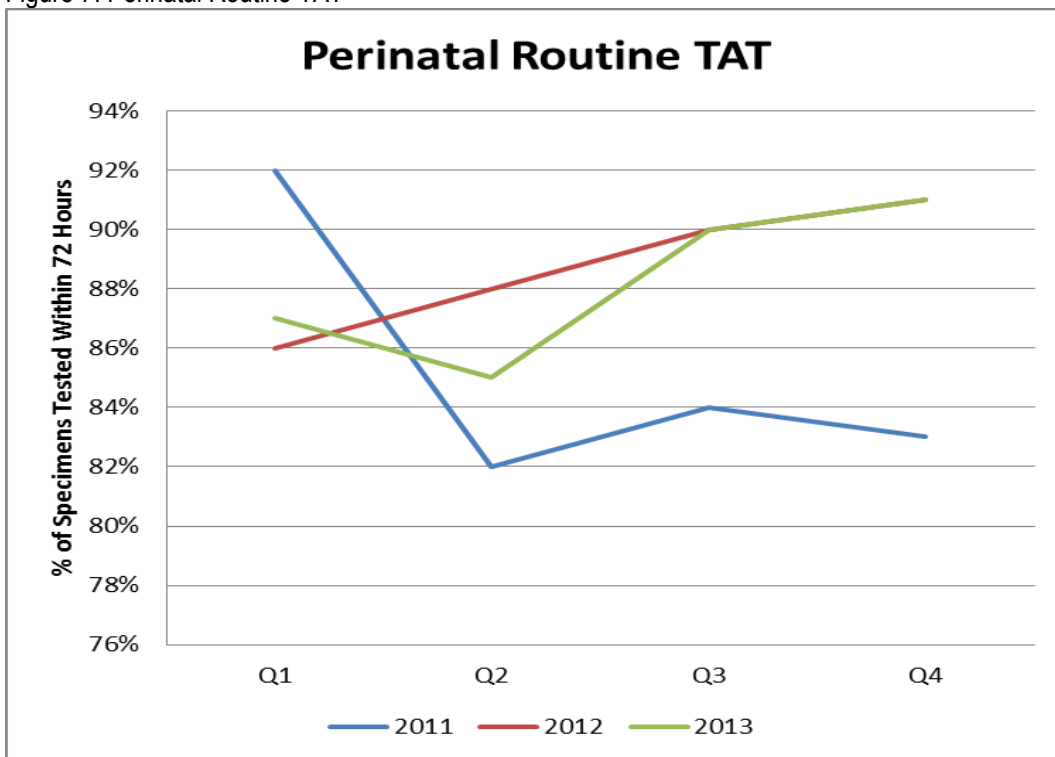
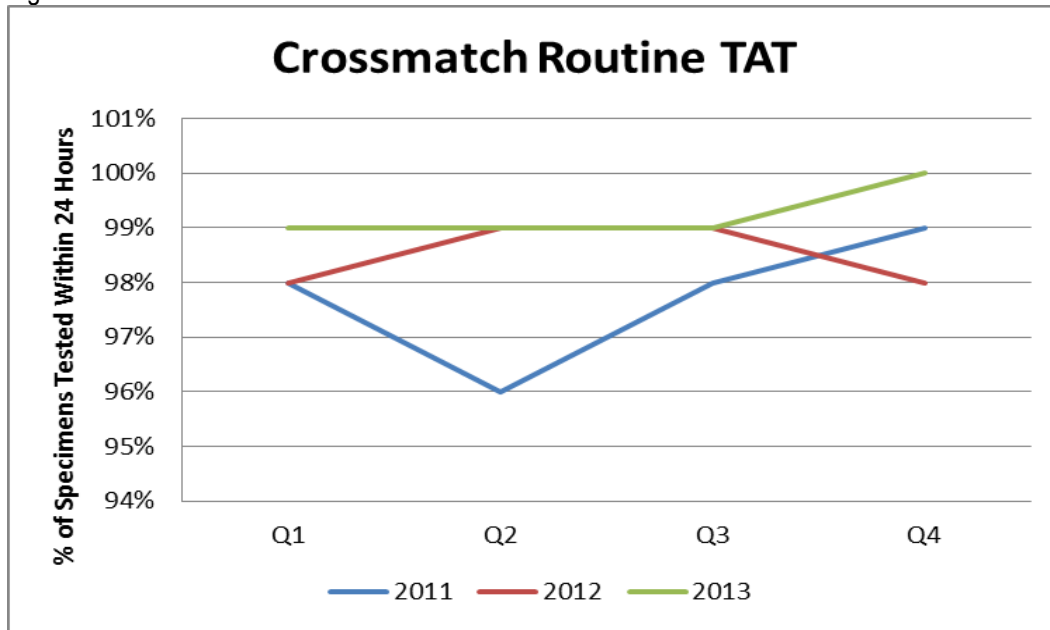


Table 9: Turn Around Time – Routine Crossmatch Specimens

| Turn Around Time (TAT) | 2011 | 2012 | 2013 |
|---------------------------------------|-------|-------|-------|
| % of Specimens Tested within 24 hours | 97.6% | 98.6% | 99.4% |
| % of Specimens Tested > 24 hours | 2.4% | 1.4% | 0.6% |

Figure 8: Crossmatch Routine TAT



Rejected Specimens

Rejection Reasons / Percent

Each time a specimen is rejected, a reason for rejection is entered into our laboratory information system (LIS). This data is then retrieved and analysed on a quarterly basis.

As described in *Table 10*, the reasons for rejecting specimens in the Perinatal Laboratory are distributed similarly between problems with requisitions and discrepancies between the requisition and the specimen. Average rejection rates have decreased slightly from 4.4% in 2012 to 3.6% in 2013 which correlates with increased efforts to contact customers and educate them on acceptable labelling criteria.

Table 11 describes the reasons for rejecting specimens in the Crossmatch Laboratory; the majority of which involve problems with specimens. Problems with specimen labelling and discrepancies between the requisition and the specimen tube label constitute the main reasons for specimen rejection. Missing or incorrect information on the label and discrepancies in the name or PHN are the most common specimen labelling errors seen. Specimens are also rejected if the sample is a duplicate. The rejection rate for crossmatch specimens decreased in Q2 which correlates with the implementation of the Trace Line® LIS at the two tertiary care hospitals in Winnipeg. With this implementation hospital blood bank staff became responsible for the accessioning of patient samples into the LIS and a more rigorous scrutiny of specimens to ensure they meet acceptance criteria is now taking place. As a result, the average rejection rates have decreased from 2.9% in 2012 to 1.8% in 2013.

The rejection rates for perinatal specimens are higher than for crossmatch (pre-transfusion) specimens. The collection process for crossmatch specimens is controlled with stringent best practices and standards that must be followed. As noted above, crossmatch specimens are usually collected in hospitals and are sent to Canadian Blood Services via the hospital blood banks where the samples are pre-screened to determine if there are discrepancies between the sample and requisition. Perinatal specimens are most often collected in clinics and community collection sites where the identification and labelling process may be more variable. Although there may be differences in the collection

process all specimens are scrutinized using the same stringent acceptance criteria prior to testing at Canadian Blood Services.

As previously mentioned, many specimens for crossmatch have already been rejected by the referring hospital laboratory and total numbers of these rejected specimens are not included in our data.

Table 12 describes the reasons for rejecting specimens in the Platelet Immunology Laboratory; the majority of which involve specimens. Three quarters of the specimens in this category were rejected because they were duplicate specimens that would not be tested; missing date of collection on the specimen was the next most common reason. Average rejection rates have increased slightly from 12.1% in 2012 to 13.9% in 2013. Efforts to reduce the number of duplicate specimens by working with hospital customers are underway.

Table 10: Quarterly Rejection Rates - Perinatal Specimens

| Rejection Category | Q1 | Q2 | Q3 | Q4 |
|--|-------------|-------------|-------------|-------------|
| Requisition | 108 | 128 | 122 | 118 |
| Specimen | 76 | 54 | 49 | 51 |
| Discrepancies Between Requisition & Specimen | 86 | 107 | 87 | 97 |
| Discrepancies Between Current Requisition & Historical Records | 70 | 52 | 57 | 50 |
| Other | 2 | 7 | 3 | 1 |
| Total # specimens rejected | 342 | 348 | 318 | 317 |
| Total # specimens received | 8,633 | 9,924 | 9,140 | 8,839 |
| Rejections as a % of total | 4.0% | 3.5% | 3.5% | 3.6% |

Figure 9: Perinatal Rejection Reasons

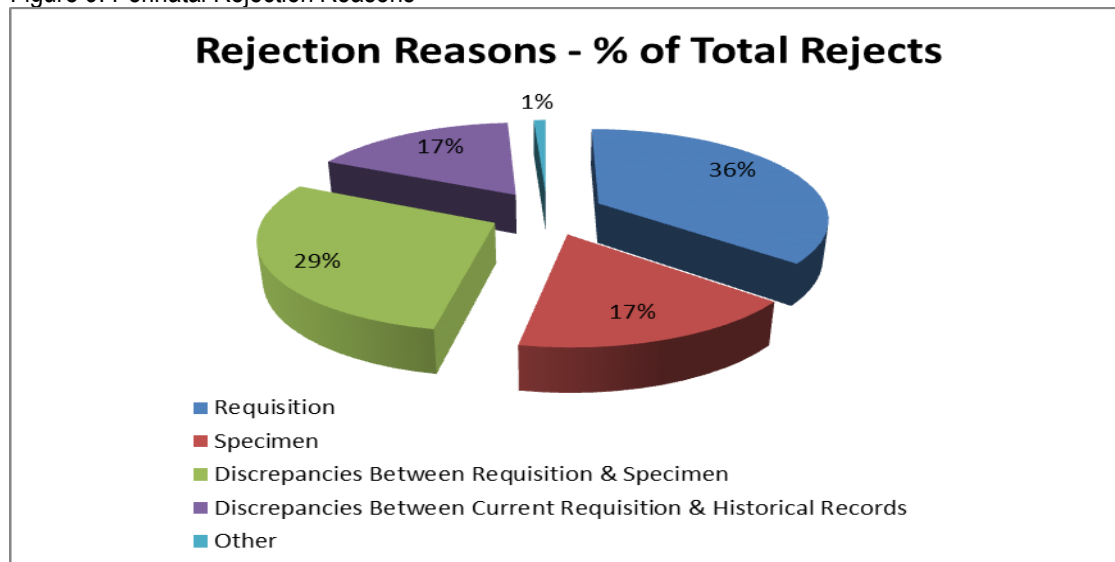


Table 11: Quarterly Rejection Rates - Crossmatch Specimens

| Rejection Category | Q1 | Q2 | Q3 | Q4 |
|--|-------------|-------------|-------------|-------------|
| Requisition | 16 | 20 | 17 | 20 |
| Specimen | 161 | 111 | 112 | 101 |
| Discrepancies Between Requisition & Specimen | 88 | 87 | 56 | 68 |
| Discrepancies Between Current Requisition & Historical Records | 18 | 13 | 8 | 9 |
| Other | 2 | 3 | 2 | 2 |
| Total # specimens rejected | 285 | 234 | 195 | 200 |
| Total # specimens received | 12,110 | 12,982 | 12,753 | 13,081 |
| Rejections as a % of total | 2.4% | 1.8% | 1.5% | 1.5% |

Figure 10: Crossmatch Rejection Reasons

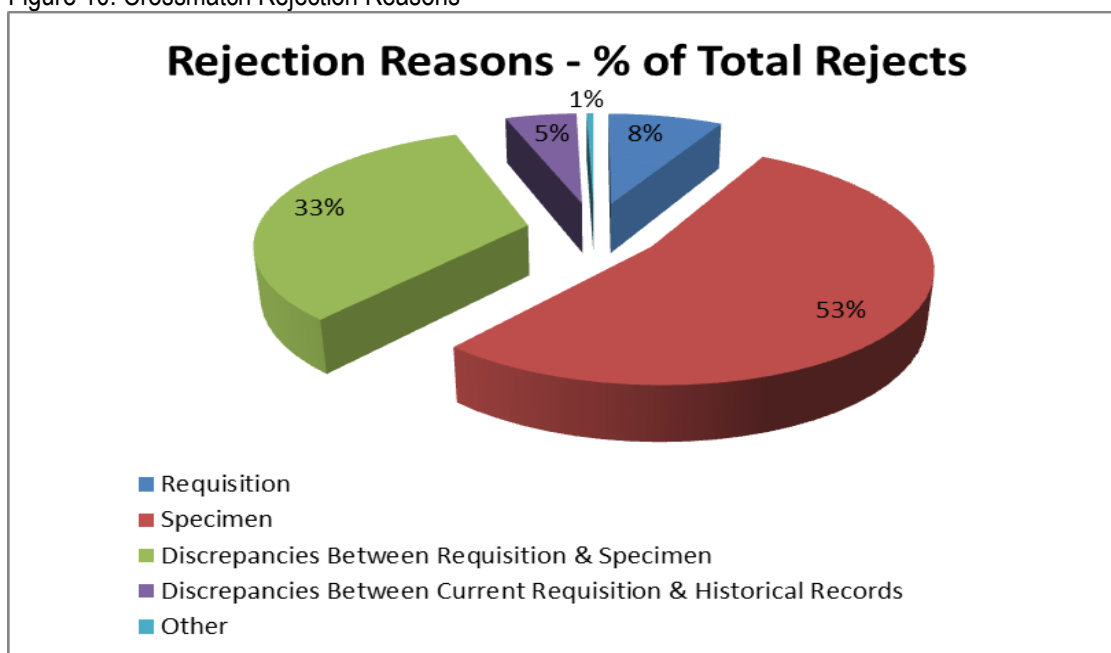
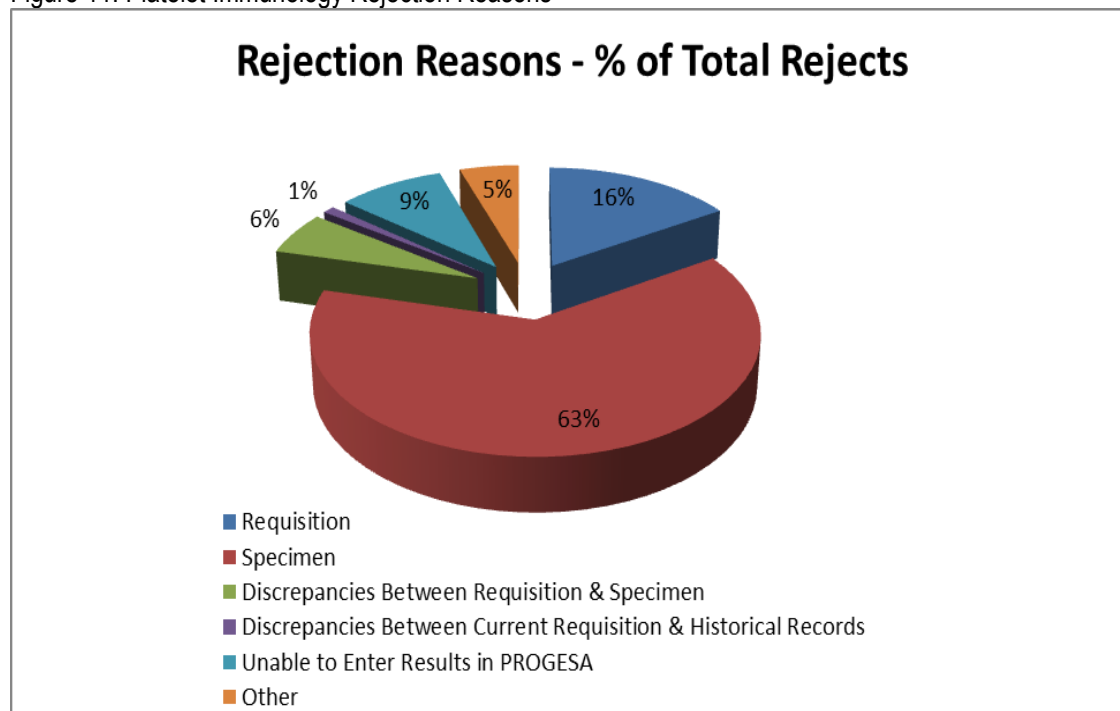


Table 12: Quarterly Rejection Rates – Platelet Immunology Specimens

| Rejection Category | Q1 | Q2 | Q3 | Q4 |
|--|--------------|--------------|--------------|--------------|
| Requisition | 10 | 17 | 18 | 17 |
| Specimen | 57 | 84 | 57 | 53 |
| Discrepancies Between Requisition & Specimen | 6 | 3 | 9 | 6 |
| Discrepancies Between Current Requisition & Historical Records | 2 | 0 | 0 | 0 |
| Unable to Enter Results in PROGESA | 5 | 13 | 13 | 6 |
| Other | 3 | 5 | 10 | 4 |
| Total # specimens rejected | 83 | 122 | 107 | 86 |
| Total # specimens received | 664 | 781 | 804 | 602 |
| Rejections as a % of total | 12.5% | 15.6% | 13.3% | 14.3% |

Figure 11: Platelet Immunology Rejection Reasons



E. Accomplishments in 2013

Automated Testing Instrument Upgrade

In 2013 the Diagnostic Services Red Cell Serology sites (Vancouver, Edmonton, Regina and Winnipeg) upgraded the Galileo instruments to the second generation Galileo Neo. This instrument is used for ABO/Rh typing, antibody screening and antibody identification. Winnipeg's first instrument was validated and implemented in the Perinatal Laboratory in February of 2013 and the second Galileo Neo was validated and implemented in the Crossmatch Laboratory in June 2013. The Platelet Immunology Laboratory standardized the automated DNA extraction platform to align with the current manual extraction technology by implementing the QIACube instrumentation.

ABLE (Age of Blood Evaluation) Study

Canadian Blood Services Crossmatch Laboratory, in conjunction with two tertiary care hospitals in Winnipeg, continued to be a participant in the ABLE study in 2013. The ABLE study is a multi-centre, randomized, double-blind clinical trial to determine whether red cells stored for 7 days or less improve critically ill patient outcomes as compared to standard issue red cells.

Business Continuity Planning

Canadian Blood Services continues to refine the business continuity plans for all sites. The Winnipeg Diagnostic Services plan is nearing completion and discussions are ongoing with internal and external stakeholders to ensure the Diagnostic Services plan meshes seamlessly with other plans.

College of American Pathologists (CAP) Laboratory Accreditation

The laboratories are accredited by the College of American Pathologists Laboratory Accreditation Program (LAP). An on-site inspection of the Red Cell Serology (Crossmatch and Perinatal) Laboratories took place in July 2012 and the laboratories were successful in meeting the requirements

of the LAP Standards for Accreditation and accreditation was granted for the 2 year period ending in July 2014. An on-site inspection of the Platelet Immunology Laboratory took place in March 2013 and the laboratory was successful in meeting the requirements of the LAP Standards for Accreditation and accreditation was granted for the 2 year period ending in March 2015.

Genotyping – Red Cell

Canadian Blood Services is able to provide red cell antigen genotyping services through our National Immunohematology Reference Laboratory (NIRL). A process for the referral of perinatal and pre-transfusion specimens to NIRL for genotyping was developed and implemented. This service can be used to aid in resolving complex immunohematology cases. Molecular testing combined with hemagglutination testing can provide better resolution to serological problems and guide patient transfusion requirements in some circumstances, in particular for sickle cell patients.

Massive Transfusion Protocol Development

Canadian Blood Services Crossmatch Laboratory collaborated with clinical and laboratory staff from the Health Sciences Centre in the development of a massive transfusion protocol. Implementation is expected to occur in September of 2014.

Perinatal Advisory Committee

The Diagnostic Services Medical Officers, Director, Associate Director, Managers and Supervisors from all of the Canadian Blood Services Diagnostic Laboratory sites (in Vancouver, Edmonton, Regina, Winnipeg and Toronto) meet annually to discuss operational issues and 'best practice' approaches for serological and perinatal laboratory testing. In discussions where expert advice is required, guest speakers are invited to provide input and direction. Working groups are set up as required to investigate specific issues and bring recommendations forward. Input is obtained from relevant stakeholders on planned policy changes.

Anecdotally, there had been some concern about anti-c causing HDFN even at low titres. Based on a retrospective study of clinical outcomes for antibodies other than anti-D which was done in the Edmonton area, the critical titre value for the other common antibodies appears to be valid. Patients with anti-c continue to be referred to the Fetal Assessment Unit whenever a critical titre is reached.

A review of literature regarding anti-M revealed that, although this antibody is rarely implicated in HDFN, it may cause suppression of fetal erythropoiesis and late onset anemia (Trans Med Rev 2014: 28:1-6). The Perinatal Advisory Committee recommended that a comment be added to reports of anti-M advising that the baby be monitored for symptoms of late onset anemia for up to 2 months of age.

Platelet Donor Selection (PDS) Software Stabilization

The software used to select platelet donors for patients requiring HLA/HPA compatible platelet transfusions was upgraded in order to stabilize the operating platform. In addition, enhancements were added for entering search criteria resulting in the ability to further customize the eligible donors to the patient needs.

Provision of Red Cell Aliquots to Hospital Customers

A Decision Document recommending that Diagnostic Services be responsible for the provision of red cell aliquots upon request from our hospital customers was developed and signed off by senior management in February 2013.

Trace Line® Laboratory Information System (LIS)

The pilot phase of the Trace Line® Phase II project closed in February 2013 with the implementation at the Health Sciences Centre. St. Boniface Hospital was the second tertiary care facility to go live with Trace Line® at the end of April 2013. The laboratories continued to provide support for the implementation at these sites and collaborated to ensure policies and procedures between all of the sites were aligned.

F. Goals for 2014

Automated Antibody Screen Investigation Algorithm

All Diagnostic Services sites (Vancouver, Edmonton, Regina and Winnipeg) collaborated to develop a common algorithm for the investigation of positive antibody screens obtained on the Galileo Neo. The intention is to standardize the investigation process to facilitate data collection and comparability of results. All sites are expected to implement the new algorithm by the end of October 2014.

Automated Testing Instrument Upgrades

In 2014 the Crossmatch Laboratory Galileo Echo automated instruments will be retired and replaced with a third Galileo Neo instrument. This will streamline instrument maintenance and staff training will be simplified. The Platelet Immunology Laboratory will retire the out-dated manual gel photo documentation system and replace it with new generation equipment that provides an automated system for photo documentation of amplified DNA products. In addition a local area network (LAN) will be created for the Fusion software which is used to perform data analysis, resulting in workflow efficiencies.

International Platelet Workshop

In 2014 the Platelet Immunology Laboratory will participate as one of only two Canadian laboratories in this international collaborative that includes 33 laboratories from around the world. The purpose/goal of the workshop is to investigate new innovations in testing methodologies to further enhance the understanding of platelet antigen systems and how they impact patient care.

National Blood Shortages Plan

In collaboration with the Manitoba Health Office of Provincial Transplant and Transfusion Services work will continue on the development of tools to assist the Regional Health Authorities in the implementation of the National Blood Shortages Plan for facilities operated by Diagnostic Services of Manitoba.

Trace Line® Laboratory Information System (LIS)

Additional hospital sites will continue to implement Trace Line® starting with Boundary Trails Health Centre and Portage District Hospital at the beginning of February 2014. Nine additional hospital facilities will implement Trace Line® by mid-December 2014. No further implementations are planned past this point.

Frequency of Kell Antibodies

A review of our Manitoba antibody data demonstrates that the frequency of Kell antibodies in the transfused patient population is approximately twice that of anti-D for the last several years. In 2014 we plan to investigate the feasibility of providing Kell negative red blood cells to female patients less than 45 years of age.