Canadian Blood Services
Société canadienne du sang

DIAGNOSTIC SERVICES

MANITOBA

YEAR IN REVIEW

JANUARY – DECEMBER 2015

Diagnostic Services “Year in Review” statistics are based on a January to December calendar year. The calendar year provides better correlation with Health Canada birth statistics.

SENIOR STAFF AND CONTACT INFORMATION

Red Cell Serology Medical Officer	204-789-1079
Debra Lane, MD, FRCPC	debra.lane@blood.ca
Platelet Immunology Medical Director	204-789-1125
Peter Nickerson, MD, FRCPC	peter.nickerson@umanitoba.ca
Diagnostic Services Manager	204-789-1128
Lee Grabner, MLT, ART	lee.grabner@blood.ca
Technical Supervisor, Testing	204-789-1149
Lynne Meilleur, MLT	lynne.meilleur@blood.ca

Charge Technologists:

Perinatal Laboratory	204-789-1090
Dora Lopes-Carvalho, MLT	dora.lopes-carvalho@blood.ca
Crossmatch Laboratory	204-789-1093
Henri Beaubien, MLT	henri.beaubien@blood.ca
Platelet Immunology Laboratory	204-789-1109
Lynnette Beaudin, MLT	lynnette.beaudin@blood.ca

Perinatal Laboratory	
Phone #	204-789-1088
Fax #	204-789-1006
Crossmatch / Accession Laboratory	
Phone #	204-789-1085
Fax #	204-779-8593
Platelet Immunology Laboratory	
Phone #	204-789-1152
Fax #	204-789-1186

Diagnostic Services Websection https://www.blood.ca/en/hospitals/DiagnosticServices-About

TABLE of CONTENTS

Figures

Tables

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.

A. 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
- 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

B. 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 two 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.

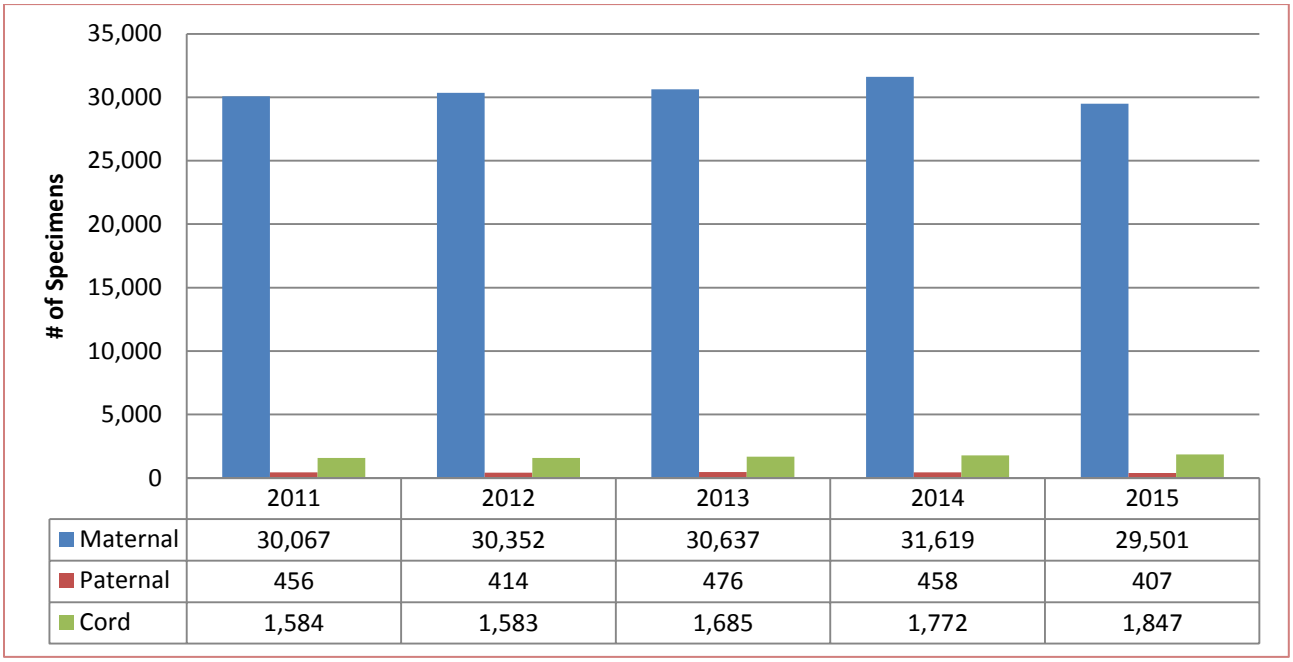
C. Specimens Tested

The data includes all women tested, including referral patients from Ontario, Saskatchewan and Nunavut. The total number of specimens tested has decreased slightly from 2014 to 2015 as seen in *Table 1* below.

Table 1: Perinatal Specimens Tested

Specimen Type	Test Type	2011	2012	2013	2014	2015
Maternal	Type and Screen	30,067	30,352	30,637	31,619	29,501
Paternal	ABO/Rh	456	414	476	458	407
Cord	ABO/Rh	1,584	1,583	1,685	1,772	1,847
Total # of Specimens Tested		32,107	32,349	32,798	33,849	31,755
Total # of Patients Tested		**N/Av**	**23,357**	**23,481**	**24,179**	**24,005**

Figure 1: Total Perinatal Specimens Tested



	2011	2012	2013	2014	2015
Maternal	30,067	30,352	30,637	31,619	29,501
Paternal	456	414	476	458	407
Cord	1,584	1,583	1,685	1,772	1,847

D. Antibodies Identified

In 2015, a total of 246 antibodies were reported (see *Table 2*). This is slightly lower than 2014. Two hundred and thirty-six women had antibodies identified during their pregnancies (decreased from 269 women in 2014), of these; thirty women had multiple antibodies. Passive anti-D data has been excluded from the preceding numbers.

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-E, anti-K, anti-Jk^{a}, anti-C, anti-c and Anti-D (see *Figure 3*) which together represented 76% of the total antibodies identified.

Titres for 5 of the clinically significant antibodies increased from non-critical to critical levels during the pregnancy with a total of 67 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

Maternal Antibodies Identified (Including Passive D) – 2015					
Clinically Significant Antibodies - Antibody	**2011**	**2012**	**2013**	**2014**	**2015**
Anti-D	20	12	11	21	10
Passive Anti-D	648	914	1228	1059	892
Anti-C	18	10	13	19	18
Anti-C^{w}	2	0	0	1	1
Anti-Ce	0	1	0	1	0
Anti-c	26	28	21	18	17
Anti-E	71	63	63	70	65
Anti-e	3	4	5	9	6
Anti-f	1	1	1	1	1
Anti-G	1	0	1	1	5
Anti-K	44	45	64	64	57
Anti-Kp^{a}	1	1	1	1	1
Anti-Kp^{b}	1	0	1	0	0
Anti-Lu^{b}	4	5	4	3	1
Anti-S	6	4	5	6	7
Anti-s	0	0	0	1	1
Anti-Fy^{a}	4	2	5	3	5
Anti-Fy^{b}	3	2	2	2	2
Anti-Jk^{a}	16	11	19	20	20
Anti-Jk^{b}	5	6	9	8	1
Anti-Di^{a}	2	2	0	2	1
Anti-Di^{b}	2	0	0	0	0
Anti-V	1	0	0	0	0
Anti-Wr^{a}	1	2	3	2	2

Clinically Insignificant Antibodies - Antibody	2011	2012	2013	2014	2015
Anti-A_1	1	2	3	0	0
Anti-JMH	2	1	0	0	0
Anti-Le^a	18	16	24	23	12
Anti-Le^b	4	5	4	3	1
Anti-M	9	19	18	11	12
Anti-N	2	2	3	0	0
Anti-P_1	3	1	0	4	0

Table 3: Perinatal Patient Antibody Titres

Antibody	Critical Level	Non-Critical Level	Non-Critical to Critical
Anti-D	4	8	1
Anti-C	2	8	1
Anti-E	4	36	0
Anti-c	0	7	0
Anti-e	1	2	1
Anti-DC	0	0	0
Anti-DE	0	0	0
Anti-Ec	4	4	1
Anti-Ce	0	1	0
Anti-G	0	0	0
Anti-K	50	0	0
Anti-Fy^a	0	2	0
Anti-Fy^b	0	0	0
Anti-Jk^a	1	13	1
Anti-Jk^b	0	0	0
Anti-M	0	7	0
Anti-S	1	4	0
Anti-s	0	1	0
Total	**67**	**93**	**5**

Note: Anti-K is considered critical at any titre. Antibody titres for Kell system antibodies continue to be performed in Manitoba at the request of the High Risk Fetal Assessment obstetricians.

Figure 2: Total Number of Perinatal Antibodies

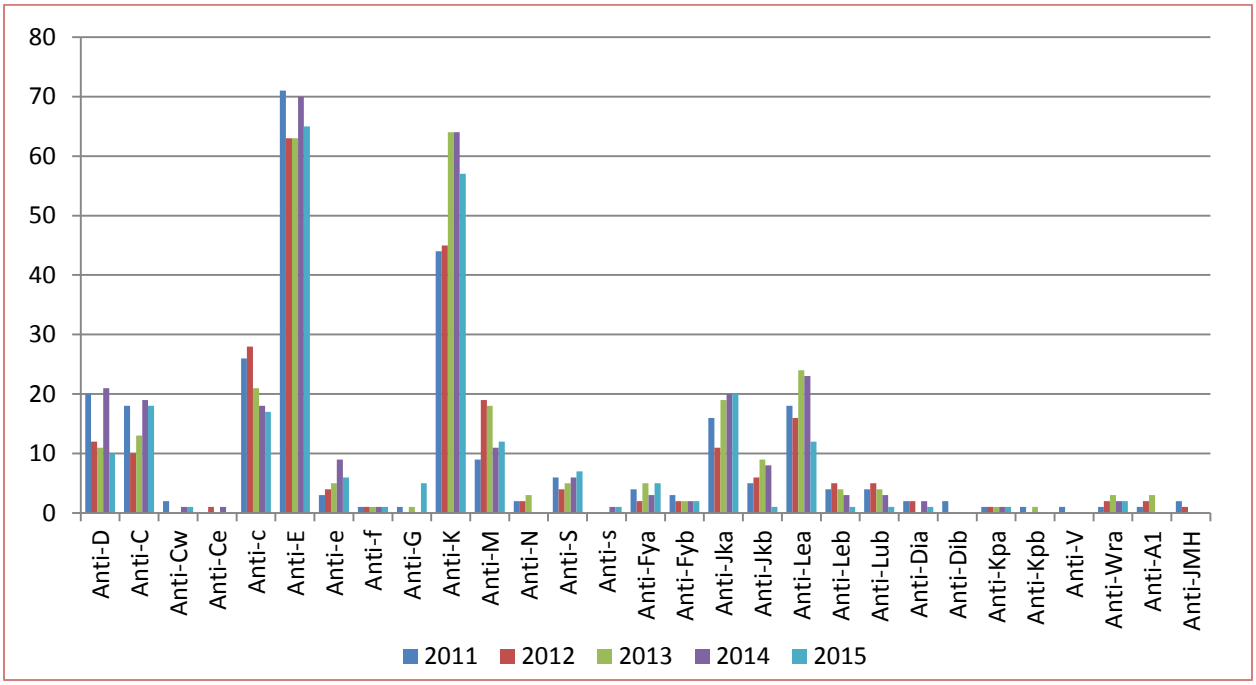


Figure 3: Frequency of Clinically Significant Antibodies

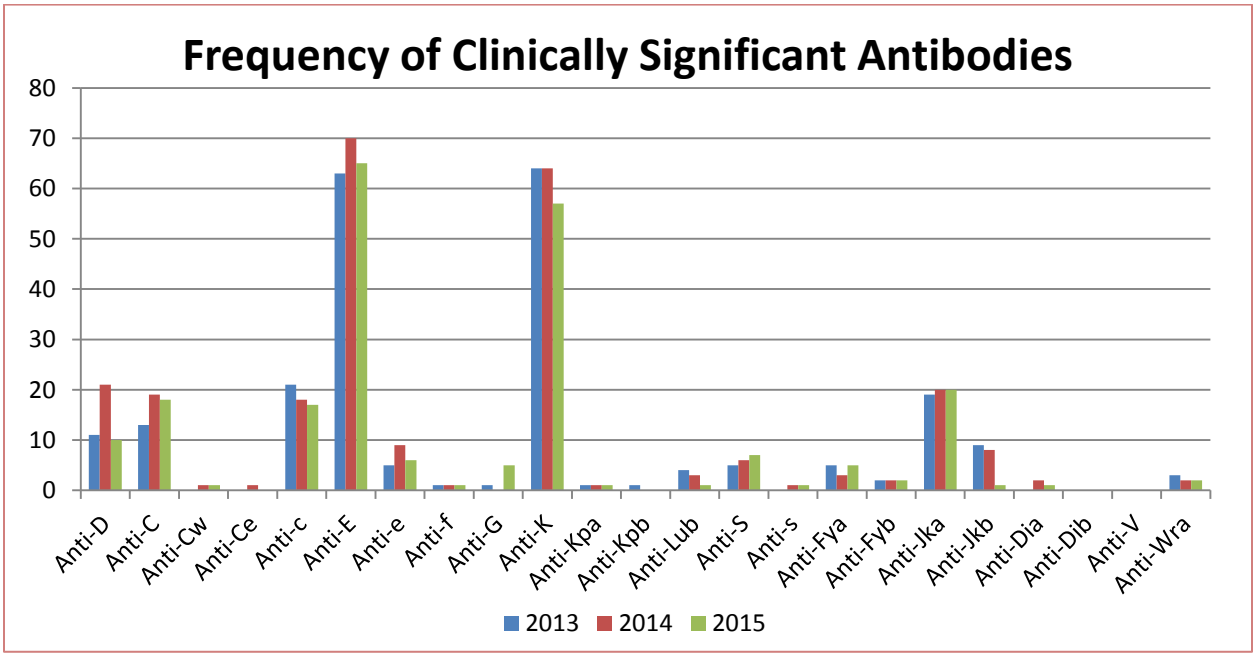


Table 4: Combination Antibodies

Antibodies	Number in 2015
Anti-C, Anti-e	1
Anti-C, Anti-K	2
Anti-C, Anti-G	3
Anti-c, Anti-Jk^{a}	1
Anti-c, Anti-E	4
Anti-E, Anti-Jk^{a}	1
Anti-E, Anti-Jk^{b}	1
Anti-E, Anti-Le^{a}	2
Anti-E, Anti-S	1
Anti-e, Anti-f	1
Anti-e, Anti-s	1
Anti-Fy^{a}, Anti-Jk^{a}	1
Anti-Jk^{a}, Anti-K	1
Anti-K, Anti-Kp^{a}	1
Anti-Le^{a}, Anti-Le^{b}	1
Anti-C, Anti-D, Anti-E	1
Anti-C, Anti-D, Anti-G	1
Anti-C, Anti-e, Anti-Fy^{a}	1
Anti-C, Anti-Fy^{a}, Anti-G	1
Anti-c, Anti-E, Anti-Jk^{a}	2
Anti-c, Anti-E, Anti-S	1
Anti-c, Anti-E, Anti-Fy^{a}, Anti-K, Anti-Le^{a}	1

CROSSMATCH / REFERENCE LABORATORY

The Crossmatch / Reference Laboratory within Diagnostic Services provides centralized transfusion medicine services and testing to 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 12 hospitals in Northwest Ontario.

A. Testing Performed

The Crossmatch/Reference 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
- Elution and Absorption
- Cold Agglutinin Screen
- Thermal Amplitude

Antibody Screening is routinely performed by automated solid phase testing. A combination of automated 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 hospitals that 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 performs complex antibody investigations and distributes crossmatch compatible (or least incompatible) red cell units.

B. Specimens Tested

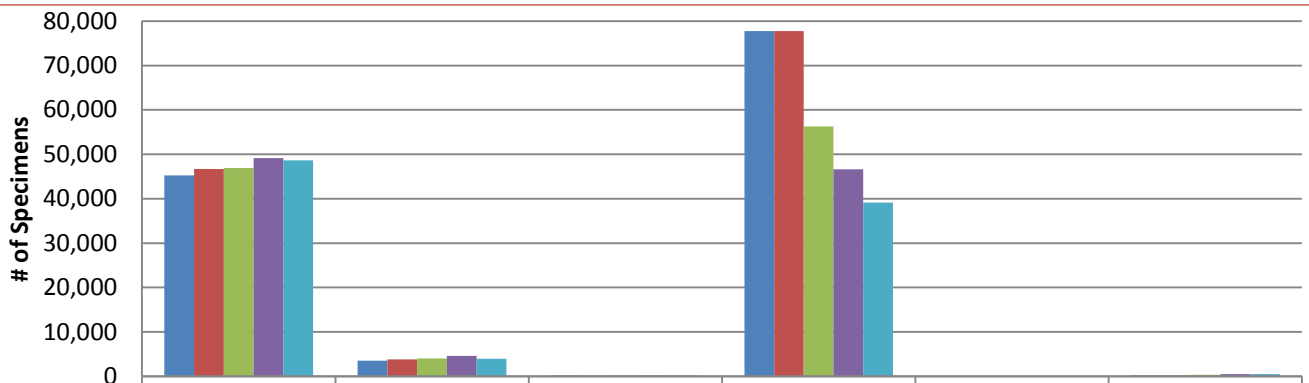
The total number of crossmatch specimens tested has remained fairly steady over the past 2 years as illustrated in *Table 5* below. The implementation of the Trace Line laboratory information system (LIS) was completed at 14 hospitals in Winnipeg and rural Manitoba in 2014. These hospitals now hold a 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. The number of red cell components distributed has continued to decrease slightly in 2015 as hospitals adjust inventories to optimal levels.

Table 5: Crossmatch/Reference Specimens Tested

Specimen Type	Test Type	2011	2012	2013	2014	2015
Crossmatch/Reference	Type and Screen	45,286	46,725	46,911	49,171	48,648
	Antibody Investigations	3,560	3,792	4,030	4,607	3,942
	Transfusion Reaction Investigations	201	164	189	192	183
	Blood Components Distributed	77,760	77,747	56,266	46,601	39,125
	Product Transformation	38	26	15	23	40
	Diagnostic Titres (Cold agglutinin, Isohemagglutinins)	212	212	367*	491	492
Test Totals (excluding components distributed)		46,821	50,919	51,512	54,484	53,305
Number of Patients Tested		**N/Av**	**28,085**	**28,498**	**29,751**	**29,219**

***Note:** Increase in diagnostic titres is due to a change in data collection method implemented in 2013.

Figure 4: Total Crossmatch Specimens Tested



	Type and Screen	Antibody Investigations	Transfusion Reactions	Blood Components Distributed	Product Transformation	Diagnostic Titres
2011	45,286	3,560	201	77,760	38	212
2012	46,725	3,792	164	77,747	26	212
2013	46,911	4,030	189	56,266	15	367
2014	49,171	4,607	192	46,601	23	491
2015	48,648	3,942	183	39,125	40	492

C. Antibodies Identified

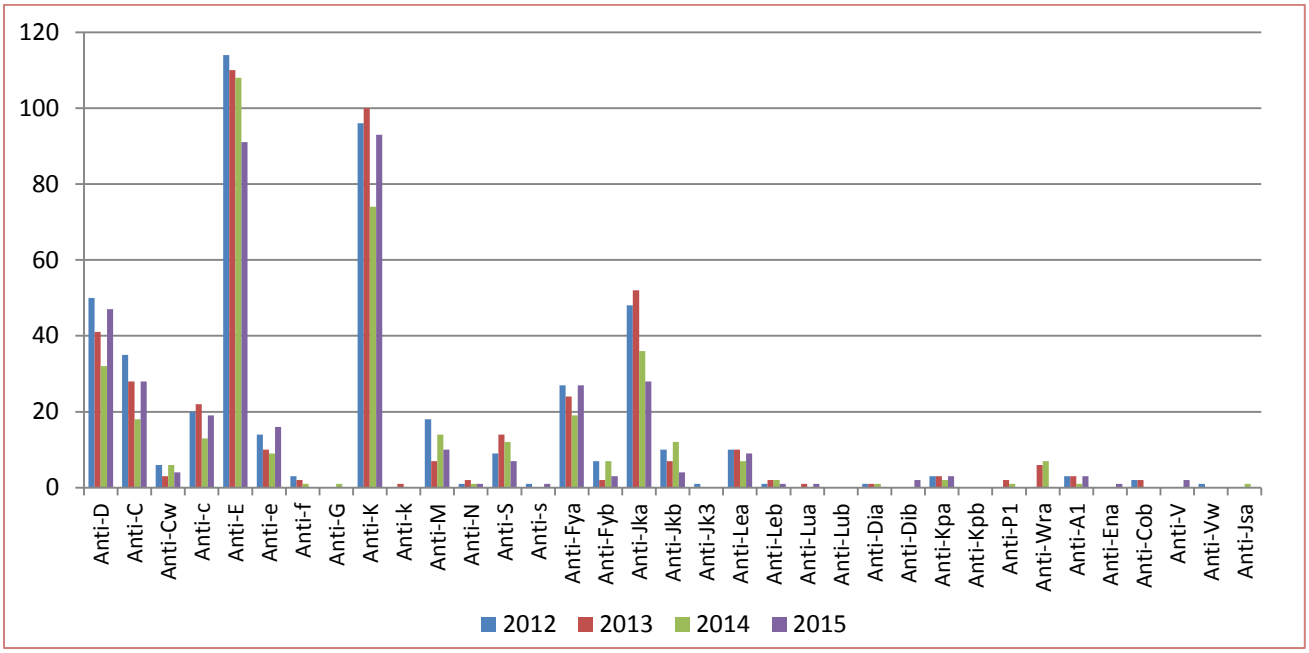
In 2015, a total of 401 antibodies were reported (see *Table 6*). The total number of antibodies detected is slightly increased from 2014, but the distribution of the most common antibodies remains consistent. Three hundred and thirty-one patients had antibodies identified, of these; fifty-seven patients 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-K, anti-E, anti-D, anti-C, anti-Jk^{a} and anti-Fy^{a} and (see *Figure 5*) which together represented 78.3% of the total antibodies identified.

Table 6: Total Number of Crossmatch Antibodies Detected

Antibody	Number Detected 2012	Number Detected 2013	Number Detected 2014	Number Detected 2015
Anti-D	50	41	32	47
Anti-C	35	28	18	28
Anti-C^w	6	3	6	4
Anti-c	20	22	13	19
Anti-E	114	110	108	91
Anti-e	14	10	9	16
Anti-f	3	2	1	0
Anti-G	0	0	1	0
Anti-K	96	100	74	93
Anti-k	0	1	0	0
Anti-M	18	7	14	10
Anti-N	1	2	1	1
Anti-S	9	14	12	7
Anti-s	1	0	0	1
Anti-Fy^a	27	24	19	27
Anti-Fy^b	7	2	7	3
Anti-Jk^a	48	52	36	28
Anti-Jk^b	10	7	12	4
Anti-Jk^3	1	0	0	0
Anti-Le^a	10	10	7	9
Anti-Le^b	1	2	2	1
Anti-Lu^a	0	1	0	1
Anti-Lu^b	0	0	0	0
Anti-Di^a	1	1	1	0
Anti-Di^b	0	0	0	2
Anti-Kp^a	3	3	2	3
Anti-Kp^b	0	0	0	0
Anti-P_1	0	2	1	0
Anti-Wr^a	0	6	7	0
Anti-A_1	3	3	1	3
Anti-En^a	0	0	0	1
Anti-Co^b	2	2	0	0
Anti-V	0	0	0	2
Anti-Vw	1	0	0	0
Anti-Jsa	0	0	1	0
Total	**481**	**455**	**385**	**401**

Figure 5: Total Number of Crossmatch Antibodies



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.

A. Testing Performed

The Platelet Immunology Laboratory routinely performs the following tests:

- HLA Genotyping
- HLA Antibody Screen
- HLA Antibody Identification, if antibodies are detected
- HLA Antigen Typing for disease association
- HPA Genotyping
- HPA Screening
- HPA Antibody Identification, if antibodies are detected
- Platelet Crossmatching
- 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.

B. Specimens Tested

Table 7 below illustrates the total number of Platelet Immunology specimens tested.

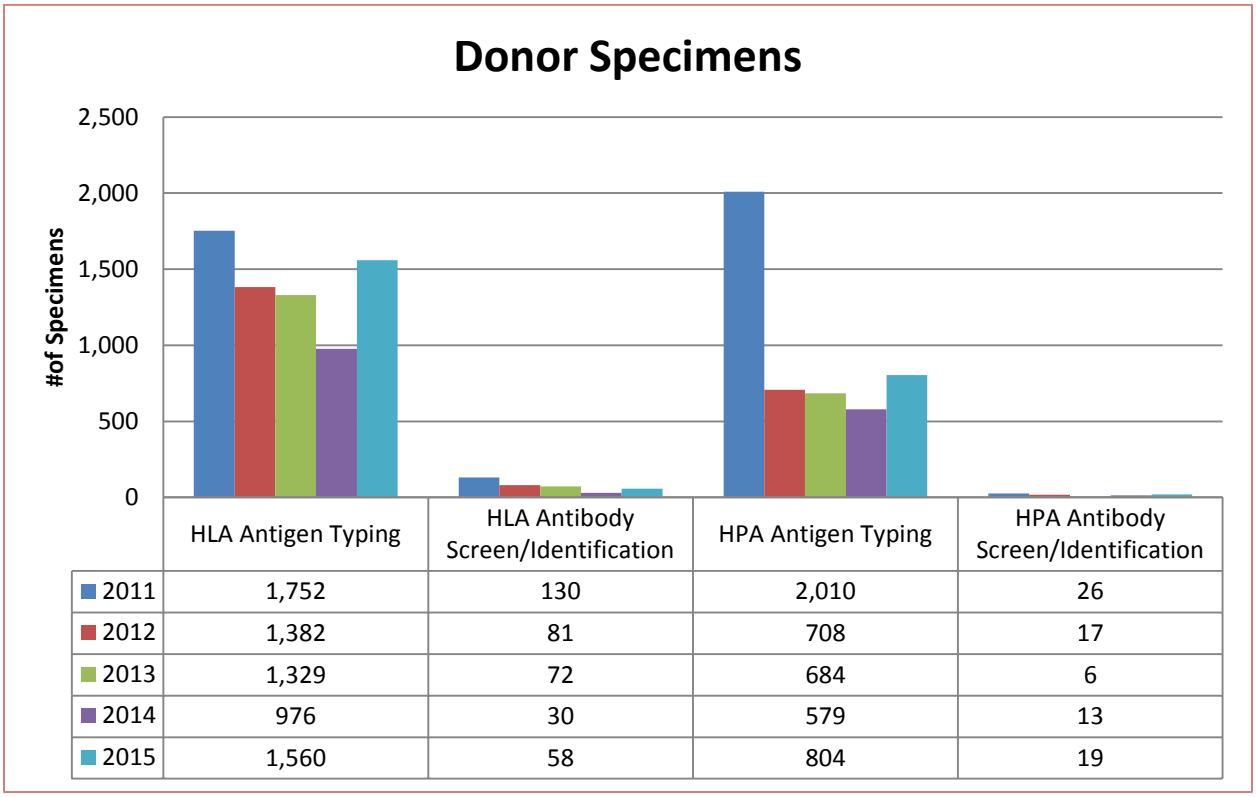
In 2015 increasing the number of new HLA/HPA genotyped male apheresis platelet donors was made a high priority for Canadian Blood Services which is reflected in the significant increase in the total number of donor specimens tested. Having a sufficient number of new HLA/HPA donors tested and available for donation of HLA/HPA selected compatible platelets will increase CBS' ability to provide this specialized product for high risk patients.

The total number of patient HLA antigen typing and antibody screen specimens has remained relatively stable over the past 5 years. However, the total number of requests for patient HPA antigen typing and HPA antibody screening/identification has increased significantly as a result of the transfer of this testing from Canadian Blood Services Toronto Diagnostic Services Laboratory to Winnipeg which occurred on December 15, 2014.

Table 7: Platelet Immunology Specimens Tested

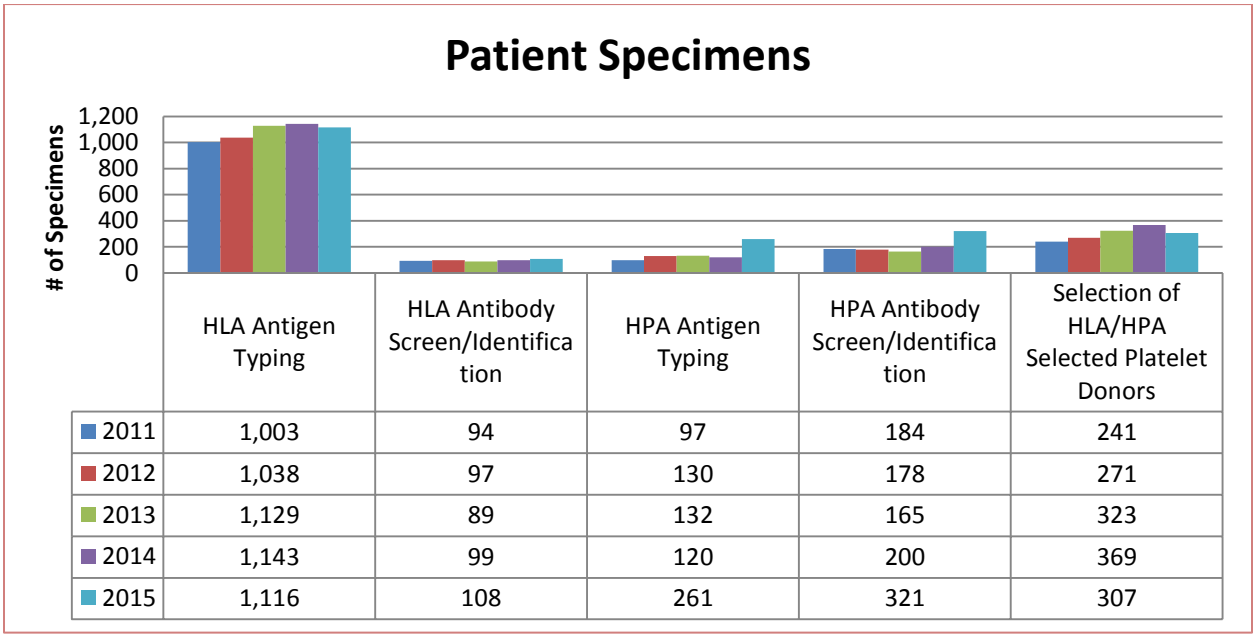
Specimen Type	Test Type	2011	2012	2013	2014	2015
Donor	HLA Antigen Typing	1,752	1,382	1,329	976	1,560
	HLA Antibody Screen/Identification	130	81	72	30	58
	HPA Antigen Typing	2,010	708	684	579	804
	HPA Antibody Screen/Identification	26	17	6	13	19
Patient	HLA Antigen Typing	1,003	1,038	1,129	1,143	1,116
	HLA Antibody Screen/Identification	94	97	89	99	108
	HPA Antigen Typing	97	130	132	120	261
	HPA Antibody Screen/Identification	184	178	165	200	321
	Selection of HLA/HPA Matched Platelet Donors	241	271	323	369	307
Test Totals		**5,537**	**3,902**	**3,929**	**3,529**	**4,354**

Figure 6: Total Platelet Immunology Donor Specimens Tested



	HLA Antigen Typing	HLA Antibody Screen/Identification	HPA Antigen Typing	HPA Antibody Screen/Identification
2011	1,752	130	2,010	26
2012	1,382	81	708	17
2013	1,329	72	684	6
2014	976	30	579	13
2015	1,560	58	804	19

Figure 7: Total Platelet Immunology Patient Specimens Tested



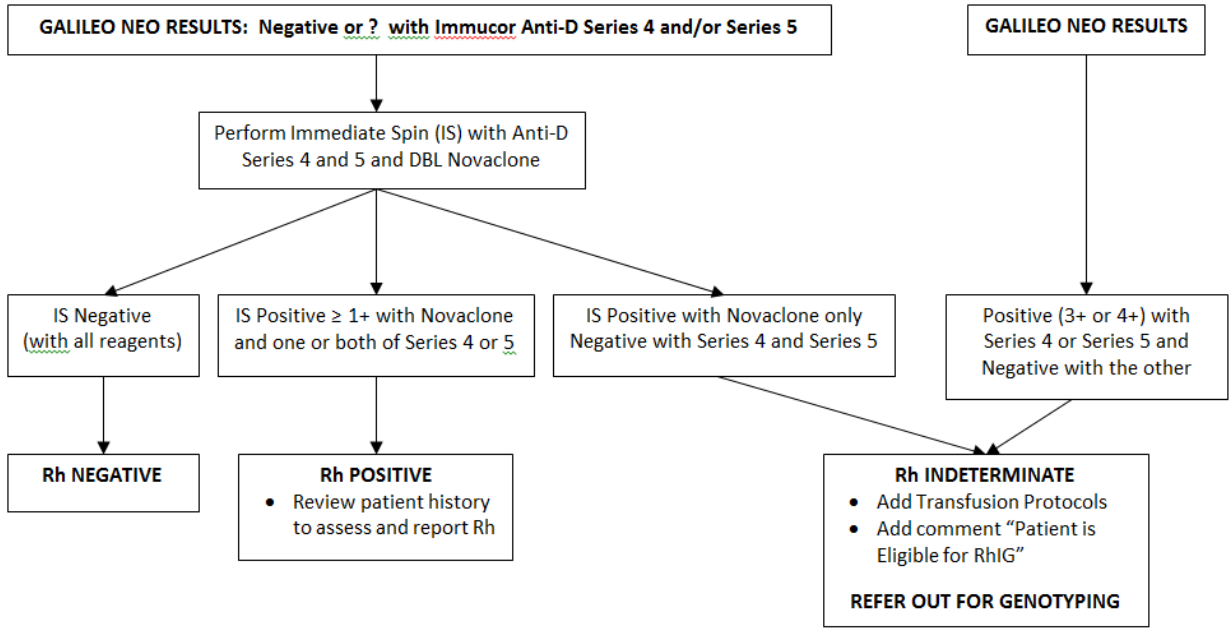
	HLA Antigen Typing	HLA Antibody Screen/Identification	HPA Antigen Typing	HPA Antibody Screen/Identification	Selection of HLA/HPA Selected Platelet Donors
2011	1,003	94	97	184	241
2012	1,038	97	130	178	271
2013	1,129	89	132	165	323
2014	1,143	99	120	200	369
2015	1,116	108	261	321	307

RED CELL GENOTYPING

Canadian Blood Services is able to provide red cell antigen genotyping services through our National Immunohematology Reference Laboratory (NIRL) and Edmonton Diagnostic Services Laboratory. A process for the referral of perinatal specimens to Edmonton and pre-transfusion specimens to NIRL for genotyping was developed and implemented. This service is 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 and patients with frequent transfusion requirements.

Based on the following testing algorithm patients with a serologically variable Rh D typing results may have a genetic testing for the RHD gene.

Figure 8: Rh D Testing Algorithm



For 2015, the following results were obtained in patients using one of the two red cell antigen genotyping platforms available at CBS:

Table 8: RHD Genotyping Results

Patient	RHD Genotype	Predicted Phenotype	RHD Sequencing	Rh Group
1	Weak D type 2	Weak D	Not performed	Positive
2	Weak D type 5	Weak D	Not performed	Negative
3	Weak D type 2	Weak D	Not performed	Positive
4	Weak D type 1	Weak D	Not performed	Positive
5	Weak D type 4.0 or 4.3	Weak D	Not performed	Negative
6	RHD* Weak D type 31	Weak D	Not performed	Negative
7	Weak D type 1	Weak D	Not performed	Positive
8	Weak D type 1	Weak D	Not performed	Positive
9	Sample does not contain any of the RHD polymorphisms interrogated by the kit	Possible D Variant	Not performed	Negative
10	Weak D type 1	Weak D	Not performed	Positive
11	Weak D type 2	Weak D	Not performed	Positive

QUALITY INDICATORS

The laboratories monitor many quality indicators and the two which are most relevant to this document are turnaround times and rejected specimens which are presented below.

A. Turnaround Times

To ensure timely reporting of patient test results, Canadian Blood Services monitors turnaround 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.

Table 9: Turnaround Time – Routine Criteria by Specimen Type

Specimen Type	Expected Turnaround 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%
Reference Specimens	72 hours	75%
Routine Platelet Immunology Specimens (NAIT, PTP, Platelet alloimmunization, HLA B*5701)	14 days	90%
HLA Disease Association Specimens	28 days	90%
Donor HLA/HPA Typing Specimens	60 days	90%

Table 10: Turnaround Time – Routine Perinatal Specimens

Turnaround Time (TAT)	2012	2013	2014	2015
% of Specimens Tested within 72 hours	88.9%	88.3%	89.3%	92.3%
% of Specimens Tested > 72 hours	11.1%	11.7%	10.7%	7.7%

Figure 9: Perinatal Routine TAT

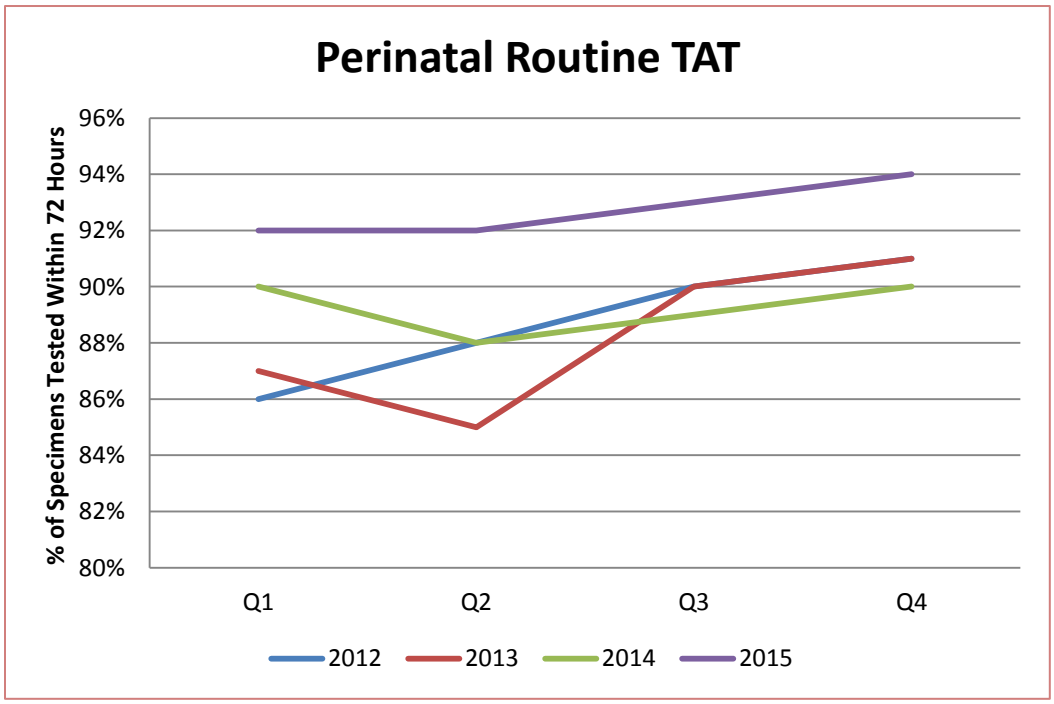


Table 11: Turnaround Time – Routine Crossmatch Specimens

Turnaround Time (TAT)	2012	2013	2014	2015
% of Specimens Tested within 24 hours	98.6%	99.4%	99.6%	99.8%
% of Specimens Tested > 24 hours	1.4%	0.6%	0.4%	0.2%

Figure 10: Crossmatch Routine TAT

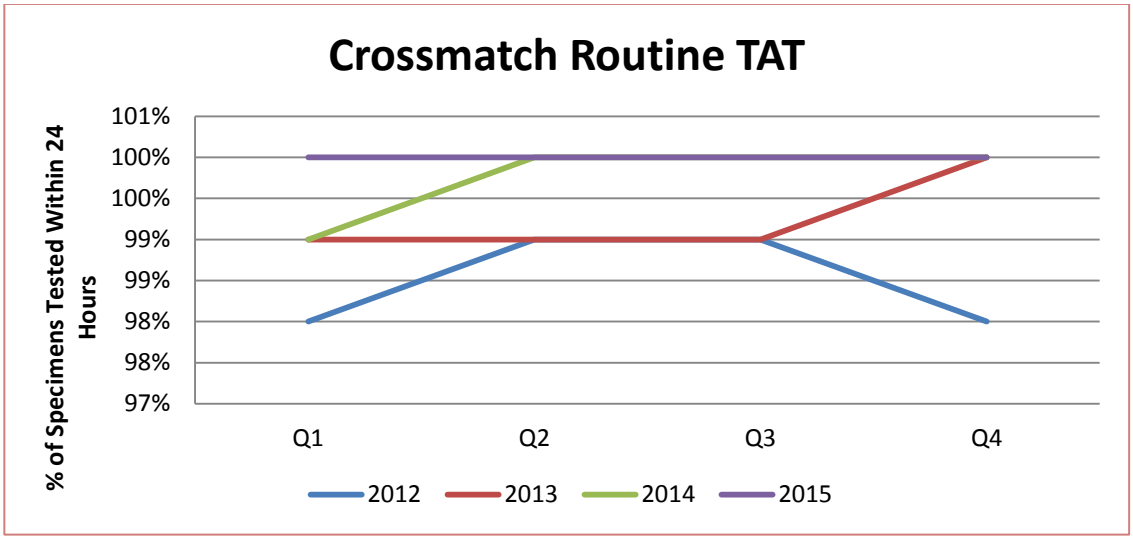


Table 12: Turnaround Time – Reference Specimens

Turnaround Time (TAT)	2012	2013	2014	2015
% of Specimens Tested within 24 hours	96.5%	93.3%	96.8%	98.8%
% of Specimens Tested > 24 hours	3.5%	6.7%	3.2%	1.2%

Figure 11: Reference TAT

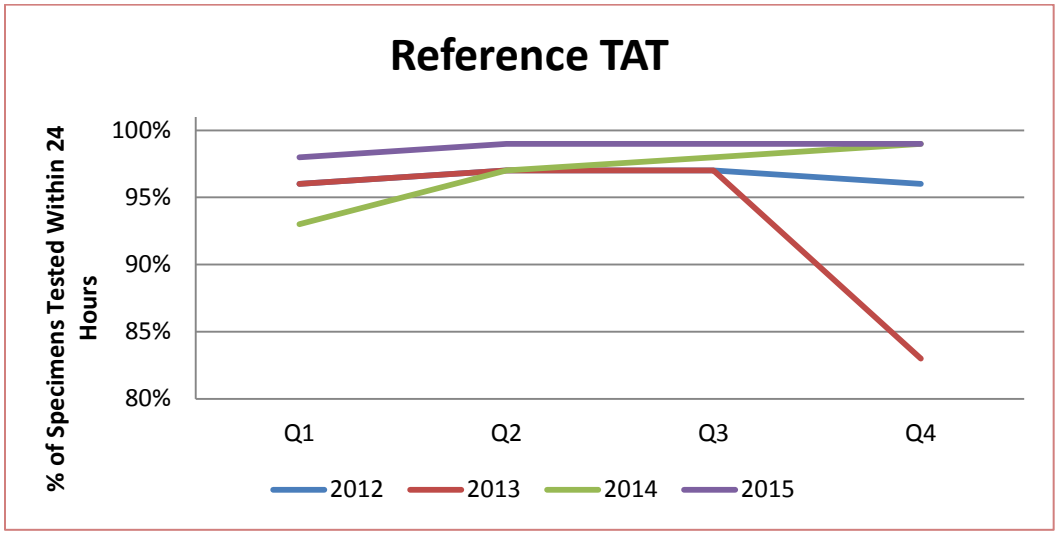
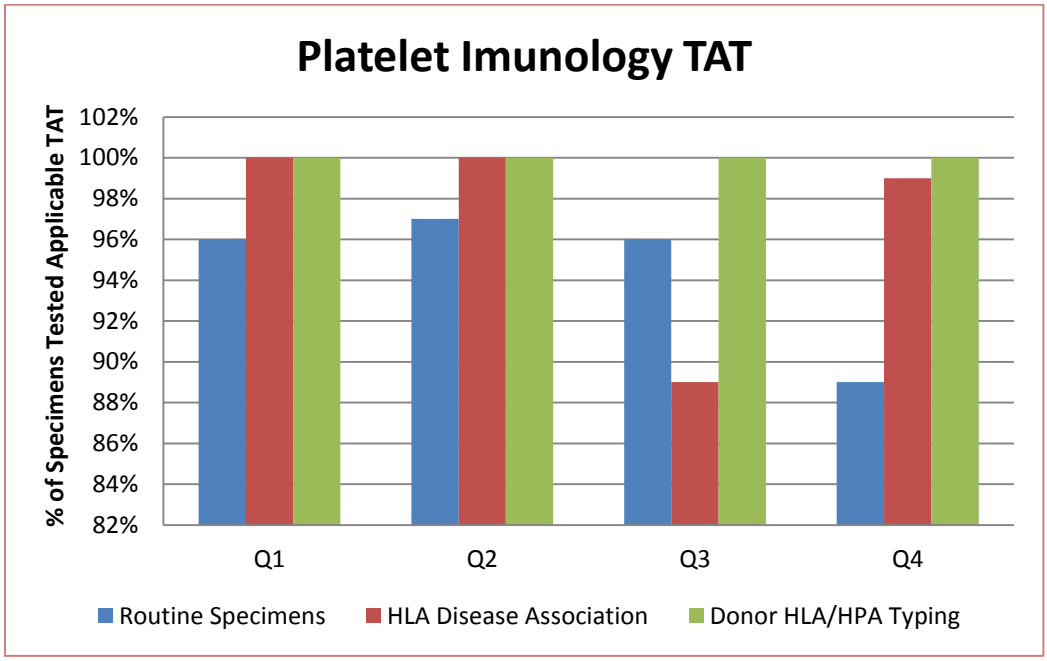


Table 13: Turnaround Time – Platelet Immunology Specimens

Turnaround Time (TAT)	2012	2013	2014	2015
% of Specimens Tested within 14 days	N/A	N/A	91.8%	94.5%
% of Specimens Tested within 28 days	N/A	N/A	98.9%	96.8%
% of Specimens Tested within 60 days	N/A	N/A	100%	100%

Figure 12: Platelet Immunology TAT



B. Rejected Specimens

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

As described in *Table 14*, the reasons for rejecting specimens in the Perinatal Laboratory are primarily problems with requisitions and discrepancies between the requisition and the specimen. Average rejection rates have continued to decrease from a high of 4.4% in 2012 to 3.3% in 2015 which correlates with increased efforts to contact customers and educate them on acceptable labelling criteria.

Table 15 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 continued to decrease throughout 2015 which correlates with the implementation of the Trace Line® LIS at two additional facilities in rural Manitoba. With each implementation the hospital blood bank/laboratory 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 a high of 2.9% in 2012 to 1.1% in 2015.

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 16 describes the reasons for rejecting specimens in the Platelet Immunology Laboratory; the majority of which involve specimens. Eighty-seven percent 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. Efforts to educate hospital customers continued throughout 2015. Average rejection rates remained stable from 11.5% in 2014 to 11.8% in 2015.

Table 14: Quarterly Rejection Rates – Perinatal Specimens

Rejection Category	Q1	Q2	Q3	Q4
Requisition	127	125	100	110
Specimen	61	53	65	82
Discrepancies Between Requisition & Specimen	79	94	77	57
Discrepancies Between Current Requisition & Historical Records	22	44	34	30
Other	1	2	4	6
Total # specimens rejected	290	318	280	285
Total # specimens received	9,762	8,354	8,610	9,081
Rejections as a % of total	**3.0%**	**3.8%**	**3.3%**	**3.1%**

Figure 13: Perinatal Rejection Reasons

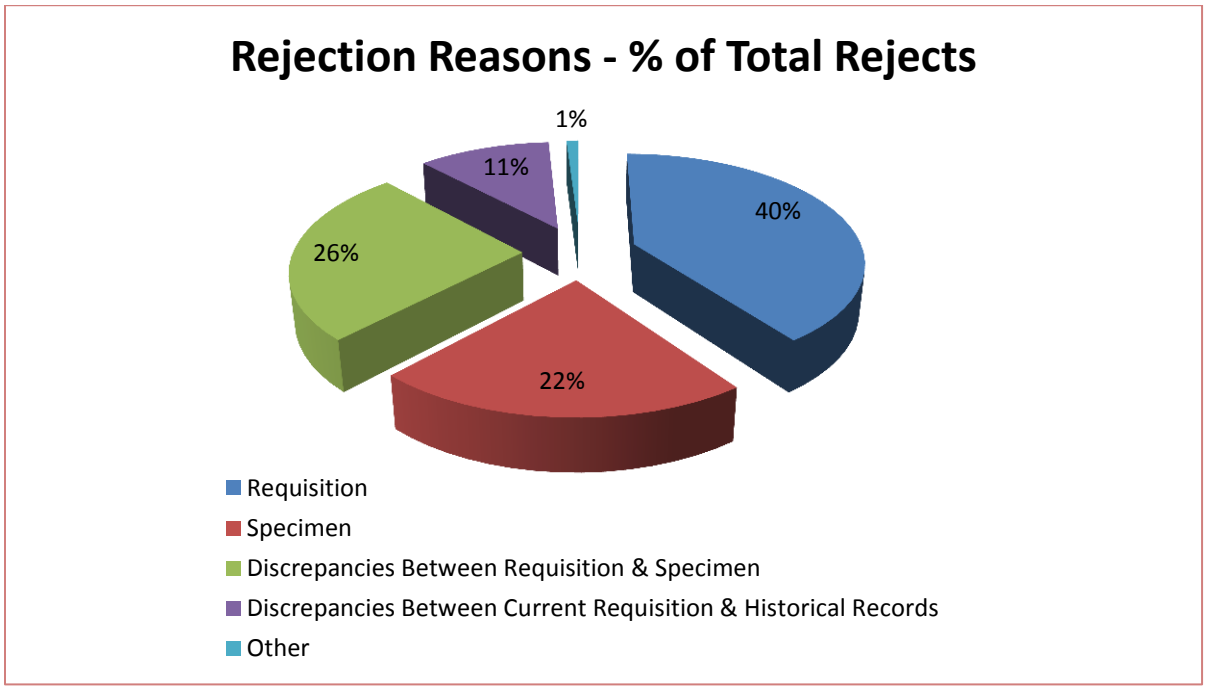


Table 15: Quarterly Rejection Rates – Crossmatch Specimens

Rejection Category	Q1	Q2	Q3	Q4
Requisition	25	15	14	15
Specimen	71	65	66	71
Discrepancies Between Requisition & Specimen	73	57	56	64
Discrepancies Between Current Requisition & Historical Records	6	4	3	1
Other	5	1	2	0
Total # specimens rejected	180	142	141	151
Total # specimens received	13,057	12,460	13,129	14,120
Rejections as a % of total	**1.4%**	**1.1%**	**1.1%**	**1.1%**

Figure 14: Crossmatch Rejection Reasons

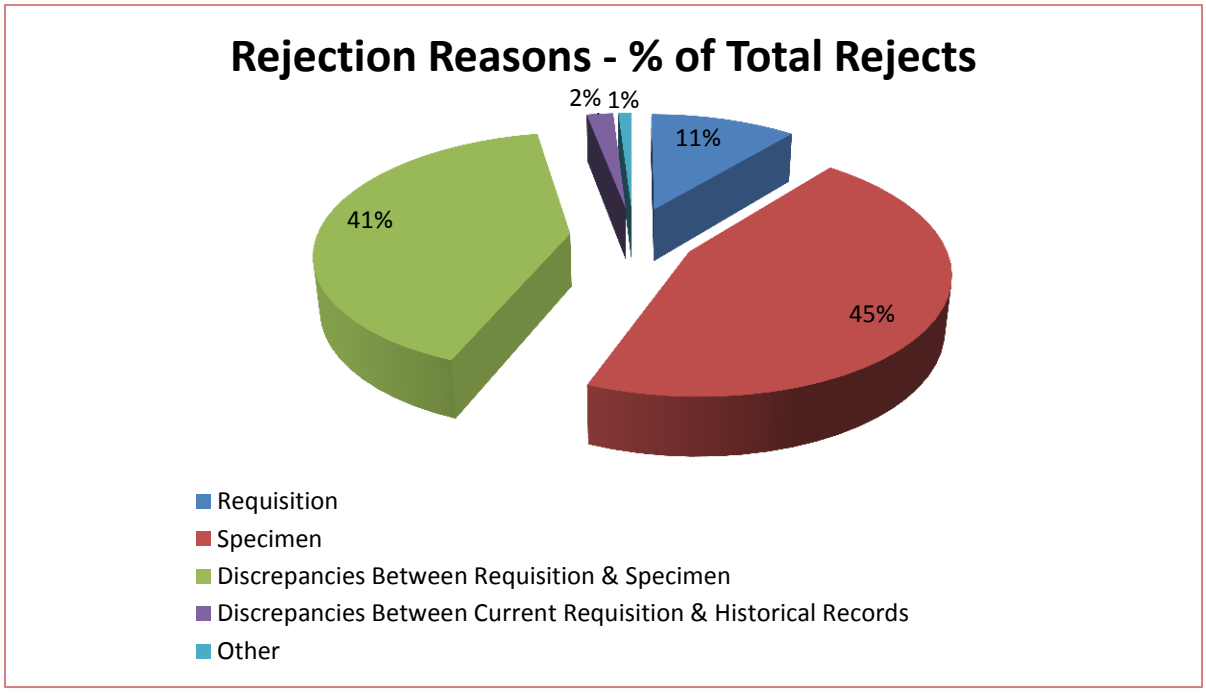
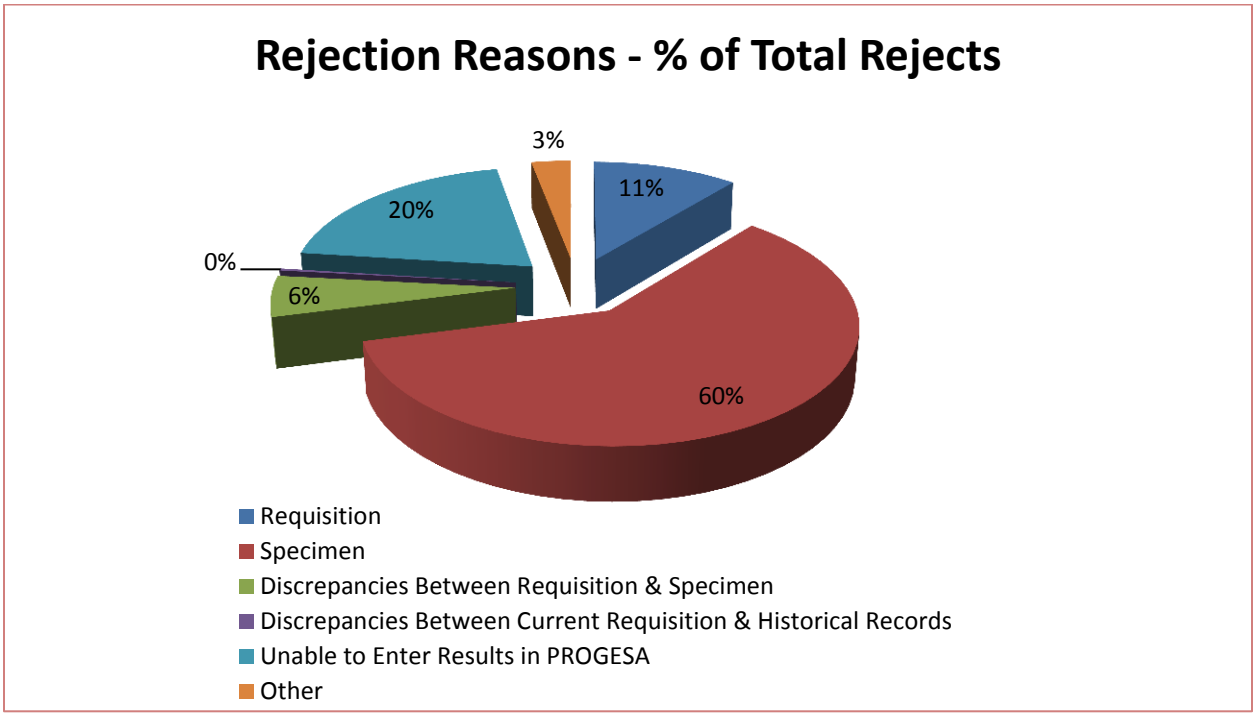


Table 16: Quarterly Rejection Rates – Platelet Immunology Specimens

Rejection Category	Q1	Q2	Q3	Q4
Requisition	6	6	20	8
Specimen	57	60	50	44
Discrepancies Between Requisition & Specimen	10	3	2	5
Discrepancies Between Current Requisition & Historical Records	0	1	0	0
Unable to Enter Results in PROGESA	26	17	17	9
Other	2	6	1	2
Total # specimens rejected	101	93	90	68
Total # specimens received	779	775	691	722
Rejections as a % of total	**13.0%**	**12.0%**	**13.0%**	**9.4%**

Figure 15: Platelet Immunology Rejection Reasons



ACCOMPLISHMENTS IN 2015

A. Automated Antibody Screen Investigation Algorithm

In 2015 all Diagnostic Services sites (Vancouver, Edmonton, Regina and Winnipeg) participated in the post implementation review of the common algorithm for the investigation of positive antibody screens obtained on the Galileo Neo.

B. Automated Testing Instrument Upgrade

The Platelet Immunology Laboratory completed the validation of the QIAxcel automated photo documentation system at the end of 2015 and will implement this new technology in February 2016.

C. College of American Pathologists (CAP) Laboratory Accreditation

The laboratories are accredited by the College of American Pathologists Laboratory Accreditation Program (LAP). The Red Cell Serology (Crossmatch and Perinatal) Laboratories have met the requirements of the LAP Standards for Accreditation and accreditation is granted for the 2 year period ending in July 2016. An on-site inspection of the Platelet Immunology Laboratory took place in March 2015 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 2017.

D. Massive Transfusion Protocol Development

Canadian Blood Services Crossmatch Laboratory collaborated with clinical and laboratory staff from the St. Boniface Hospital and Diagnostic Services Manitoba in the development of a massive transfusion protocol which was successfully implemented in December 2015.

E. Mis-Transfusion Risk Reduction Strategy

In order to remain an accredited facility with the College of American Pathologists (CAP) the Red Cell Serology laboratories are required to implement a system to reduce the risk of mis-transfusion of ABO incompatible red cell components due to misidentification of the intended recipient. The laboratories collaborated with Diagnostic Services Manitoba to develop the appropriate strategy and gained the support of the Transfusion Practices Committees and Chief Medical and Nursing Officers from all Manitoba Regional Health Authorities. Completion of the project is expected to occur in April 2016.

F. Perinatal Advisory Committee

The annual Perinatal Advisory Committee meeting for 2016 is planned for June 13 and 14 2016 in Winnipeg MB. The PNAC meeting will be followed by an Educational Event sponsored by Grifols. Attendees will include Laboratory Directors, Associate Directors and Managers as well as perinatal supervisory staff and laboratory physicians who oversee perinatal testing. We will also welcome some hospital colleagues, both technologists and physicians, who are involved with perinatal testing laboratories. Ongoing work on standardization among our laboratories is a theme for this year. Our meeting plan and ongoing work plan for the remainder of 2016 will include:

- Discussion and consensus on appropriate follow up for perinatal patients with inconclusive antibodies.
- Planning for investigation of patients with possible antibodies to low prevalence antigens in the perinatal setting. We will discuss the development of a standard “low prevalence” panel of cells

that will allow for investigation of antibodies to low prevalence antigens which may be clinically significant in pregnancy.

- Discussion and consensus on the timing of repeat samples for patients with clinically significant or potentially significant antibodies in the perinatal setting.
- We will discuss the functionality of our standardized antibody investigation algorithm, including any necessary changes following one year of use.
- We will optimize and standardize the use of our algorithm used for RHD genotyping in perinatal patients with weak or variable Rh D serological typing.
- We will discuss the optimal serological evaluation for anti G, especially in the presence of passive anti D.
- We will discuss the results of an audit of Kell negative donor unit availability in transfusion of Kell negative (or Kell unknown) females of child bearing potential.
- We will have some updates and final discussions on completed projects including a study of anti Mia antisera in the BC perinatal testing lab as well as an update of testing and labeling strategies for platelet products in fetal/neonatal alloimmune thrombocytopenia.

G. Pooling Products for Exchange Transfusion

Under the new Blood Regulations which came into effect on October 23, 2014, facilities (including hospital blood banks) that prepare pooled products (other than cryoprecipitate) are required to register with Health Canada by 2015-01-23. The Crossmatch Laboratory falls under this regulation for the production of pooled red cell/plasma components for exchange transfusion. Section 97 of the Blood Regulations requires documented evidence that demonstrates that the operating procedures used in processing and transforming blood will consistently lead to expected results. Although the procedure has been in place in Winnipeg for many years, to comply with Section 97, the process was validated and documented evidence is now available that demonstrates that the process used to transform blood is consistent and meets acceptance criteria. The project was completed on June 22, 2015.

H. Trace Line® Laboratory Information System (LIS)

Phase II of the Trace Line® project concluded in February 2015 with implementations at the last two hospital sites; Flin Flon General Hospital and Thompson General Hospital. The laboratories continued to provide support for the implementation at these sites and collaborated with Diagnostic Services Manitoba to ensure policies and procedures between all of the sites were aligned. Collaboration with the DSM facilities continues at regularly scheduled meetings. The Manitoba Rh Clinical Program, based out of the Winnipeg Health Sciences Centre, implemented Trace Line® with read-only access to review the complete pregnancy history, testing results, etc. for their perinatal patients on June 22, 2015.

I. Transfer of HPA Testing from BC&Y Diagnostic Services to Platelet Immunology Laboratory

On December 31, 2015 all HPA antibody screen testing for Neonatal Alloimmune Thrombocytopenia (NAIT), Post Transfusion Purpura (PTP) and Platelet Refractory patients from British Columbia that was being performed at BC&Y Diagnostic Services was transferred to the Platelet Immunology Laboratory.

GOALS FOR 2016

A. Automated Testing Instrument Upgrade

The Platelet Immunology Laboratory is anticipated to acquire LABScan3D which is a high throughput instrument that can process 500 bead regions simultaneously and allows the user to make assignments of HLA antibodies and HLA typing.

B. Health Canada Licensure of Platelet Immunology Laboratory

The Platelet Immunology Laboratory provides HLA/HPA antigen testing and HPA antibody screening for new apheresis platelet donors. CBS' license with Health Canada does not currently extend to donor HLA or HPA testing for the selection of matched platelets. A project team will be assembled to assess the preparation required for a Health Canada submission.

C. Mis-transfusion Risk Reduction Strategy

Implementation of the mis-transfusion risk reduction strategy is planned for April 2016.

D. New Requisition for Neonatal Patients

Development and implementation of a new requisition specifically for requesting pre-transfusion testing for neonate patients is planned. This requisition will facilitate the provision of irradiated components to those patients requiring them based on birth weight and other clinical criteria.

E. Splitting Red Cells and Platelets for Pediatric Patients

Investigation into the process for producing split red cell and platelet aliquots for pediatric patients will commence in 2016.