Canadian Blood Services
Société canadienne du sang

DIAGNOSTIC SERVICES

MANITOBA

YEAR IN REVIEW

JANUARY – DECEMBER 2017

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.

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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 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.

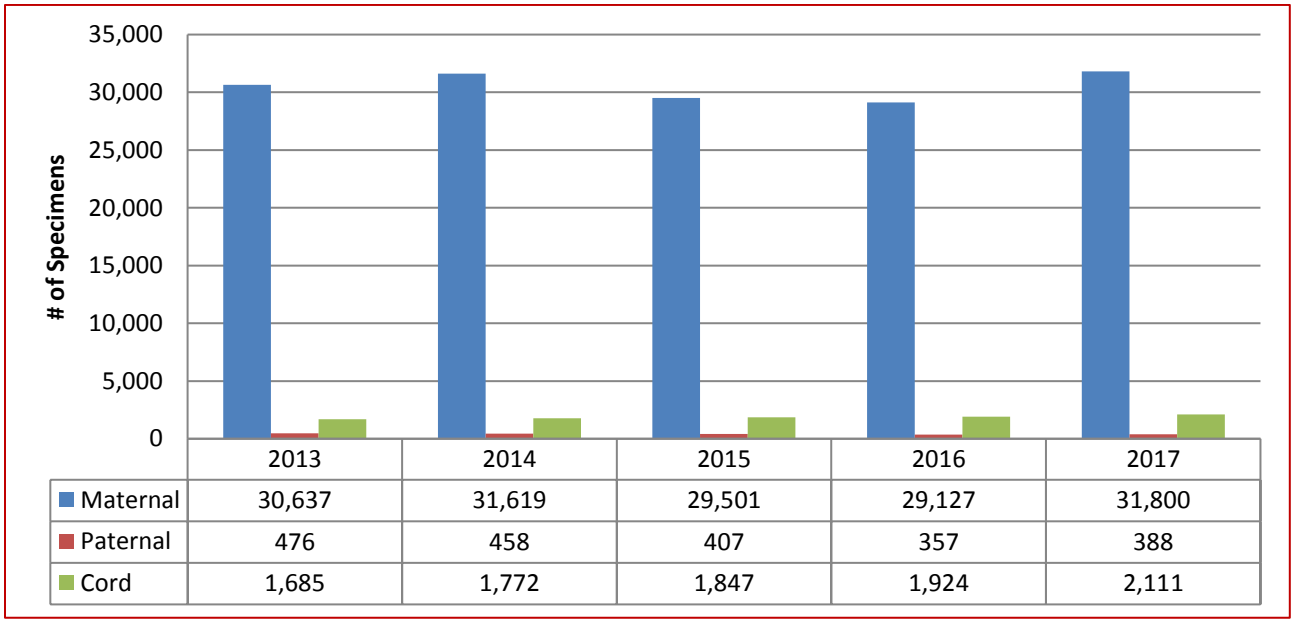
C. Specimens Tested

The data includes all women tested, including referral patients from Ontario, Saskatchewan and Nunavut. The total number of specimens tested has remained stable when compared to the last 3 years as seen in *Table 1* below.

Table 1: Perinatal Specimens Tested

Specimen Type	Test Type	2013	2014	2015	2016	2017
Maternal	Type and Screen	30,637	31,619	29,501	29,127	31,800
Paternal	ABO/Rh	476	458	407	357	388
Cord	ABO/Rh	1,685	1,772	1,847	1,924	2,111
Total # of Specimens Tested		32,798	33,849	31,755	31,408	34,299
Total # of Patients Tested		**23,481**	**24,179**	**24,005**	**23,980**	**24,248**

Figure 1: Total Perinatal Specimens Tested



D. Antibodies Identified

In 2017, a total of 259 antibodies were reported (see *Table 2*). This is slightly higher than 2016. Two hundred and thirty-seven women had antibodies identified during their pregnancies (increased from 216 women in 2016), of these; 198 women had clinically significant antibodies, 21 had clinically insignificant antibodies and 42 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-D and, anti-C (see *Figure 3*) which together represented 70.3% of the total antibodies identified.

Titres for 9 of the clinically significant antibodies increased from non-critical to critical levels during the pregnancy with a total of 55 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 Clinically Significant Antibodies Identified– 2017					
Clinically Significant Antibodies	**2013**	**2014**	**2015**	**2016**	**2017**
Anti-D	11	21	10	12	11
Anti-C	13	19	18	10	9
Anti-C^{w}	0	1	1	2	2
Anti-Ce	0	1	0	0	0
Anti-c	21	18	17	17	20
Anti-E	63	70	65	63	66
Anti-e	5	9	6	5	8
Anti-f	1	1	1	0	0
Anti-G	1	1	5	2	1
Anti-K	64	64	57	47	56
Anti-Kp^{a}	1	1	1	1	1
Anti-Kp^{b}	1	0	0	1	1
Anti-Lu^{a}	0	0	0	1	1
Anti-Lu^{b}	4	3	1	2	0
Anti-M*	18	11	12	9	18
Anti-S	5	6	7	6	6
Anti-s	0	1	1	1	2
Anti-Fy^{a}	5	3	5	4	4
Anti-Fy^{b}	2	2	2	1	4
Anti-Jk^{a}	19	20	20	17	20
Anti-Jk^{b}	9	8	1	5	4
Anti-Jk^{3}	0	0	0	0	1
Anti-Di^{a}	0	2	1	0	0
Anti-Di^{b}	0	0	0	0	0
Anti-V	0	0	0	1	1
Anti-Wr^{a}	3	2	2	2	2
TOTAL: Clinically Significant Antibodies	**246**	**264**	**233**	**209**	**238**

*Anti-M – IgG antibody component detected

Clinically Insignificant Antibodies - Antibody	2013	2014	2015	2016	2017
Anti-A_1	3	0	0	0	1
Anti-He	0	0	0	0	1
Anti-JMH	0	0	0	0	1
Anti-Le^a	24	23	12	13	11
Anti-Le^b	4	3	1	2	2
Anti-N	3	0	0	0	2
Anti-P_1	0	4	0	0	3
Passive Anti-D (not included in totals)	1228	1059	892	738	813
TOTAL: Clinically Insignificant Antibodies	**34**	**30**	**13**	**15**	**21**

Table 3: Perinatal Patient Antibody Titres

Antibody	Critical Level	Non-Critical Level	Non-Critical to Critical
Anti-D	5	9	2
Anti-C	0	5	0
Anti-E	5	39	3
Anti-c	0	7	0
Anti-e	2	3	1
Anti-DC	0	0	0
Anti-DE	0	0	0
Anti-Ec	4	5	2
Anti-Ce	0	1	0
Anti-G	0	0	0
Anti-DG	0	0	0
Anti-CG	0	1	0
Anti-K	37*	0	0
Anti-Fya	0	3	0
Anti-Fyb	0	3	0
Anti-Jka	0	13	0
Anti-Jkb	0	0	0
Anti-M	0	14	0
Anti-S	2	2	1
Anti-s	0	1	0
Total	**55**	**106**	**9**

***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

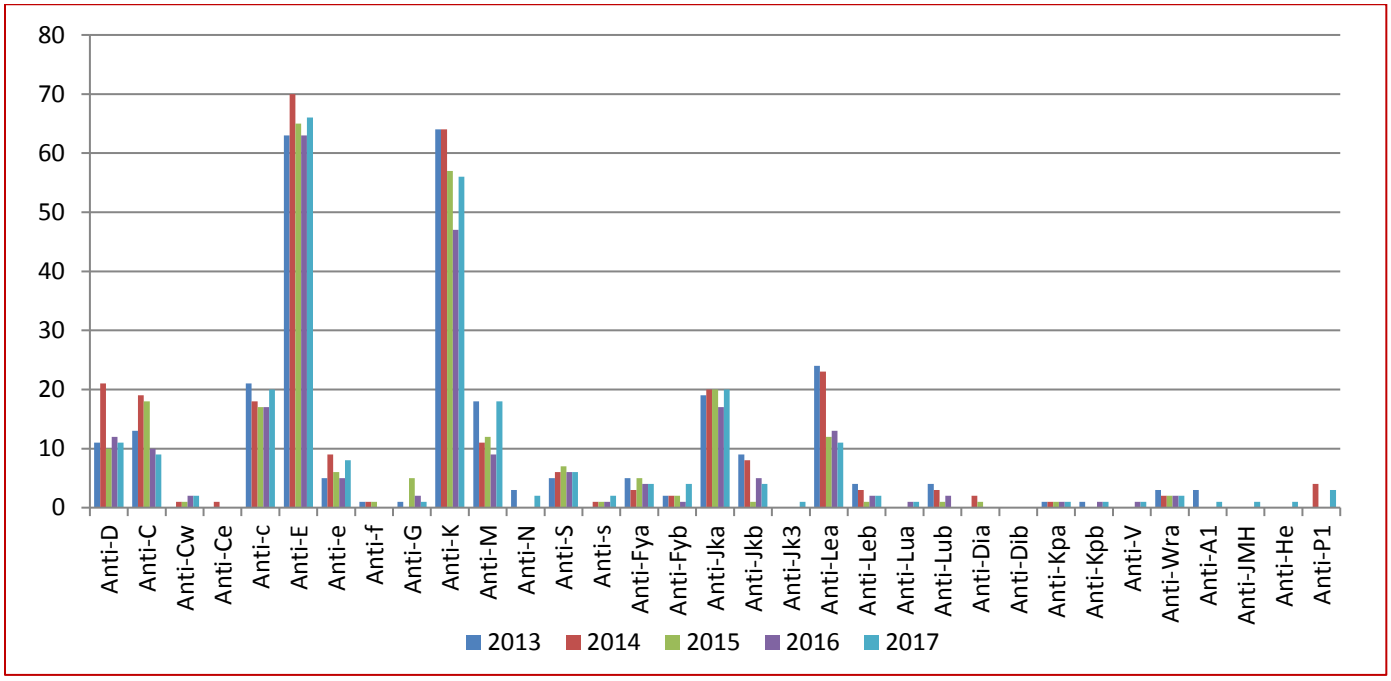


Figure 3: Frequency of Clinically Significant Antibodies

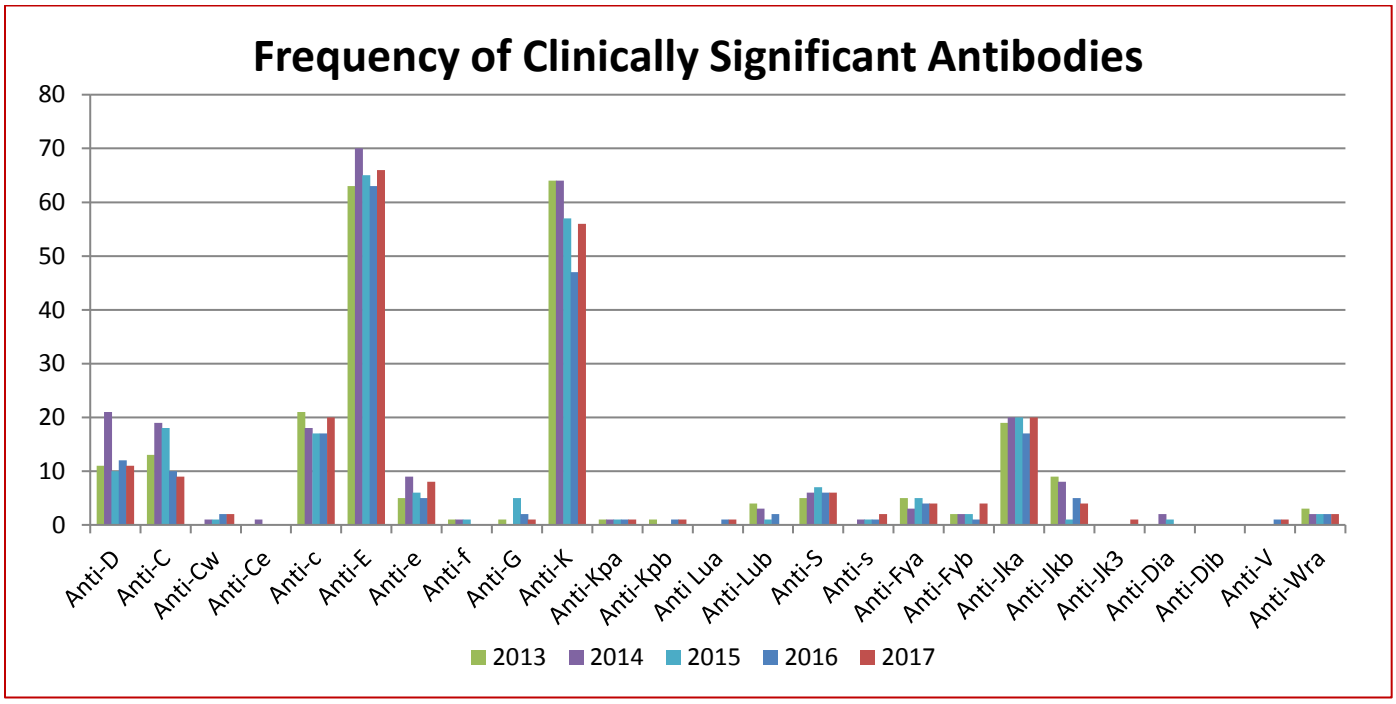


Table 4: Combination Antibodies

Antibodies	Number in 2017
Anti-C, Anti-D	1
Anti-C, Anti-G	1
Anti-c, Anti-E	8
Anti-c, Anti-K	1
Anti-c, Anti-Jkb	1
Anti-Cw, Anti-E	1
Anti-D, Anti-Jka	1
Anti-D, Anti-G	1
Anti-E, Anti-Fyb	2
Anti-E, Anti-Fya	1
Anti-E, Anti-Lea	1
Anti-e, Anti-Jkb	1
Anti-e, Anti-K	2
Anti-e, Anti-s	1
Anti-Fya, Anti-Jka	1
Anti-Fyb, Anti-Dib	1
Anti-Fyb, Anti-K	1
Anti-He, Anti-M	1
Anti-Jka, Anti-K	4
Anti-Lea, Anti-Leb	2
Anti-c, Anti-E, Anti-Jka	1
Anti-c, Anti-E, Anti-S	1
Anti-C, Anti-Fya, Anti-G	1
Anti-C, Anti-K, Anti-S	1
Anti-C, Anti-Jka, Anti-K	1
Anti-C, Anti-e, Anti-K	1
Anti-Fya, Anti-K, Anti-Lea	1
Anti-C, Anti-D, Anti-Jka, Anti-S	1
Anti-E, Anti-K, Anti-Kpa,Anti-S	1
Total	**42**

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.

MB Diagnostic Services contributes to continuing technologist education at provincial or national transfusion medicine conferences. (Refer to Accomplishments – page XX)

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 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 blood cell and platelet components to those hospitals which receive all of their transfusion medicine services from Canadian Blood Services.
As a Reference Laboratory, the Crossmatch Laboratory performs complex antibody investigations and distributes crossmatch compatible (or least incompatible) red blood cell units.

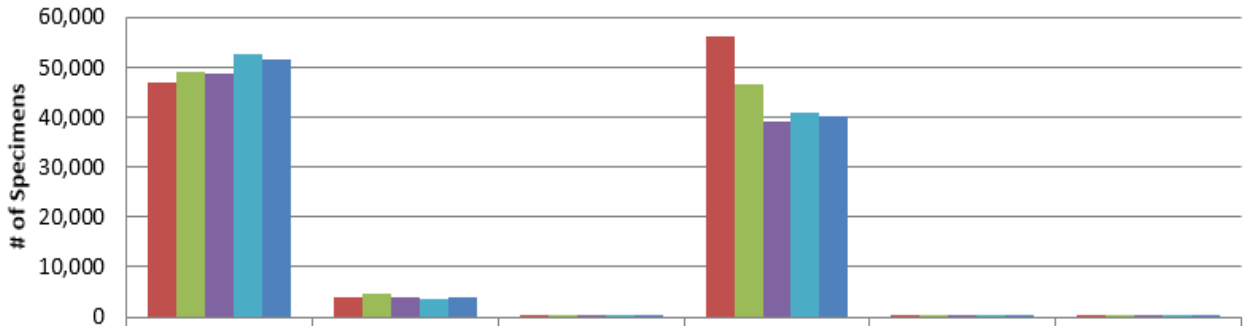
B. Specimens Tested

The total number of crossmatch specimens tested has remained fairly consistent over the last 4 years as illustrated in *Table 5* below. The implementation of the Trace Line laboratory information system (LIS) was completed at 16 hospitals in Winnipeg and rural Manitoba in 2015. These hospitals now hold a stock inventory of red blood cell components and perform electronic crossmatch on demand; thus reducing the number of red blood cells issued and reserved for specific patients on hand in the hospital Blood Bank. The number of red blood cell components distributed has stabilized as hospitals appear to have adjusted inventories to optimal levels. Product transformations showed a significant increase in 2017. This was primarily due to one patient who required chronic platelet transfusions with plasma reduced platelets as a result of mild allergic, anaphylactic transfusion reaction.

Table 5: Crossmatch/Reference Specimens Tested

Specimen Type	Test Type	2013	2014	2015	2016	2017
Crossmatch/Reference	Type and Screen	46,911	49,171	48,648	52,642	51,628
	Antibody Investigations	4,030	4,607	3,942	3,714	3,801
	Transfusion Reaction Investigations	189	192	183	193	167
	Blood Components Distributed	56,266	46,601	39,125	40,820	40,125
	Product Transformation	15	23	40	56	193
	Diagnostic Titres (Cold agglutinin, Isohemagglutinins)	367	491	492	443	446
Test Totals (excluding components distributed)		51,512	54,484	53,305	57,048	56,235
Number of Patients Tested		**28,498**	**29,751**	**29,219**	**31,200**	**30,553**

Figure 4: Total Crossmatch Specimens Tested



	Type and Screen	Antibody Investigations	Transfusion Reactions	Blood Components Distributed	Product Transformation	Diagnostic Titres
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
2016	52,642	3,714	193	40,820	56	443
2017	51,628	3,801	167	40,125	193	446

C. Antibodies Identified

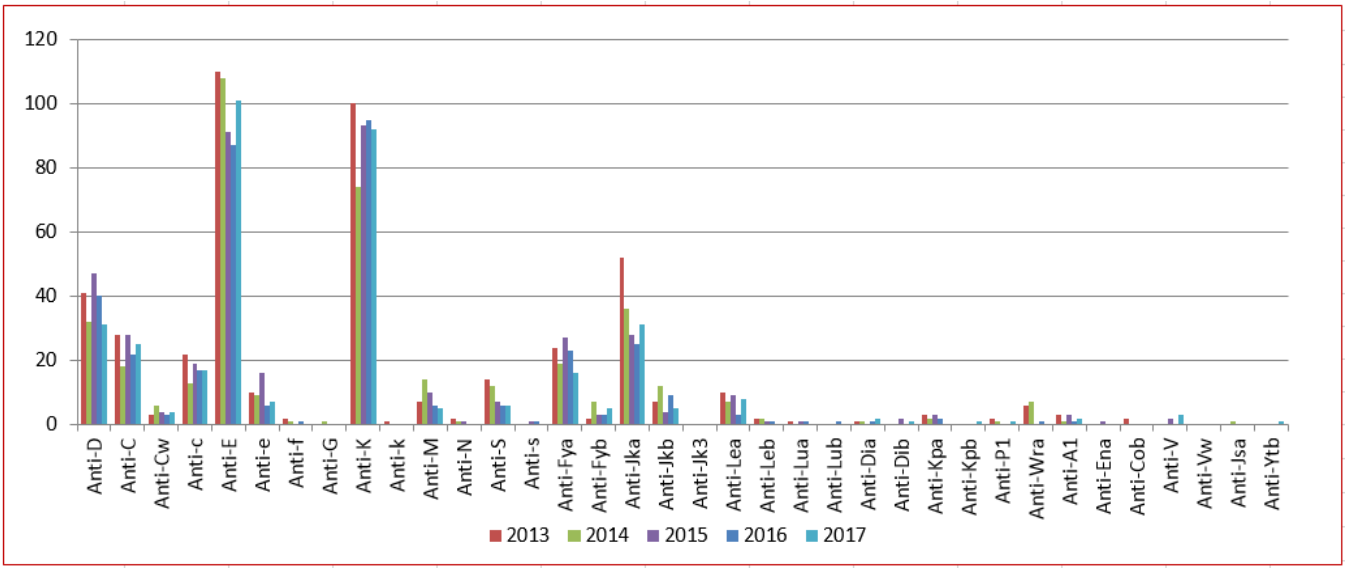
In 2017, a total of 364 antibodies were reported (see *Table 6*). The total number of antibodies detected is slightly increased from 2016, but the distribution of the most common antibodies remains consistent. Three hundred and five patients had antibodies identified, of these; 51 patients had multiple 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-D, anti-Jk^{a}, anti-C and anti-Fy^{a} (see *Figure 5*) which together represented 81.3% of the total antibodies identified.

Table 6: Total Number of Crossmatch Antibodies Detected

Antibody	Number Detected 2013	Number Detected 2014	Number Detected 2015	Number Detected 2016	Number Detected 2017
Anti-D	41	32	47	40	31
Anti-C	28	18	28	22	25
Anti-C^w	3	6	4	3	4
Anti-c	22	13	19	17	17
Anti-E	110	108	91	87	101
Anti-e	10	9	16	6	7
Anti-f	2	1	0	1	0
Anti-G	0	1	0	0	0
Anti-K	100	74	93	95	92
Anti-k	1	0	0	0	0
Anti-M	7	14	10	6	5
Anti-N	2	1	1	0	0
Anti-S	14	12	7	6	6
Anti-s	0	0	1	1	0
Anti-Fy^a	24	19	27	23	16
Anti-Fy^b	2	7	3	3	5
Anti-Jk^a	52	36	28	25	31
Anti-Jk^b	7	12	4	9	5
Anti-Jk^3	0	0	0	0	0
Anti-Le^a	10	7	9	3	8
Anti-Le^b	2	2	1	1	0
Anti-Lu^a	1	0	1	1	0
Anti-Lu^b	0	0	0	1	0
Anti-Di^a	1	1	0	1	2
Anti-Di^b	0	0	2	0	1
Anti-Kp^a	3	2	3	2	0
Anti-Kp^b	0	0	0	0	1
Anti-P_1	2	1	0	0	1
Anti-Wr^a	6	7	0	1	0
Anti-A_1	3	1	3	1	2
Anti-En^a	0	0	1	0	0
Anti-Co^b	2	0	0	0	0
Anti-V	0	0	2	0	3
Anti-Vw	0	0	0	0	0
Anti-Jsa	0	1	0	0	0
Anti-Ytb	0	0	0	0	1
Total	**455**	**385**	**401**	**355**	**364**

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 Antigen Typing
- HLA Antibody Screen
- HLA Antibody Identification, if antibodies are detected
- HLA Antigen Typing for disease association
- HPA Typing
- HPA Screening
- 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® multiplex technology, Bioarray eMAP® (Elongation-mediated Multiplexed Analysis of Polymorphisms) technology and/or MicroSSP are the primary HLA and HPA genotyping methods utilized for genotyping 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.

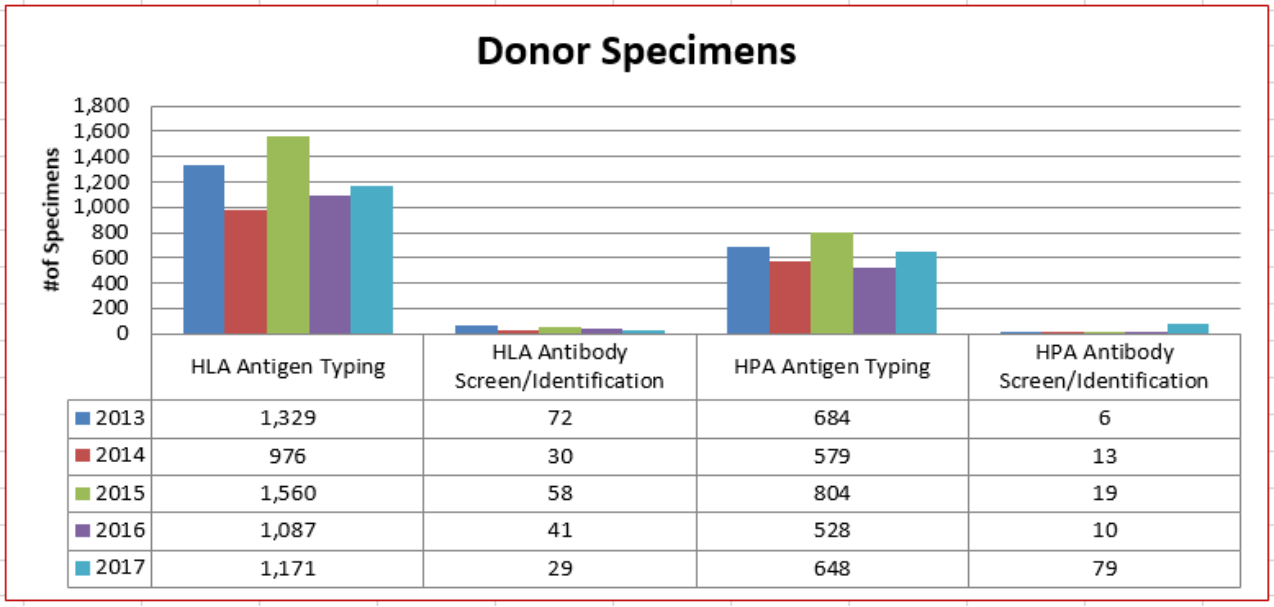
B. Specimens Tested

Table 7 below illustrates the total number of Platelet Immunology specimens tested.
Having a sufficient number of new male HLA/HPA donors tested and available for donation of HLA/HPA selected compatible platelets is a high priority for Canadian Blood Services and will increase CBS' ability to provide this specialized product for high risk patients.
There was an increase in donor HPA typing and antibody screens this year. This was due to a new process that involved coding donors who had an initial HPA typing as HPA-1b/1b to have a confirmation HPA-1b/1b typing performed.

Table 7: Platelet Immunology Specimens Tested

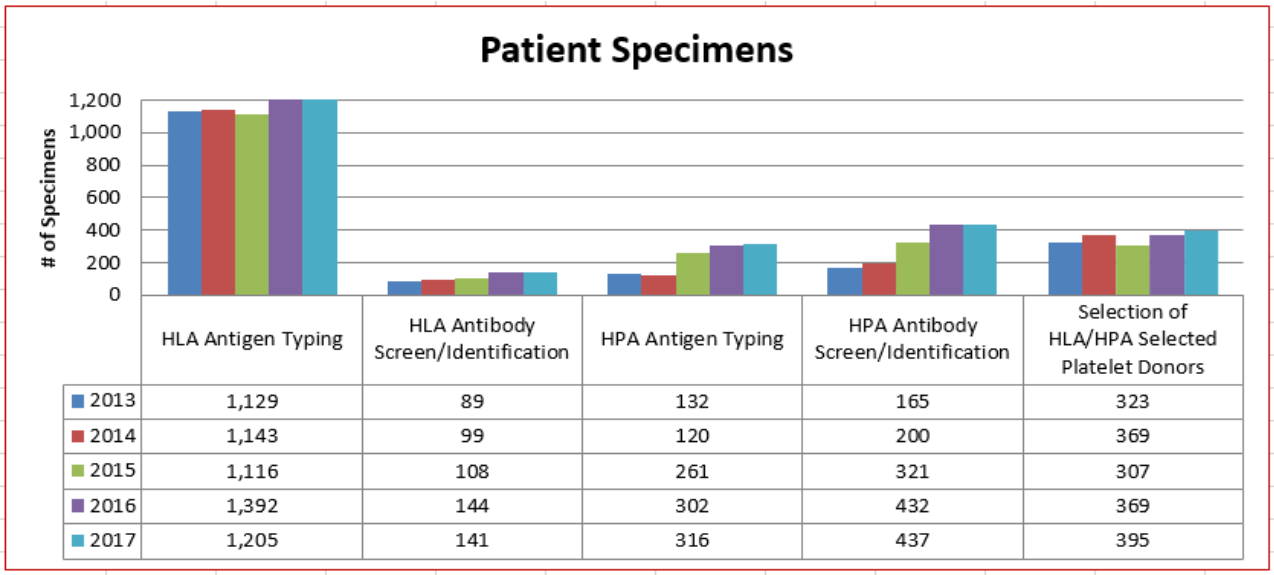
Specimen Type	Test Type	2013	2014	2015	2016	2017
Donor	HLA Antigen Typing	1,329	976	1,560	1,087	1,171
	HLA Antibody Screen/Identification	72	30	58	41	29
	HPA Antigen Typing	684	579	804	528	648
	HPA Antibody Screen/Identification	6	13	19	10	79
Patient	HLA Antigen Typing	1,129	1,143	1,116	1,392	1,205
	HLA Antibody Screen/Identification	89	99	108	144	141
	HPA Antigen Typing	132	120	261	302	316
	HPA Antibody Screen/Identification	165	200	321	432	437
	Selection of HLA/HPA Matched Platelet Donors	323	369	307	369	395
Test Totals		**3,929**	**3,529**	**4,354**	**4,305**	**4,510**

Figure 6: Total Platelet Immunology Donor Specimens Tested



	HLA Antigen Typing	HLA Antibody Screen/Identification	HPA Antigen Typing	HPA Antibody Screen/Identification
2013	1,329	72	684	6
2014	976	30	579	13
2015	1,560	58	804	19
2016	1,087	41	528	10
2017	1,171	29	648	79

Figure 7: Total Platelet Immunology Patient Specimens Tested



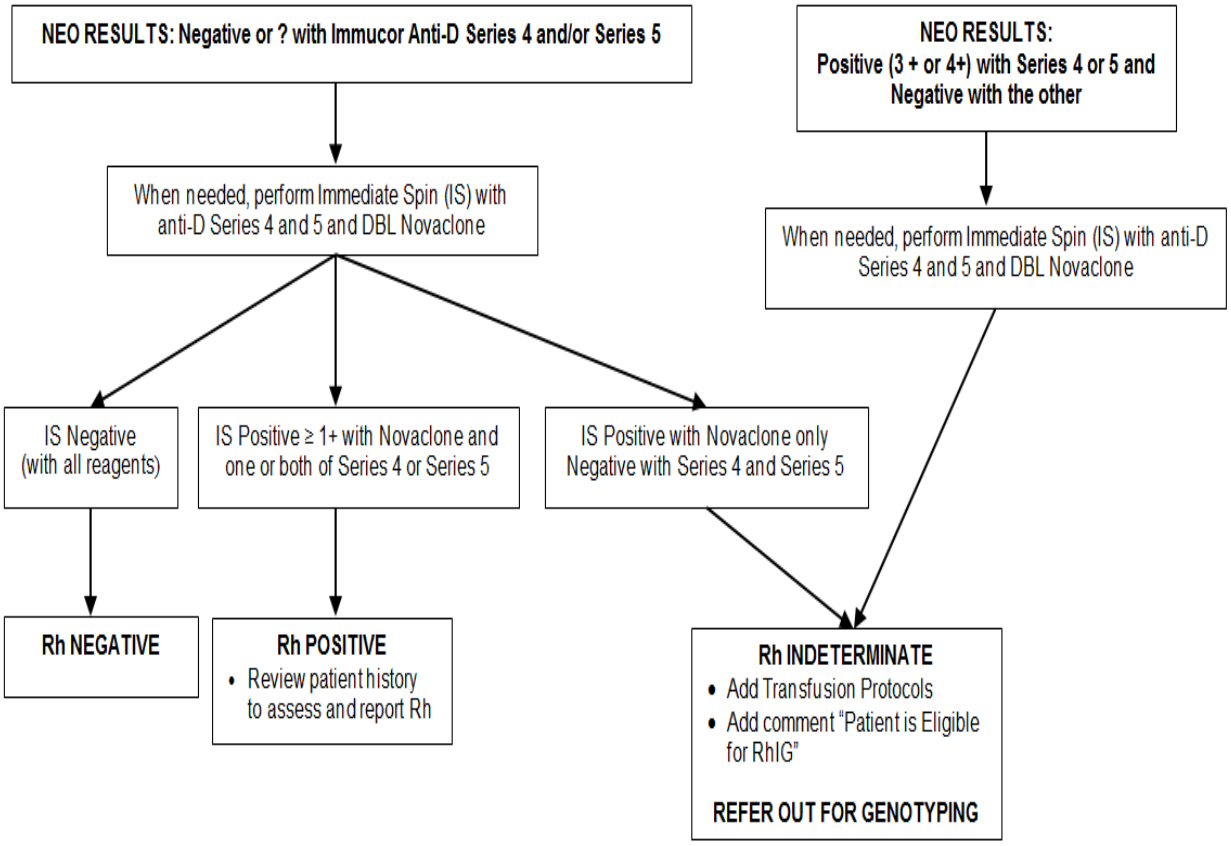
	HLA Antigen Typing	HLA Antibody Screen/Identification	HPA Antigen Typing	HPA Antibody Screen/Identification	Selection of HLA/HPA Selected Platelet Donors
2013	1,129	89	132	165	323
2014	1,143	99	120	200	369
2015	1,116	108	261	321	307
2016	1,392	144	302	432	369
2017	1,205	141	316	437	395

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 serologically variable Rh D typing results may require genetic testing for the RHD gene.

Figure 8: Rh D Testing Algorithm



For 2017, the following results were obtained in patients using one of the two red cell antigen genotyping platforms available at CBS:

Table 8: Patient # - RHD Type/Result

Patient	RHD Genotype	Predicted Phenotype	RHD Sequencing	Rh Group
1	Weak D type 2	Weak D	Not performed	Positive
2	RhD Deletion	-	Not performed	Negative
3	Weak D type 1	Weak D	Not performed	Positive
4	Weak D type 1	Weak D	Not performed	Positive
5	Weak D type 1	Weak D	Not performed	Positive
6	RhD Deletion	-	Not performed	Negative
7	DAR	Partial D	Not performed	Negative
8	Weak D type 2	Weak D	Not performed	Positive
9	DAU2	Partial D	Not performed	Negative
10	Weak D type 2	Weak D	Not performed	Positive
11	Weak D type 1	Weak D	Not performed	Positive
12	Weak D type 2	Weak D	Not performed	Positive
13	Weak D type 1	Weak D	Not performed	Positive
14	Weak D type 1	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

% of Specimens Tested within 72 hours	88.3%	89.3%	92.3%	91%	94%
% of Specimens Tested > 72 hours	11.7%	10.7%	7.7%	9%	6%

Figure 9: Perinatal Routine TAT

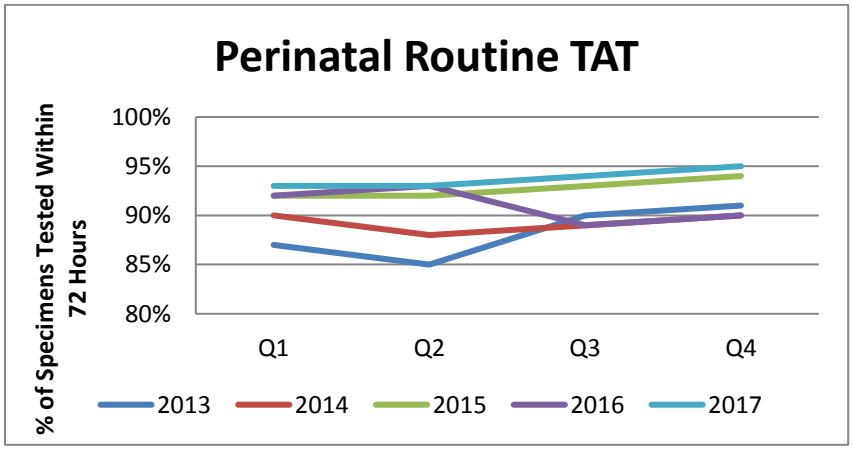


Table 11: Turnaround Time – Routine Crossmatch Specimens

% of Specimens Tested within 24 hours	99.4%	99.6%	99.8%	99.8%	99.8%
% of Specimens Tested > 24 hours	0.6%	0.4%	0.2%	0.2%	0.2%

Figure 10: Crossmatch Routine TAT

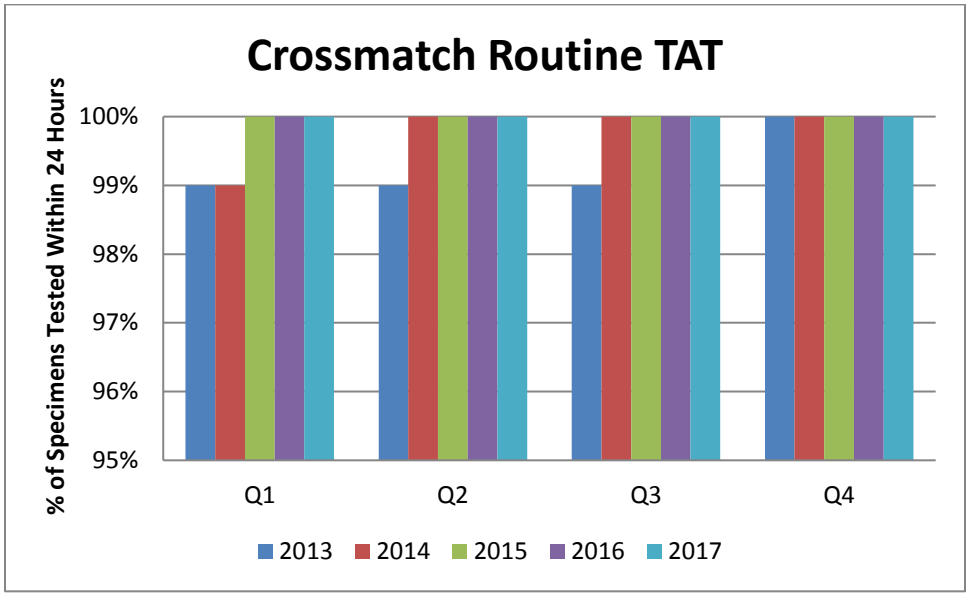


Table 12: Turnaround Time – Reference Specimens

% of Specimens Tested within 24 hours	93.3%	96.8%	98.8%	98.5%	99%
% of Specimens Tested > 24 hours	6.7%	3.2%	1.2%	1.5%	1%

Figure 11: Reference TAT

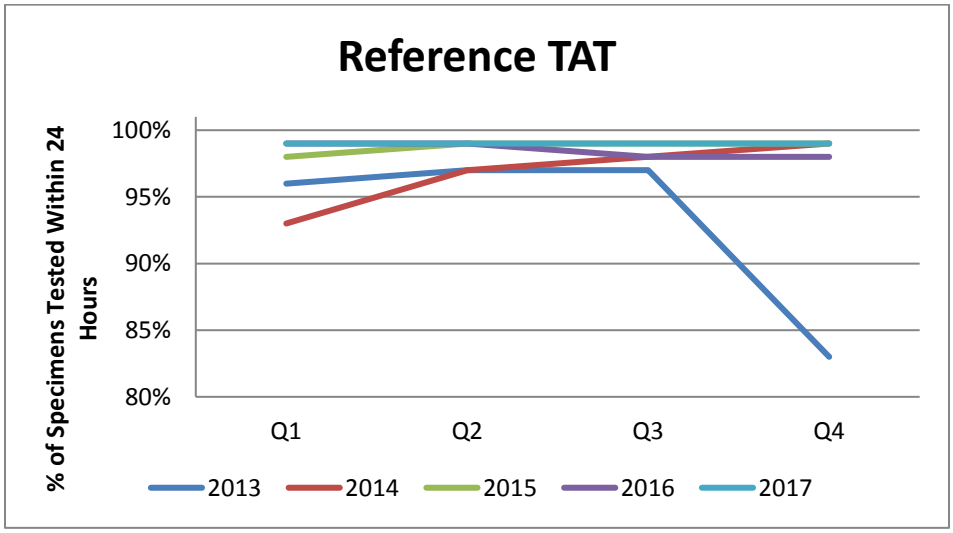
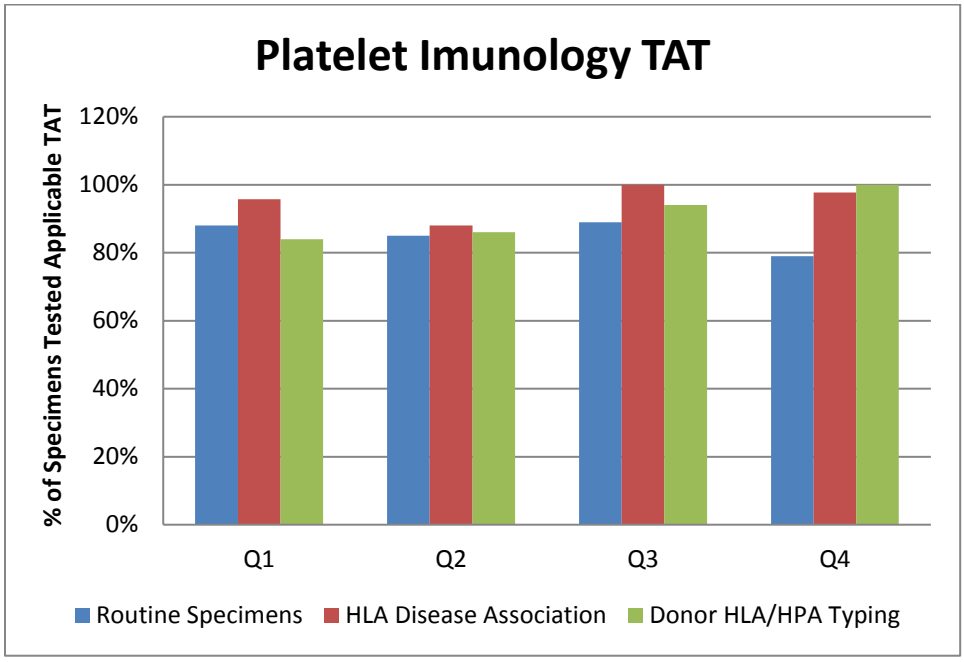


Table 13: Turnaround Time - Platelet Immunology Specimens

% of Specimens Tested within 14 days	N/A	91.8%	94.5%	91.6%	85.3%*
% of Specimens Tested within 28 days	N/A	98.9%	96.8%	94.0%	95.3%
% of Specimens Tested within 60 days	N/A	100%	100%	95.0%	91%

* Preliminary results reported within 1-2 days of sample receipt.

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 and Figure 13*, 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 2017 which correlates with increased efforts to contact customers and educate them on acceptable labelling criteria.

Table 15 and Figure 14 describe 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, personal health number (PHN) or date of collection continue to be 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 remain low throughout 2017. The average rejection rates have decreased from a high of 2.9% in 2012 to 1.3% in 2017.

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. 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 and Figure 15 describe the reasons for rejecting specimens in the Platelet Immunology Laboratory; the majority of which involve specimens. Eighty-six percent of the specimens in this category were rejected because they were duplicate specimens that would not be tested; wrong tube type was the next most common reason. Efforts to educate hospital customers continued throughout 2017. Average rejection rates have decreased from 9.6% in 2016 to 7.5% in 2017.

Table 14: Quarterly Rejection Rates – Perinatal Specimens

Rejection Category	Q1	Q2	Q3	Q4
Requisition	117	107	104	114
Specimen	77	65	71	89
Discrepancies Between Requisition & Specimen	76	83	83	81
Discrepancies Between Current Requisition & Historical Records	19	16	22	12
Other (Duplicates, etc.)	5	15	11	10
Total # specimens rejected	294	286	291	306
Total # specimens received	9186	8600	8732	8516
Rejections as a % of total	**3.2%**	**3.3%**	**3.3%**	**3.6%**

Figure 13: Perinatal Rejection Reasons

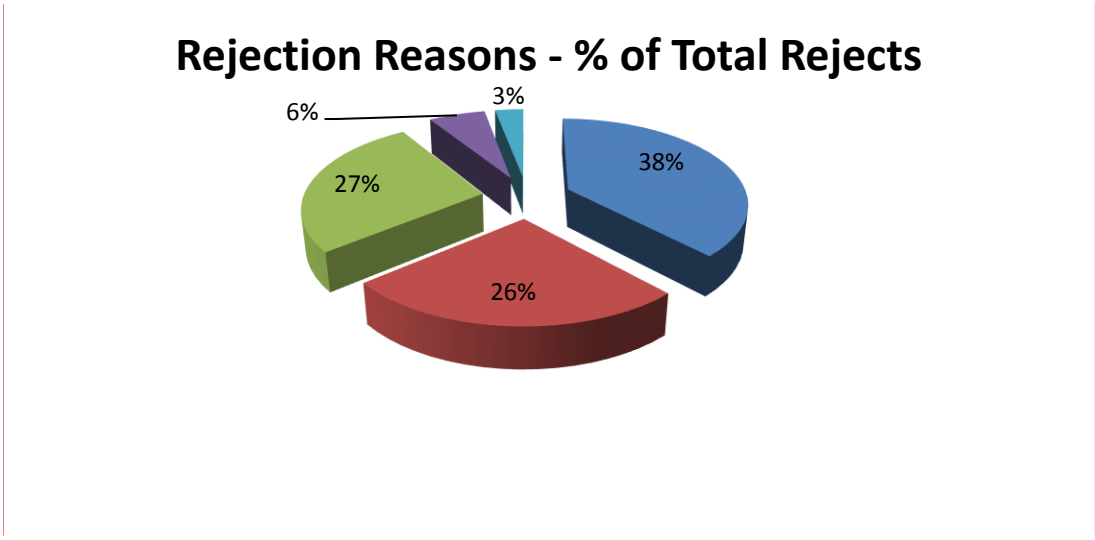


Table 15: Quarterly Rejection Rates – Crossmatch Specimens

Rejection Category	Q1	Q2	Q3	Q4
Requisition	34	20	18	28
Specimen	95	91	96	76
Discrepancies Between Requisition & Specimen	49	54	47	59
Discrepancies Between Current Requisition & Historical Records	11	2	1	3
Other (Duplicates, etc.)	7	11	7	16
Total # specimens rejected	196	178	169	182
Total # specimens received	14,900	13,928	14,368	14,047
Rejections as a % of total	**1.3%**	**1.3%**	**1.2%**	**1.3%**

Figure 14: Crossmatch Rejection Reasons

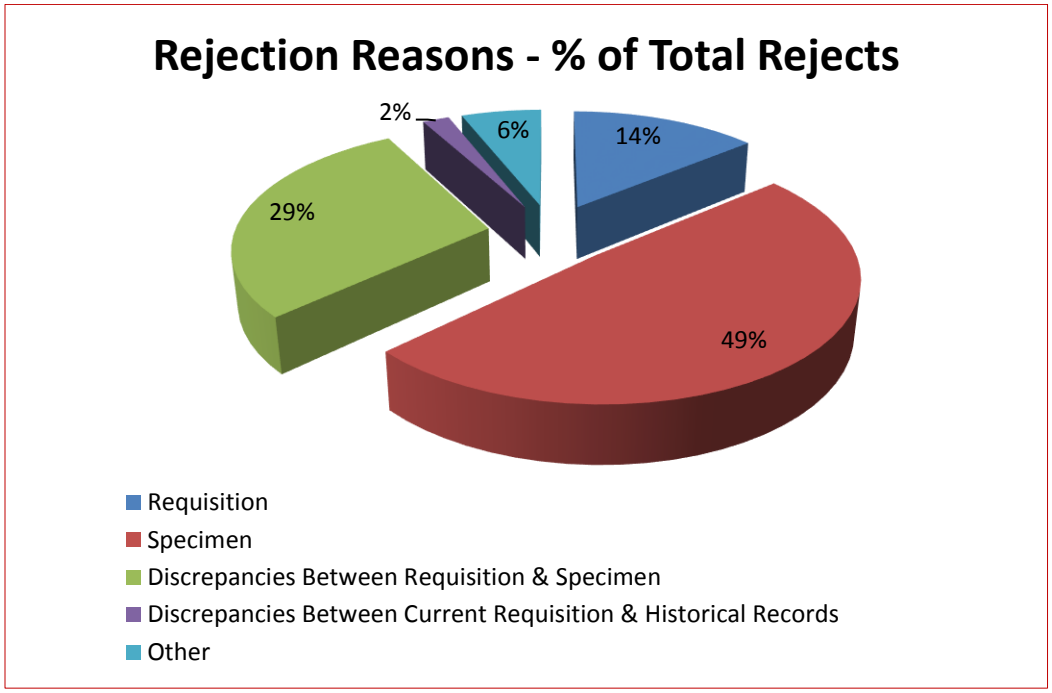
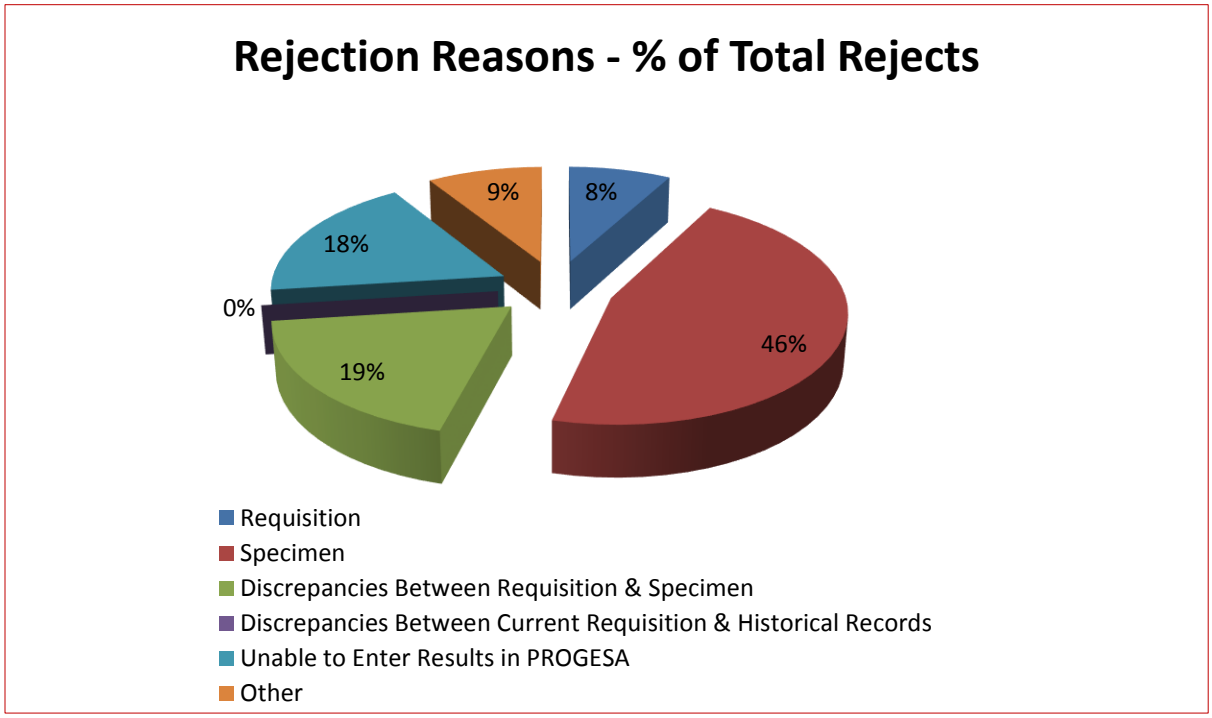


Table 16: Quarterly Rejection Rates – Platelet Immunology Specimens

Rejection Category	Q1	Q2	Q3	Q4
Requisition	4	4	4	2
Specimen	18	25	18	24
Discrepancies Between Requisition & Specimen	8	16	8	4
Discrepancies Between Current Requisition & Historical Records	0	0	0	0
Unable to Enter Results in PROGESA	11	11	8	4
Other (Duplicates, etc.)	4	2	4	6
Total # specimens rejected	45	58	42	40
Total # specimens received	599	633	673	561
Rejections as a % of total	**7.5%**	**9.2%**	**6.2%**	**7.1%**

Figure 15: Platelet Immunology Rejection Reasons



ACCOMPLISHMENTS IN 2017

A. Automated Testing Instrument Upgrade

The Platelet Immunology Laboratory replaced the Luminex® 100 with Luminex® 200 instrument in March of 2017. The BioArray™ Automated Imaging System HPA BeadChip™ for platelet genotyping was implemented in October of 2017.

B. College of American Pathologists (CAP) Laboratory Accreditation

The laboratories are accredited by the College of American Pathologists Laboratory Accreditation Program (LAP). The Platelet Immunology Laboratory had an on-site inspection in March 2017 and met the requirements of the LAP Standards for Accreditation. Accreditation is granted for the 2 year period

C. Diagnostic Services Web Page Redesign

All Diagnostic Services sites (Vancouver, Edmonton, Regina, Winnipeg, Brampton) collaborated in a project to redesign and refresh the current Diagnostic Services webpages on www.blood.ca that will include new features (Test Catalogue and QuickLinks) and information to make the site more user friendly for hospital customers. The new websection is anticipated to go live in 2018.

D. 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. The project team continued the work on the preparation the documentation required for a Health Canada submission. The documentation is anticipated to be submitted in the spring of 2018.

E. Perinatal Advisory Committee

The Perinatal Advisory Council meeting for 2017 was held in Brampton, Ontario on November 20th. In addition to the Canadian Blood Services Testing group members, an invited hospital guest in 2017 was Dr. Oksana Prokopchuk- Gauk from the Saskatoon Health Region.

The PNAC meeting included a discussion of plans for conversion and standardization of work instructions across all patient testing sites. In addition, a number of ongoing standardization initiatives, including automated solid phase testing for detection of passive anti D, and an adjusted algorithm for RHD genotyping of prenatal patients were updated.

The process for implementation of new initiatives was outlined by the leadership group. This was followed by a presentation of commercially available software for cataloguing and tracking reagent red cells and antisera. This software provides a searchable database of reagent cells that could be viewed from any Canadian Blood Services laboratory across the country, potentially enhancing complex antibody identification in prenatal or pre-transfusion patients.

Non- invasive prenatal testing as a means of targeting antenatal Rh immune globulin to only those Rh(D) negative pregnant women who are carrying an Rh-positive fetus was also discussed as a potential future initiative.

F. Strategy for the Reduction of Platelet Discards

In collaboration with Diagnostic Services Manitoba, a strategy to redistribute platelets from a large rural hospital to an urban tertiary care hospital was developed to reduce the current high discard rate. The new redistribution process is expected to be implemented in early 2018.

G. Presentations / Abstracts / Publications

Anti-G Testing and Titration Strategy in Prenatal Patients CSTM Poster 2017

An Approach to Ensuring Quality in Cell-Free Fetal DNA (cffDNA) Testing - CSTM Poster 2017

GOALS FOR 2018

H. BEST Collaborative TUBE (Testing the Utility of Collecting Blood Samples Electronically) Study Part 2

The laboratory has been invited to participate in the BEST Collaborative TUBE Study Part 2 which is designed to determine the rate of Wrong Blood in Tube (WBIT) errors in mislabeled samples that would normally be rejected. An ABO and RhD type will be performed on these mislabeled samples and compared to the historical ABO and RhD type on file in the laboratory. Data will be collected for a period of 6 months or until 200 mislabeled samples have been collected.

I. Cell Free Fetal DNA Testing (cff DNA)

Cell free fetal DNA testing is available by referral to the National Health Services (NHS) Laboratories in Bristol, UK. This testing would be performed on selected patients, referred by maternal fetal medicine physicians based on clinically significant red cell allo antibodies known to cause hemolytic disease of the fetus and newborn. Results of this DNA testing will help to determine which patients require follow up in a high risk obstetrical clinic and which can return to routine prenatal care setting. This new service is being proposed to the Manitoba Ministry of Health.

J. College of American Pathologists (CAP) Laboratory Accreditation

An on-site inspection of the Red Cell Serology Laboratories is anticipated to occur in the spring of 2018.

K. Diagnostic Services Web Page Redesign

All Diagnostic Services sites (Vancouver, Edmonton, Regina, Winnipeg, Brampton) will continue to collaborate in the project to redesign and refresh the current Diagnostic Services webpages on www.blood.ca. The redesigned site with its' new features (Test Catalogue and QuickLinks), expanded information and functionality is anticipated to go live in spring of 2018.

L. LEAN Continuous Improvement Review of Red Cell Serology Laboratories

A LEAN continuous improvement review of the Red Cell Serology Laboratories was conducted in late 2016. In late 2017 a project team was assembled to assess and implement the recommendations made in the review. Improvements include redesign of the workflow and layout of the Red Cell Serology Laboratories and cross-

training all staff to both perinatal and pre-transfusion testing. The goal is to improve quality, eliminate waste/re-work, reduce movement and wait time and more efficiently use people's talents. The renovations are other improvements are expected to be completed by December 2018.

F. National Advisory Committee (NAC) Recommendations for Use of Irradiated Blood Components

The NAC recommendations for the use of irradiated blood components is expected to be released in 2018. A review of these recommendations is planned to assess the impact on current operations. It is expected that a new requisition specifically for requesting pre-transfusion testing for neonate patients may need to be developed.