

# DIAGNOSTIC SERVICES MANITOBA YEAR IN REVIEW JANUARY – DECEMBER 2016

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
Lynne Meilleur, MLT

204-789-1149
Lynne.meilleur@blood.ca

Charge Technologists:

Red Cell Serology:

Perinatal Laboratory and Crossmatch Laboratory

Sherry Watt, MLT 204-789-1090 sherry.watt@blood.ca

Henri Beaubien, MLT 204-789-1093

henri.beaubien@blood.ca

<u>Platelet Immunology Laboratory</u>

Lynnette Beaudin, MLT 204-789-1109

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

SEN	NIOR STAFF AND CONTACT INFORMATION2					
PEF	RINATAL LABORATORY	7				
Α.	Testing Performed	7				
	ABO/Rh blood type	7				
	Screen for red blood cell antibodies					
	Antibody Identification, if antibodies are detected					
	Antibody Identification, if dribbodies 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	7				
В.	Testing Frequency	7				
C.	Specimens Tested	8				
D.	Antibodies Identified	9				
CRO	OSSMATCH / REFERENCE LABORATORY	12				
A.	Testing Performed	12				
	ABO/Rh blood type	12				
	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	13				
	Direct Antiglobulin Test	13				
	Elution and Absorption	13				
	Cold Agglutinin Screen	13				
	Thermal Amplitude	13				
В.	Specimens Tested	13				
C.	Antibodies Identified	14				
PLA	ATELET IMMUNOLOGY LABORATORY	16				
A.	Testing Performed	16				
	LILA Antigan Turing	4.0				
	HLA Antigen Typing  HLA Antibody Screen					
	HLA Antibody Screen	b				

	HLA Antibody Identification, if antibodies are detected	16
	HLA Antigen Typing for disease association	
	HPA Typing	
	HPA Screening	
	<ul> <li>HPA Antibody Identification, if antibodies are detected</li> <li>Platelet Crossmatch</li> </ul>	
	Selection of HLA/HPA Compatible Donors for Platelet Transfusion	
	Selection of the Aftir A compatible bollors for reactelet transitusion	10
В.	Specimens Tested	17
KEI	D CELL GENOTYPING	19
QU	JALITY INDICATORS	20
A.	Turnaround Time	20
D	Rejected Specimens	24
В.	Rejected Specimens	24
AC	COMPLISHMENTS IN 2016	28
A.	Automated Testing Instrument Upgrade	28
	Posteron Continuity Diameter	20
В.	Business Continuity Planning	28
c.	College of American Pathologists (CAP) Laboratory Accreditation	28
•		
D.	Electronically Fillable Platelet Immunology Requisition	28
E.	Mis-transfusion Risk Reduction Strategy	28
F.	Perinatal Advisory Committee	28
۲.	rematal Advisory Committee	20
G.	Revision of Transfusion Reaction Algorithm and Requisition	29
GO	ALS FOR 2017	29
^	Automatod Tastina lustrumout Unavado	20
Α.	Automated Testing Instrument Upgrade	29
В.	College of American Pathologists (CAP) Laboratory Accreditation	29
	, , , , , , , , , , , , , , , , , , , ,	
C.	Diagnostic Services Web Page Redesign	29
D.	Health Canada Licensure of Platelet Immunology Laboratory	30
E.	New Requisition for Neonatal Patients	30
F.	Strategy for the Provision of Small Volume Pediatric Red Blood Cell Units	30
6	Stratogy for the Poduction of Platelet Discards	20

# Figures

Figure 1: Total Perinatal Specimens Tested	8
Figure 2: Total Number of Perinatal Antibodies	11
Figure 3: Frequency of Clinically Significant Antibodies	11
Figure 4: Total Crossmatch Specimens Tested	14
Figure 5: Total Number of Crossmatch Antibodies	16
Figure 6: Total Platelet Immunology Donor Specimens Tested	18
Figure 7: Total Platelet Immunology Patient Specimens Tested	18
Figure 8: Rh D Testing Algorithm	19
Figure 9: Perinatal Routine TAT	21
Figure 10: Crossmatch Routine TAT	22
Figure 11: Reference TAT	22
Figure 12: Platelet Immunology TAT	23
Figure 13: Perinatal Rejection Reasons	25
Figure 14: Crossmatch Rejection Reasons	26
Figure 15: Platelet Immunology Rejection Reasons	27

# Tables

Table 1: Perinatal Specimens Tested	8
Table 2: Total Number of Perinatal Antibodies Detected	9
Table 3: Perinatal Patient Antibody Titres	10
Table 4: Combination Antibodies	12
Table 5: Crossmatch/Reference Specimens Tested	13
Table 6: Total Number of Crossmatch Antibodies Detected	15
Table 7: Platelet Immunology Specimens Tested	17
Table 8: RHD Genotyping Results	20
Table 9: Turnaround Time – Routine Criteria by Specimen Type	21
Table 10: Turnaround Time – Routine Perinatal Specimens	21
Table 11: Turnaround Time – Routine Crossmatch Specimens	22
Table 12: Turnaround Time – Reference Specimens	22
Table 13: Turnaround Time – Platelet Immunology Specimens	23
Table 14: Quarterly Rejection Rates – Perinatal Specimens	25
Table 15: Quarterly Rejection Rates – Crossmatch Specimens	26
Table 16: Quarterly Rejection Rates – Platelet Immunology Specimens	27

# 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.

<u>Mothers – 26-28 Weeks Gestation:</u> 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).

<u>Mothers – Antibody Present:</u> 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.

<u>Mothers – Postnatal:</u> 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).

<u>Partners:</u> 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.

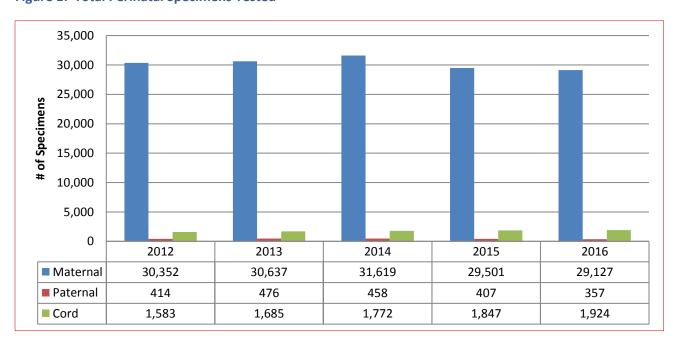
## C. Specimens Tested

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 2015 as seen in *Table 1* below.

**Table 1: Perinatal Specimens Tested** 

Specimen Type	Test Type	2012	2013	2014	2015	2016
Maternal	Type and Screen	30,352	30,637	31,619	29,501	29,127
Paternal	ABO/Rh	414	476	458	407	357
Cord	ABO/Rh	1,583	1,685	1,772	1,847	1,924
Total # of Specimens Tested		32,349	32,798	33,849	31,755	31,408
Total # of Patients Tested		23,357	23,481	24,179	24,005	23,980

Figure 1: Total Perinatal Specimens Tested



#### D. Antibodies Identified

In 2016, a total of 224 antibodies were reported (see *Table 2*). This is slightly lower than 2015. Two hundred and sixteen women had antibodies identified during their pregnancies (decreased from 236 women in 2015), 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<sup>a</sup>, anti-c, anti-D and, anti-C (see *Figure 3*) which together represented 74% of the total antibodies identified.

Titres for 6 of the clinically significant antibodies increased from non-critical to critical levels during the pregnancy with a total of 48 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) – 2016						
Clinically <u>Significant</u> Antibodies - Antibody	2012	2013	2014	2015	2016	
Anti-D	12	11	21	10	12	
Passive Anti-D	914	1228	1059	892	738	
Anti-C	10	13	19	18	10	
Anti-C <sup>w</sup>	0	0	1	1	2	
Anti-Ce	1	0	1	0	0	
Anti-c	28	21	18	17	17	
Anti-E	63	63	70	65	63	
Anti-e	4	5	9	6	5	
Anti-f	1	1	1	1	0	
Anti-G	0	1	1	5	2	
Anti-K	45	64	64	57	47	
Anti-Kp <sup>a</sup>	1	1	1	1	1	
Anti-Kp <sup>b</sup>	0	1	0	0	1	
Anti-Lu <sup>a</sup>	0	0	0	0	1	
Anti-Lu <sup>b</sup>	5	4	3	1	2	
Anti-S	4	5	6	7	6	
Anti-s	0	0	1	1	1	
Anti-Fy <sup>a</sup>	2	5	3	5	4	
Anti-Fy <sup>b</sup>	2	2	2	2	1	
Anti-Jk <sup>a</sup>	11	19	20	20	17	
Anti-Jk <sup>b</sup>	6	9	8	1	5	
Anti-Di <sup>a</sup>	2	0	2	1	0	
Anti-Di <sup>b</sup>	0	0	0	0	0	
Anti-V	0	0	0	0	1	
Anti-Wr <sup>a</sup>	2	3	2	2	2	

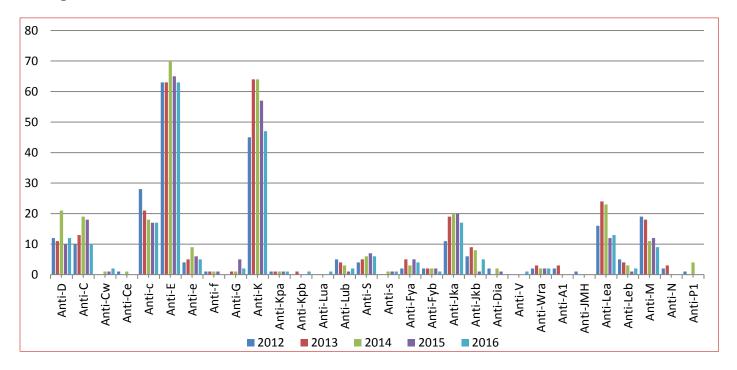
Clinically <u>Insignificant</u> Antibodies - Antibody	2012	2013	2014	2015	2016
Anti-A₁	2	3	0	0	0
Anti-JMH	1	0	0	0	0
Anti-Le <sup>a</sup>	16	24	23	12	13
Anti-Le <sup>b</sup>	5	4	3	1	2
Anti-M	19	18	11	12	9
Anti-N	2	3	0	0	0
Anti-P <sub>1</sub>	1	0	4	0	0

**Table 3: Perinatal Patient Antibody Titres** 

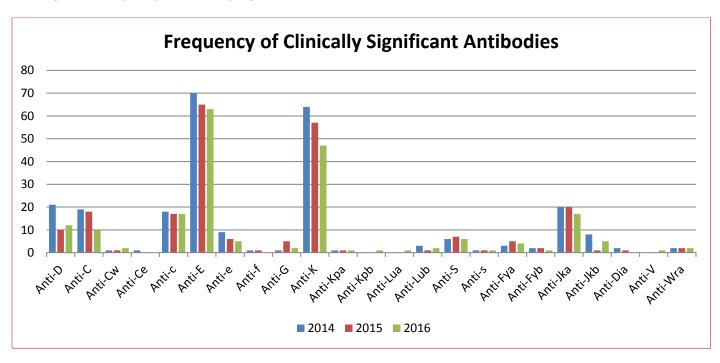
Antibody	Critical Level	Non-Critical Level	Non-Critical to Critical
Anti-D	10	9	4
Anti-C	0	0	0
Anti-E	2	40	1
Anti-c	1	12	1
Anti-e	0	0	0
Anti-DC	0	0	0
Anti-DE	0	0	0
Anti-Ec	2	2	0
Anti-Ce	0	2	0
Anti-G	0	0	0
Anti-K	32*	0	0
Anti-Fy <sup>a</sup>	0	4	0
Anti-Fy <sup>b</sup>	0	1	0
Anti-Jk <sup>a</sup>	0	10	0
Anti-Jk <sup>b</sup>	0	2	0
Anti-M	1	7	0
Anti-S	0	1	0
Anti-s	0	1	0
Total	48	91	6

<sup>\*</sup>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 2016
Anti-A1, Anti-P1	1
Anti-C, Anti-D	1
Anti-C, Anti-E	1
Anti-C, Anti-G	1
Anti-c, Anti-E	11
Anti-c, Anti-N	1
Anti-Cw, Anti-P1	1
Anti-D, Anti-E	2
Anti-D, Anti-P1	2
Anti-E, Anti-Fya	1
Anti-E, Anti-Lea	1
Anti-e, Anti-K	1
Anti-Jka, Anti-K	1
Anti-Lea, Anti-Leb	1
Anti-Lea, Anti-M	1
Anti-Lea, Anti-P1	1
Anti-Leb, Anti-P1	1
Anti-M, Anti-P1	1
Anti-C, Anti-D, Anti-G	2
Anti-C, Anti-D, Anti-Jkb	1
Anti-C, Anti-D, Anti-S	1
Anti-D, Anti-G, Anti-S	1
Anti-E, Anti-Fya, Anti-M	1
Anti-E, Anti-K, Anti-Lea	1
Anti-C, Anti-E, Anti-Lea, Anti-M	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 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. As a Reference Laboratory, the Crossmatch Laboratory performs complex antibody investigations and distributes crossmatch compatible (or least incompatible) red cell units.

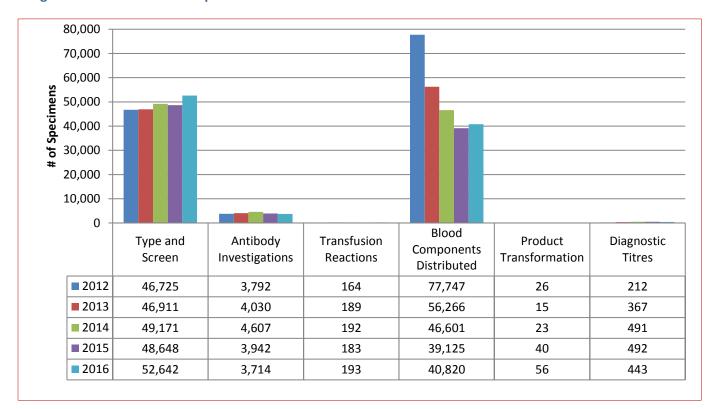
#### **B.** Specimens Tested

The total number of crossmatch specimens tested has increased slightly over 2015 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 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 remained stable compared to 2015 as hospitals appear to have adjusted inventories to optimal levels.

Table 5: Crossmatch/Reference Specimens Tested

Specimen Type	Test Type	2012	2013	2014	2015	2016
Crossmatch/Reference	Type and Screen	46,725	46,911	49,171	48,648	52,642
	Antibody Investigations	3,792	4,030	4,607	3,942	3,714
	Transfusion Reaction Investigations		189	192	183	193
	Blood Components Distributed		56,266	46,601	39,125	40,820
	Product Transformation		15	23	40	56
	Diagnostic Titres (Cold agglutinin, Isohemagglutinins)	212	367*	491	492	443
Test Totals (excluding components distributed)		50,919	51,512	54,484	53,305	57,048
Number of Patients Tested			28,498	29,751	29,219	31,200

<sup>\*</sup>Note: Increase in diagnostic titres is due to a change in data collection method implemented in 2013.



**Figure 4: Total Crossmatch Specimens Tested** 

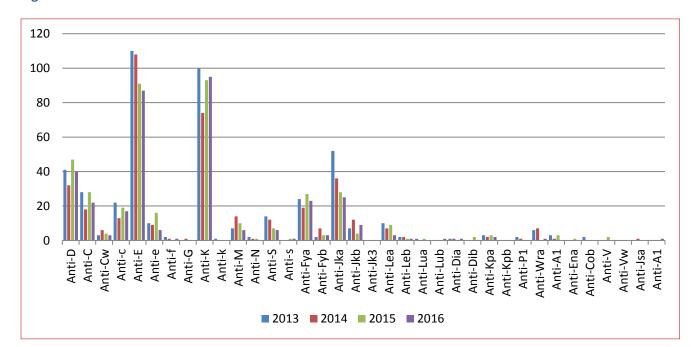
#### C. Antibodies Identified

In 2016, a total of 354 antibodies were reported (see *Table 6*). The total number of antibodies detected is slightly decreased from 2015, but the distribution of the most common antibodies remains consistent. Three hundred and one patients had antibodies identified, of these; thirty 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-Jk<sup>a</sup>, anti-Fy<sup>a</sup> and anti-C (see *Figure 5*) which together represented 82.5% of the total antibodies identified.

**Table 6: Total Number of Crossmatch Antibodies Detected** 

Antibody	Number Detected 2013	Number Detected 2014		
Anti-D	41	32	47	40
Anti-C	28	18	28	22
Anti-C <sup>w</sup>	3	6	4	3
Anti-c	22	13	19	17
Anti-E	110	108	91	87
Anti-e	10	9	16	6
Anti-f	2	1	0	1
Anti-G	0	1	0	0
Anti-K	100	74	93	95
Anti-k	1	0	0	0
Anti-M	7	14	10	6
Anti-N	2	1	1	0
Anti-S	14	12	7	6
Anti-s	0	0	1	1
Anti-Fy <sup>a</sup>	24	19	27	23
Anti-Fy <sup>b</sup>	2	7	3	3
Anti-Jk <sup>a</sup>	52	36	28	25
Anti-Jk <sup>b</sup>	7	12	4	9
Anti-Jk <sup>3</sup>	0	0	0	0
Anti-Le <sup>a</sup>	10	7	9	3
Anti-Le <sup>b</sup>	2	2	1	1
Anti-Lu <sup>a</sup>	1	0	1	0
Anti-Lu <sup>b</sup>	0	0	0	1
Anti-Di <sup>a</sup>	1	1	0	1
Anti-Di <sup>b</sup>	0	0	2	0
Anti-Kp <sup>a</sup>	3	2	3	2
Anti-Kp <sup>b</sup>	0	0	0	0
Anti-P <sub>1</sub>	2	1	0	0
Anti-Wr <sup>a</sup>	6	7	0	1
Anti-A <sub>1</sub>	3	1	3	0
Anti-En <sup>a</sup>	0	0	1	0
Anti-Co <sup>b</sup>	2	0	0	0
Anti-V	0	0	2	0
Anti-Vw	0	0	0	0
Anti-Jsa	0	1	0	0
Anti-A <sub>1</sub>	0	0	0	1
Total	455	385	401	354



**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 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.

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.

The total number of patient HLA and HPA antigen typing and antibody screen specimens and requests for selection of HLA/HPA matched platelet donors has increased significantly in the past year.

**Table 7: Platelet Immunology Specimens Tested** 

Specimen Type	Test Type	2012	2013	2014	2015	2016
Donor	HLA Antigen Typing	1,382	1,329	976	1,560	1,087
	HLA Antibody Screen/Identification	81	72	30	58	41
	HPA Antigen Typing	708	684	579	804	528
	HPA Antibody Screen/Identification	17	6	13	19	10
Patient	HLA Antigen Typing	1,038	1,129	1,143	1,116	1,392
	HLA Antibody Screen/Identification	97	89	99	108	144
	HPA Antigen Typing	130	132	120	261	302
	HPA Antibody Screen/Identification	178	165	200	321	432
	Selection of HLA/HPA Matched Platelet Donors	271	323	369	307	369
Test Totals		3,902	3,929	3,529	4,354	4,305

Figure 6: Total Platelet Immunology Donor Specimens Tested

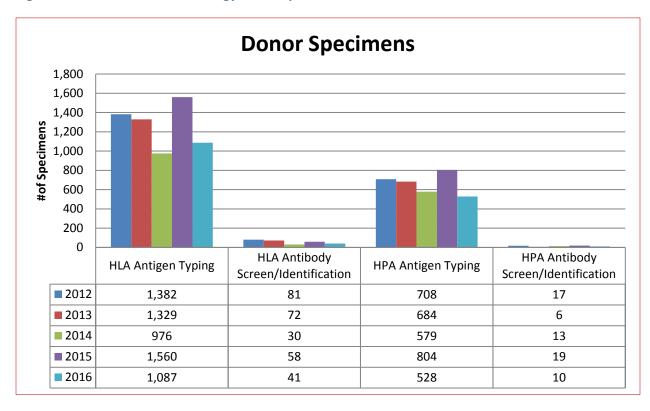
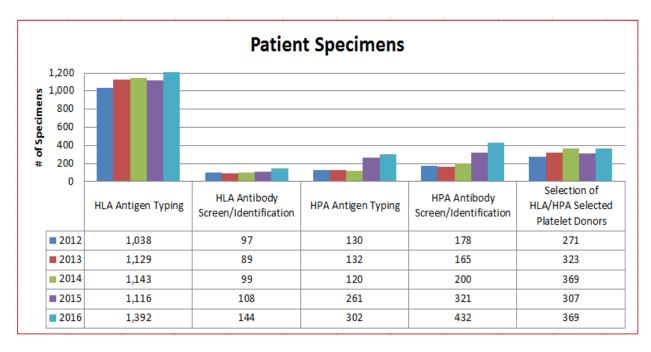


Figure 7: Total Platelet Immunology Patient Specimens Tested

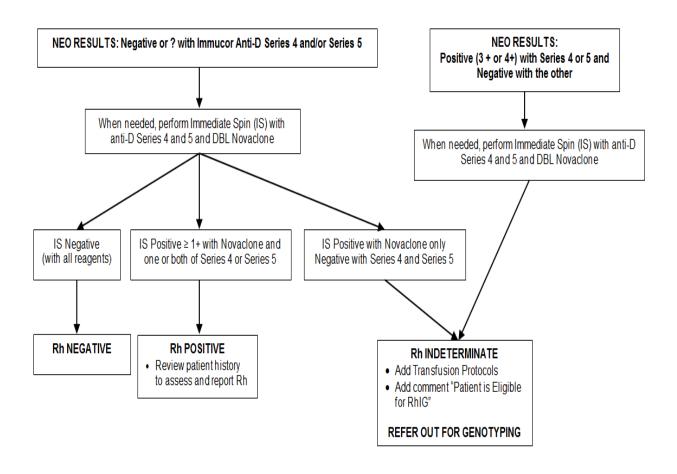


# **RED CELL GENOTYPING**

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 have a genetic testing for the RHD gene.

Figure 8: Rh D Testing Algorithm



For 2016, 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	DAU4 or DV type 5	Partial D	Not performed	Negative
3	RHD Deletion	-	Not performed	Negative
4	DAU4 or DV type 5	Partial D	Not performed	Negative
5	Weak D type 1	Weak D	Not performed	Positive
6	DVI (RhD*06)	Partial 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	RHD Deletion	-	Not performed	Negative
10	"Possible D" (may indicate presence of wild type RHD allele)	-	Not performed	Negative

# **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 Time

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.

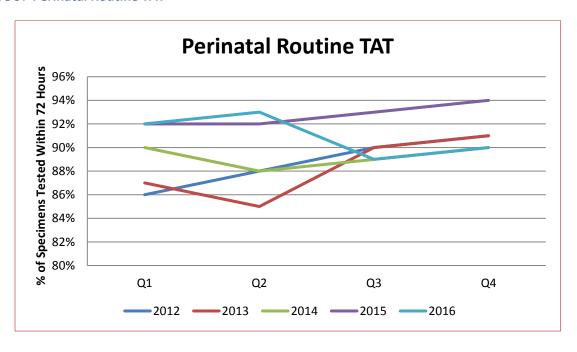
**Table 9: Turnaround Time – Routine Criteria by Specimen Type** 

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	2016
% of Specimens Tested within 72 hours	88.9%	88.3%	89.3%	92.3%	91%
% of Specimens Tested > 72 hours	11.1%	11.7%	10.7%	7.7%	9%

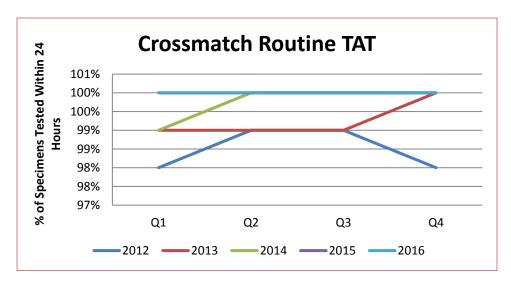
**Figure 9: Perinatal Routine TAT** 



**Table 11: Turnaround Time – Routine Crossmatch Specimens** 

Turnaround Time (TAT)	2012	2013	2014	2015	2016
% of Specimens Tested within 24 hours	98.6%	99.4%	99.6%	99.8%	99.8%
% of Specimens Tested > 24 hours	1.4%	0.6%	0.4%	0.2%	0.2%

**Figure 10: Crossmatch Routine TAT** 



**Table 12: Turnaround Time – Reference Specimens** 

Turnaround Time (TAT)	2012	2013	2014	2015	2016
% of Specimens Tested within 24 hours	96.5%	93.3%	96.8%	98.8%	98.5%
% of Specimens Tested > 24 hours	3.5%	6.7%	3.2%	1.2%	1.5%

Figure 11: Reference TAT

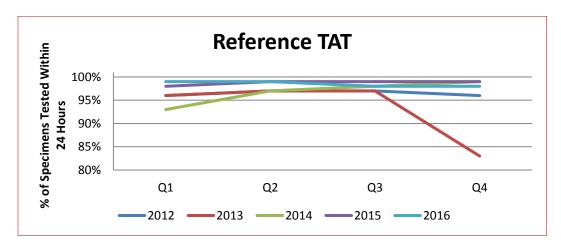
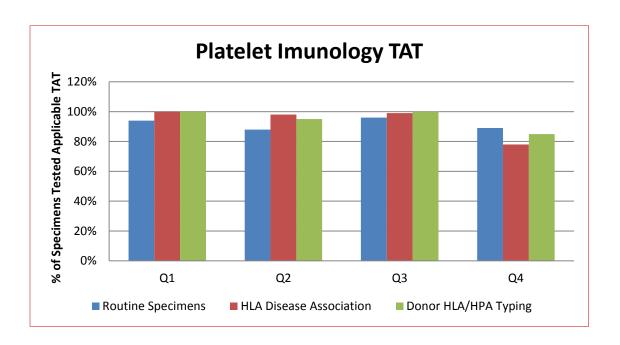


Table 13: Turnaround Time – Platelet Immunology Specimens

Turnaround Time (TAT)	2013	2014	2015	2016
% of Specimens Tested within 14 days	N/A	91.8%	94.5%	91.6%
% of Specimens Tested within 28 days	N/A	98.9%	96.8%	94.0%
% of Specimens Tested within 60 days	N/A	100%	100%	95.0%

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 3.4% in 2016 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, PHN or date of collection 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 remain low throughout 2016. The average rejection rates have decreased from a high of 2.9% in 2012 to 1.3% in 2016.

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.

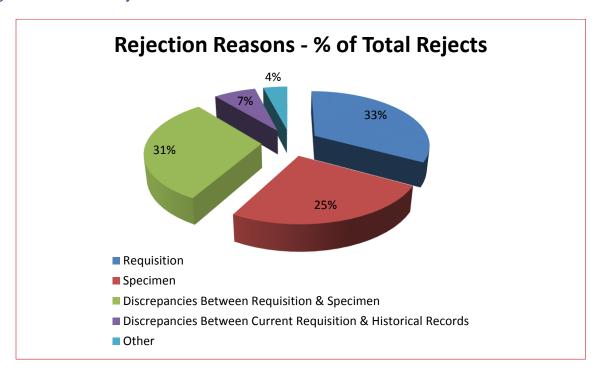
As previously mentioned, many specimens for crossmatch have already been rejected by the referring hospital laboratory and total numbers of these rejected specimens are not included in our data.

Table 16 describes the reasons for rejecting specimens in the Platelet Immunology Laboratory; the majority of which involve specimens. Eighty-four 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 2016. Average rejection rates have decreased from 11.8% in 2015 to 9.6% in 2016.

**Table 14: Quarterly Rejection Rates – Perinatal Specimens** 

Rejection Category	Q1	Q2	Q3	Q4
Requisition	99	98	94	102
Specimen	83	76	77	64
Discrepancies Between Requisition & Specimen	88	131	76	80
Discrepancies Between Current Requisition & Historical Records	25	13	18	27
Other (Duplicates, etc.)	2	3	27	19
Total # specimens rejected	297	321	292	292
Total # specimens received	9170	8446	8337	8686
Rejections as a % of total	3.2%	3.8%	3.5%	3.3%

**Figure 13: Perinatal Rejection Reasons** 



**Table 15: Quarterly Rejection Rates – Crossmatch Specimens** 

Rejection Category	Q1	Q2	Q3	Q4
Requisition	26	20	22	28
Specimen	55	66	111	105
Discrepancies Between Requisition & Specimen	67	92	56	71
Discrepancies Between Current Requisition & Historical Records	0	5	0	1
Other (Duplicates, etc.)	3	1	5	3
Total # specimens rejected	151	184	194	208
Total # specimens received	14,366	14,694	14,170	13,960
Rejections as a % of total	1.0%	1.3%	1.4%	1.5%

**Figure 14: Crossmatch Rejection Reasons** 

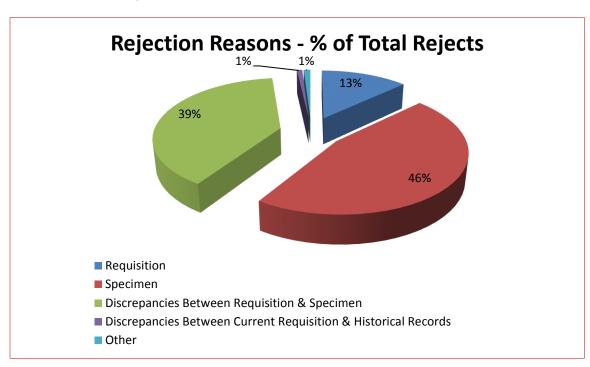
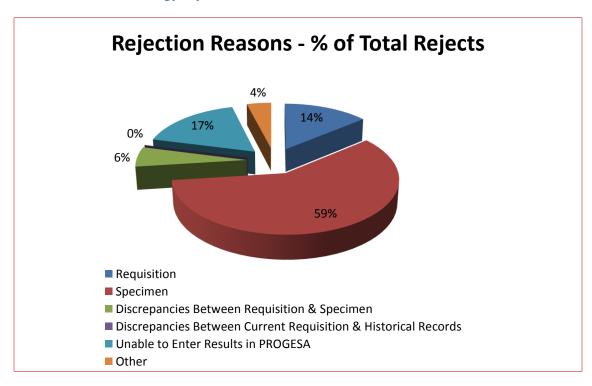


Table 16: Quarterly Rejection Rates – Platelet Immunology Specimens

Rejection Category	Q1	Q2	Q3	Q4
Requisition	15	11	5	7
Specimen	40	39	36	43
Discrepancies Between Requisition & Specimen	7	1	2	6
Discrepancies Between Current Requisition & Historical Records	0	0	0	0
Unable to Enter Results in PROGESA	15	21	3	7
Other (Duplicates, etc.)	0	5	4	0
Total # specimens rejected	77	77	50	63
Total # specimens received	740	720	645	652
Rejections as a % of total	10.4%	10.6%	7.7%	9.7%

Figure 15: Platelet Immunology Rejection Reasons



# **ACCOMPLISHMENTS IN 2016**

#### A. Automated Testing Instrument Upgrade

The Platelet Immunology Laboratory implemented the QIAxcel automated photo documentation system in June 2016.

#### **B.** Business Continuity Planning

Collaboration with the Manitoba Health Office of Provincial Transplant and Transfusion Services and Diagnostics Services Manitoba to ensure the Diagnostic Services plan meshes seamlessly with other plans was ongoing throughout the year. The Winnipeg Diagnostic Services plan is under revision.

#### 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 had an on-site inspection in July 2016 and met the requirements of the LAP Standards for Accreditation. Accreditation is granted for the 2 year period ending in July 2018.

## D. Electronically Fillable Platelet Immunology Requisition

In November 2016 an electronically fillable version of the Platelet Immunology PI.100 requisition was posted to the Diagnostic Services web section on <a href="https://www.blood.ca">www.blood.ca</a>.

#### E. Mis-transfusion Risk Reduction Strategy

The mis-transfusion risk reduction strategy was successfully implemented on April 4, 2016. Wide stakeholder consultation and education resulted in a smooth implementation that was seamless to the clinical units throughout the province and did not have any impact on the timely provision of blood components. The strategy was built around the issuing of group O, Rh compatible red blood cells to all patients with only one sample tested for ABO/Rh at the time transfusion was requested. This was controlled by the automatic application of a protocol to the patient file within the laboratory information system. Once a second confirmatory sample was tested for ABO/Rh, the protocol is removed and the patient would then receive group specific red cells. Monitoring of the utilization of additional group O red blood cells was added as a new key performance indicator.

#### F. Perinatal Advisory Committee

The Perinatal Advisory Committee for 2016 was held on June 13th and 14th. This year, the PNAC meeting was hosted in Winnipeg and was held in conjunction with a Grifol's Transfusion Science Education Course, which followed the PNAC meeting on June 15th and 16th.

The PNAC meeting covered a range of topics relevant to the CBS diagnostic and perinatal laboratories. Our agenda included a review of laboratory internal audits which allowed us to compare practice across laboratories and identify areas for improvement and standardization. Specific standardization initiatives related to the antibody investigation algorithm for prenatal patients, the strategy and algorithm used for assessment of serological weak D patients through genotyping, and recommendations related to standard

timing for prenatal sample testing were discussed. We developed a strategy for investigation of anti G in prenatal patients and discussed the feasibility of enhanced automated testing.

Results of projects from the prior year were also reviewed. These included the results of an audit amongst hospital transfusion services regarding the feasibility of using Kell negative phenotyped red cell units for transfusion to female patients of child bearing potential, as well as the results of a study into the utility of a new monoclonal anti Mia antibody.

In follow up to the 2016 meeting several projects have been selected for additional work. These include continued work on alignment of the algorithm for assessment for weak and partial D antigens by RHD genotyping. The second involves additional work on development and standardization of automated testing for passive anti D evaluation and the third major initiative chosen for additional work was the agreement on timing of sample testing for perinatal patients.

The PNAC meeting was followed by a one and one half day Grifol's Transfusion Science Education course. The course included a distinguished panel of speakers who covered diverse topics related to both blood group serology and the utility afforded by blood group genotyping. The education day was well attended by both local transfusion medicine staff and transfusion professionals from across Canada.

#### G. Revision of Transfusion Reaction Algorithm and Requisition

In collaboration with WRHA Blood Management Services and Diagnostic Services Manitoba the Transfusion Reaction Algorithm for nursing was revised and implemented in November 2016. The Diagnostic Services Transfusion Reaction Investigation CM105 requisition was also revised to ensure the congruency of the two documents.

# **GOALS FOR 2017**

#### A. Automated Testing Instrument Upgrade

The Platelet Immunology Laboratory will replace the Luminex $^{\circ}$  100 with Luminex $^{\circ}$  200 instrument. The BioArray<sup>TM</sup> Automated Imaging System HPA BeadChip<sup>TM</sup> for platelet genotyping is expected to be implemented in the fall of 2017.

#### B. College of American Pathologists (CAP) Laboratory Accreditation

An on-site inspection of the Platelet Immunology Laboratory is anticipated to occur in the beginning of 2017.

#### C. Diagnostic Services Web Page Redesign

All Diagnostic Services sites (Vancouver, Edmonton, Regina, Winnipeg, Brampton) will collaborate in a project to redesign and refresh the current Diagnostic Services webpages on <a href="www.blood.ca">www.blood.ca</a> that will include new features and information which will make the site more user friendly for hospital customers.

#### 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. A project team will continue to prepare the documentation required for a Health Canada submission.

## E. 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 the recommendations of the National Advisory Committee on Blood and Blood products (NAC).

## F. Strategy for the Provision of Small Volume Pediatric Red Blood Cell Units

Investigation into the feasibility of providing small volume red cell units for neonatal transfusion is planned for 2017.

## G. Strategy for the Reduction of Platelet Discards

Collaboration with Diagnostic Services Manitoba to develop a strategy to reduce platelet discards at an urban and rural hospital is planned for 2017.