



Canadian Blood Services  
Soci t  canadienne du sang

DIAGNOSTIC SERVICES  
**SASKATCHEWAN**  
YEAR IN REVIEW  
JANUARY – DECEMBER 2014

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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## 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
- Direct Antiglobulin Test for detection of HDFN (Hemolytic Disease of the Fetus/Newborn)

### 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 again at 18-20 weeks, then every four weeks until 32 weeks gestation. Samples should then be submitted every two weeks until delivery.

**Newborns (Cords)** Cord blood or neonatal samples may be submitted for testing. ABO/Rh and direct antiglobulin testing is performed on the samples.

**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.

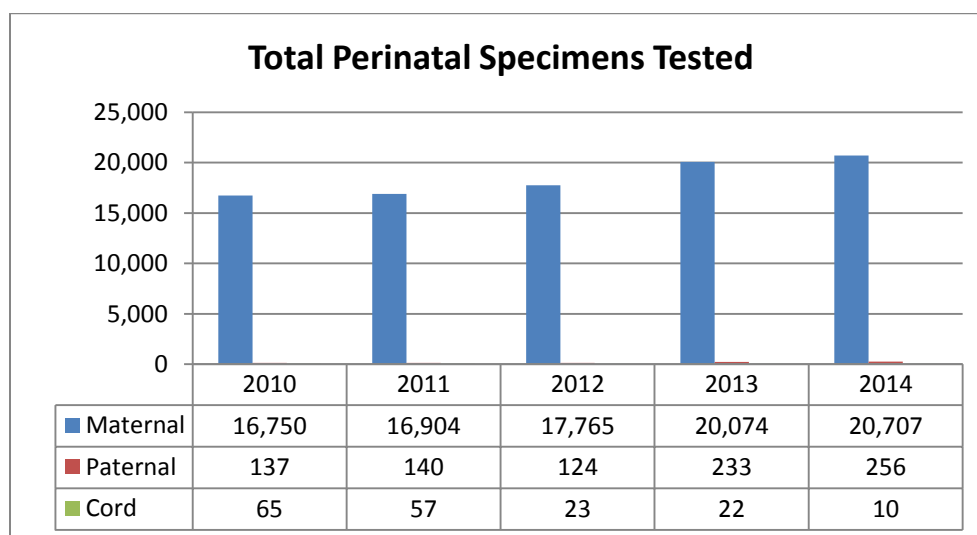
### C. Specimens Tested

The data includes all women tested, including referrals.

**Table 1: Perinatal Specimens Tested**

Specimen Type	Test Type	2010	2011	2012	2013	2014
Maternal	Type and Screen	16,750	16,904	17,765	20,074	20,707
Paternal	ABO/Rh	137	140	124	233	256
Cord	ABO/Rh	65	57	23	22	10
<b>Total # of Specimens Tested</b>		<b>16,952</b>	<b>17,101</b>	<b>17,912</b>	<b>20,329</b>	<b>20,973</b>
<b>Total # of Patients Tested</b>		<b>N/Av</b>	<b>N/Av</b>	<b>14,989</b>	<b>16,925</b>	<b>17,450</b>

**Figure 1: Total Perinatal Specimens Tested**



**D. Antibodies Identified**

In 2014, a total of 172 antibodies were reported (see *Table 2*). This is slightly higher than 2013. One hundred and forty-four women had antibodies identified during their pregnancies, of these; twenty-seven women had multiple antibodies.

Antibodies identified were considered to be clinically significant if they have been reported to cause HDFN. The most common clinically significant antibodies identified were: anti-E, anti-K, anti-D, anti-C, and anti-c which together represented 63.4% 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 28 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**

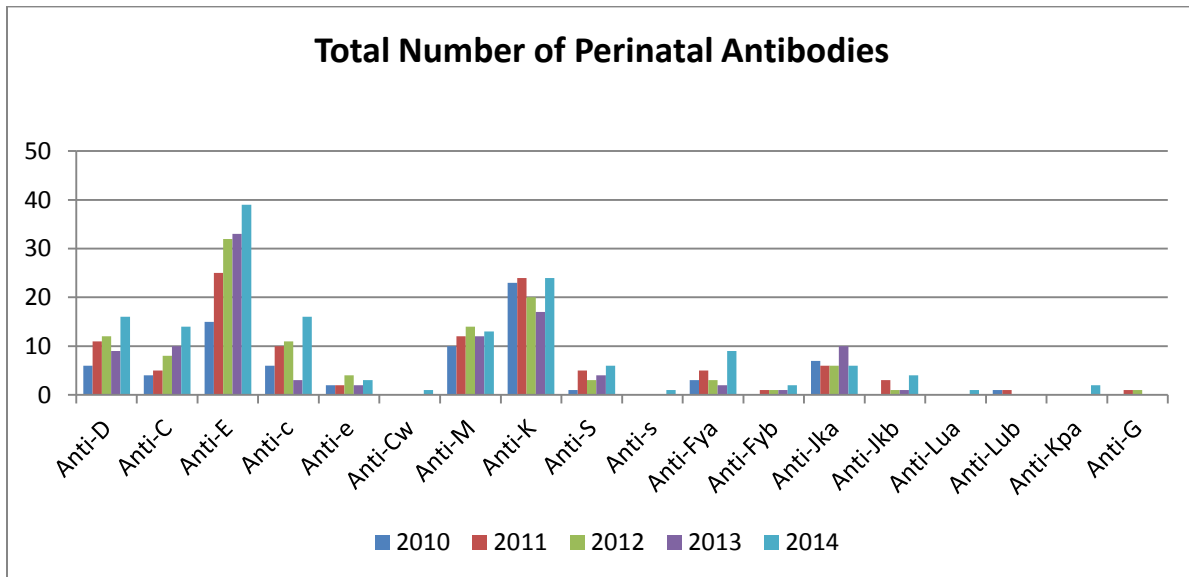
<b>Maternal Antibodies Identified (Including Passive Anti-D) – 2014</b>					
<b>Clinically <u>Significant</u> Antibodies - Antibody</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>
Anti-D	6	11	12	9	16
Anti-C	4	5	8	10	14
Anti-E	15	25	32	33	39
Anti-c	6	10	11	3	16
Anti-e	2	2	4	2	3
Anti-Cw					1
Anti-M	10	12	14	12	13
Anti-K	23	24	20	17	24
Anti-S	1	5	3	4	6
Anti-s					1
Anti-Fya	3	5	3	2	9
Anti-Fyb		1	1	1	2
Anti-Jka	7	6	6	10	6
Anti-Jkb		3	1	1	4
Anti-Lua					1
Anti-Lub	1	1			
Anti-Kpa					2
Anti-G		1	1		
Passive Anti-D			156	123	156
<b>Clinically <u>Insignificant</u> Antibodies - Antibody</b>	<b>2010/11</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>
Anti-Lea	4	9	7	10	12
Anti-Leb		1	1	1	2
Anti-N				2	1



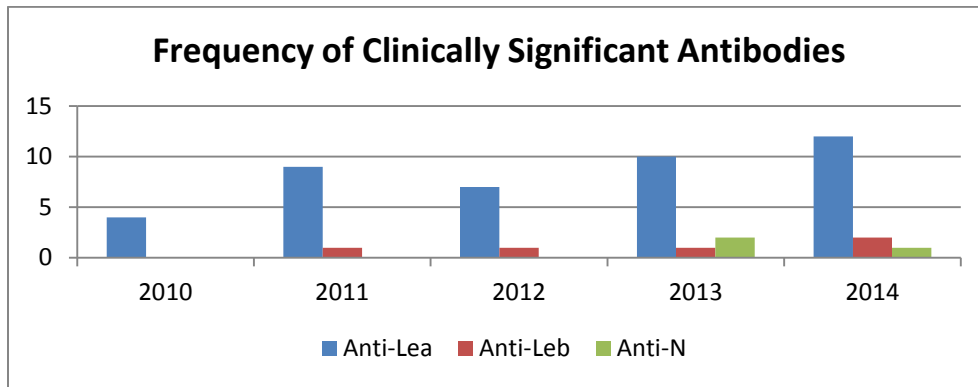
**Table 3: Perinatal Patient Antibody Titres**

Antibody	Critical Level	Non-Critical Level	Non-Critical to Critical
Anti-D	7	11	4
Anti-C		6	
Anti-E	4	27	1
Anti-c		5	
Anti-e		2	
Anti-DC	3	3	1
Anti-DE		1	
Anti-Ec	2	4	1
Anti-Ce		3	
Anti-G			
Anti-K	8	4	1
Anti-Fya	3	3	
Anti-Fyb		1	
Anti-Jka		6	
Anti-Jkb		4	
Anti-M	1	6	1
Anti-S		2	

**Figure 2: Total Number of Perinatal Antibodies**



**Figure 3: Frequency of Clinically Significant Antibodies**



**Table 4: Combination Antibodies**

Antibodies	Number in 2014
Anti-C Anti-D	3
Anti-C Anti-D Anti-E	1
Anti-C Anti-D Anti-E Anti-Lea	1
Anti-c Anti-E	5
Anti-C Anti-e	2
Anti-c Anti-E Anti-Fya Anti-K Anti-s	1
Anti-c Anti-E Anti-Jka	1
Anti-C Anti-e Anti-K	1
Anti-C Anti-K	1
Anti-Cw Anti-K	1
Anti-D Anti-E Anti-Jkb	1
Anti-D Anti-E Anti-K	1
Anti-E Anti-Fya	1
Anti-E Anti-K	1
Anti-E Anti-S	2
Anti-Fya Anti-Jkb	1
Anti-K Anti-Kpa	2
Anti-Lea Anti-Leb Anti-M	1

## CROSSMATCH / REFERENCE LABORATORY

The Crossmatch/Reference Laboratory within Diagnostic Services provides testing to (update with your demographic information)

### 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
- Phenotyping (patient and donor units)
- Transfusion Reaction Investigation
- Direct Antiglobulin Test
- Elution and Absorption
- Cold Agglutinin Screen

Antibody screening and identification is routinely performed by tube testing using PEG for enhancement.

Crossmatched blood components are distributed through the Diagnostic Services Laboratory to those hospitals which receive all of their transfusion medicine services from Canadian Blood Services. Hospitals which provide transfusion medicine services directly receive all of their blood components through the Product and Hospital Services area at Canadian Blood Services.

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

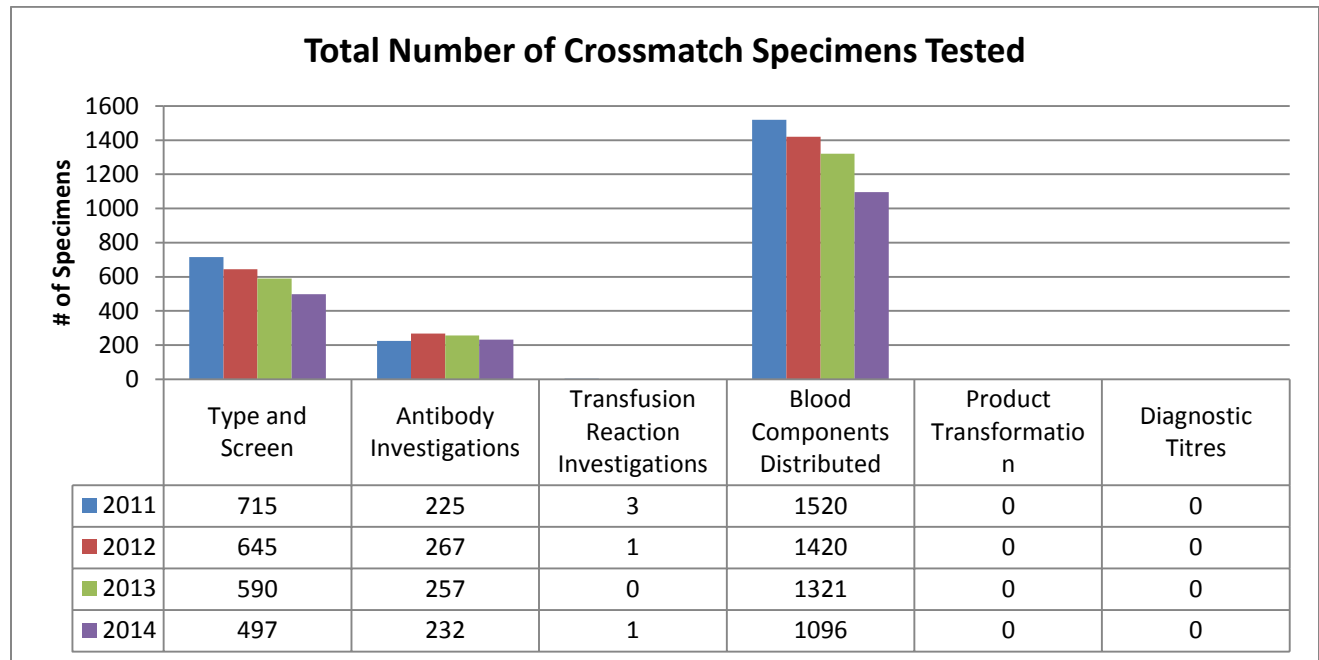
### B. Specimens Tested

The data in this report reflects a calendar year period to enable better correlation to other government statistical data. The total number of crossmatch specimens tested has shown a slight decrease over the past four years.

**Table 5: Crossmatch/Reference Specimens Tested**

Specimen Type	Test Type	2011	2012	2013	2014
Crossmatch/Reference	Type and Screen	715	645	590	497
	Antibody Investigations	225	267	257	232
	Transfusion Reaction Investigations	3	1	0	1
	Blood Components Distributed	1520	1420	1321	1096
<b>Test Totals (excluding components distributed)</b>		<b>943</b>	<b>913</b>	<b>847</b>	<b>730</b>
<b>Number of Patients Tested</b>		<b>N/Av</b>	<b>346</b>	<b>328</b>	<b>262</b>

Figure 4: Total Crossmatch Specimens Tested



**C. Antibodies Identified**

In 2014, a total of 75 antibodies were reported (see *Table 6*). The total number of antibodies detected is moderately higher than in 2013, but the distribution of the most common antibodies remains consistent.

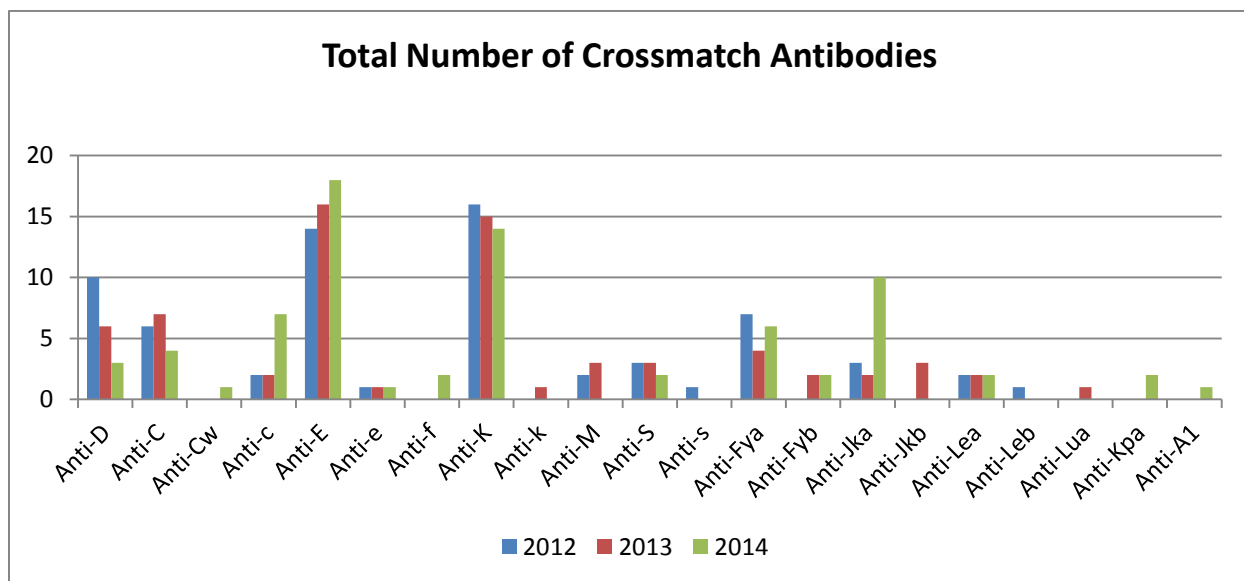
Antibodies identified were considered to be clinically significant if they have been reported to cause acute or delayed hemolytic transfusion reactions. The most common clinically significant antibodies identified were: anti-E, anti-K, anti-Jk<sup>a</sup>, anti-c and anti-Fy<sup>a</sup> (see *Figure 5*) which together represented 73.3% of the total antibodies identified.

Table 6: Total Number of Crossmatch Antibodies Detected

Antibody	Number Detected 2012	Number Detected 2013	Number Detected 2014
Anti-D	10	6	3
Anti-C	6	7	4
Anti-C <sup>w</sup>			1
Anti-c	2	2	7
Anti-E	14	16	18
Anti-e	1	1	1
Anti-f			2
Anti-K	16	15	14

Anti-k		1	
Anti-M	2	3	
Anti-S	3	3	2
Anti-s	1		
Anti-Fy <sup>a</sup>	7	4	6
Anti-Fy <sup>b</sup>		2	2
Anti-Jk <sup>a</sup>	3	2	10
Anti-Jk <sup>b</sup>		3	
Anti-Le <sup>a</sup>	2	2	2
Anti-Le <sup>b</sup>	1		
Anti-Lu <sup>a</sup>		1	
Anti-Kp <sup>a</sup>			2
Anti-A <sub>1</sub>			1
<b>Total</b>	<b>68</b>	<b>65</b>	<b>75</b>

Figure 5: Total Number of Crossmatch Antibodies



## FETAL GENOTYPING

Canadian Blood Services in Alberta has been referring out specimens for fetal genotyping (by amniocyte DNA testing) to the Blood Centre of Wisconsin for several years. We have also begun to refer specimens to the International Blood Group Reference Laboratory (NHS) in Bristol, England, as they can detect fetal DNA in maternal plasma.

Specimens are submitted through the Maternal Fetal Medicine clinics in Edmonton or Calgary and are accepted if they meet the following criteria:

- The mother has an antibody capable of causing hemolytic disease of the fetus/newborn (HDFN), AND
- The father is heterozygous for the corresponding antigen (or unknown), AND
- The antibody titre has reached a critical level, OR
- There has been a previous fetus/newborn affected by HDFN, OR
- The antibody is anti-K, OR
- Amniocentesis is being performed for another indication (ie advanced maternal age), even if the mother's antibody titre is at a non-critical level.

Discussion with a Canadian Blood Services physician is required prior to submitting specimens for testing outside of these criteria.

The number of specimens referred for fetal genotyping has ranged between two and eight specimens in recent years.

Based on the following testing algorithm patients with a serologically variable Rh D typing results may have a genetic testing for the RHD gene. For 2014, the following results were obtained in patients using one of the two Red Cell antigen genotyping platforms available at CBS:

Figure 6: Rh D Testing Algorithm

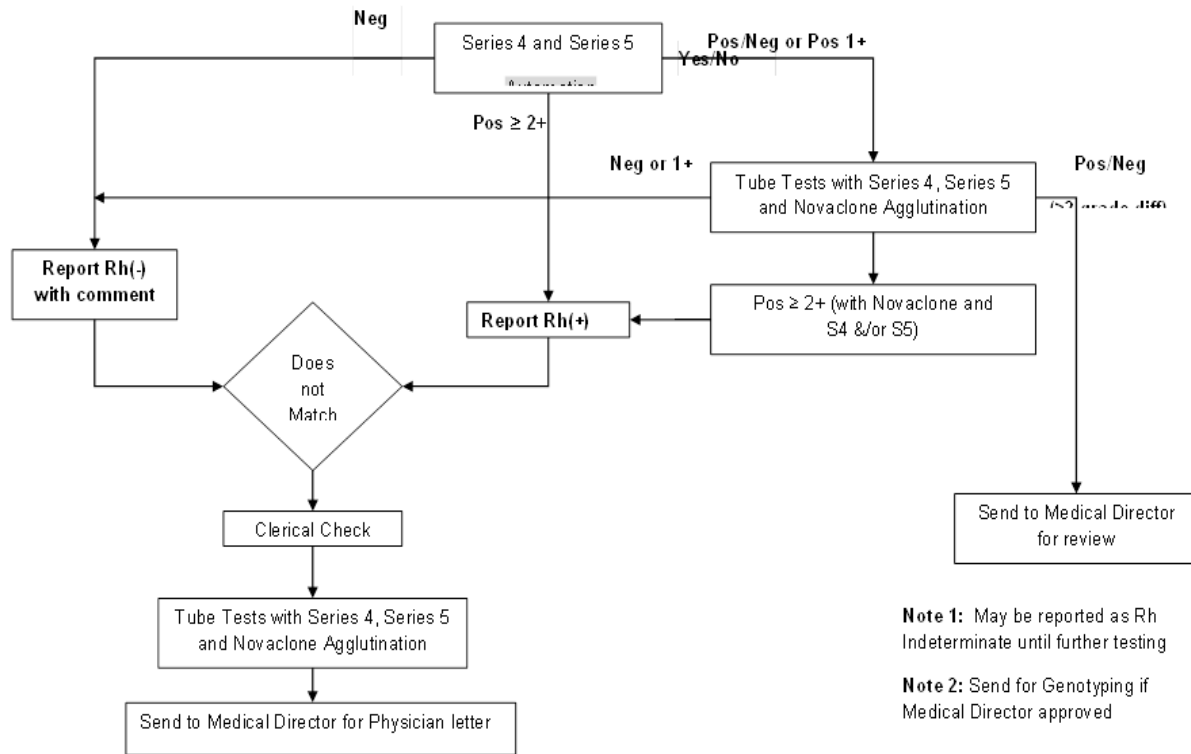


Table 7: Patient # - RHD Type/Result

Patient	RHD Genotype	Predicted Phenotype	RHD Sequencing	Rh Group
1	Weak D type 3	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

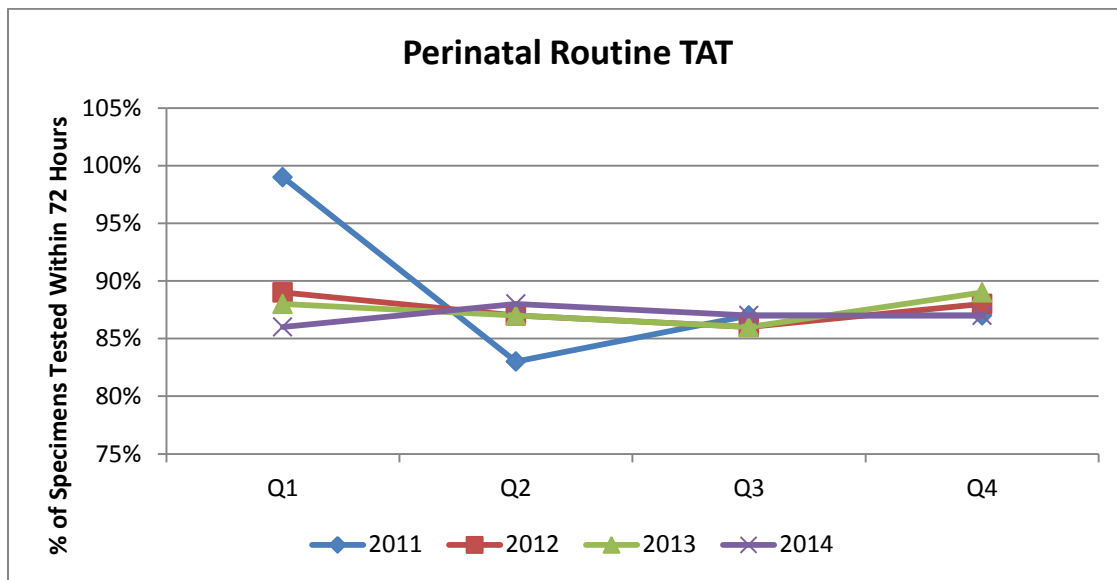
To ensure timely reporting of patient test results, Canadian Blood Services monitors turnaround time (TAT) from when the specimen is received at Canadian Blood Services in Regina to the time when the results are available. Since monitoring of this quality indicator began in 2008, the percentage of

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 8: 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%
Routine Crossmatch Specimens	24 hours	85%
Reference Specimens	72 hours	75%

**Figure 7: Perinatal Routine TAT**



**Table 9: Turnaround Time – Routine Perinatal Specimens**

Turnaround Time (TAT)	2011	2012	2013	2014
% of Specimens Tested within 72 hours	89%	87.5%	87.5%	87%
% of Specimens Tested > 72 hours	11%	12.5%	12.5%	13%



Figure 8: Crossmatch Routine TAT

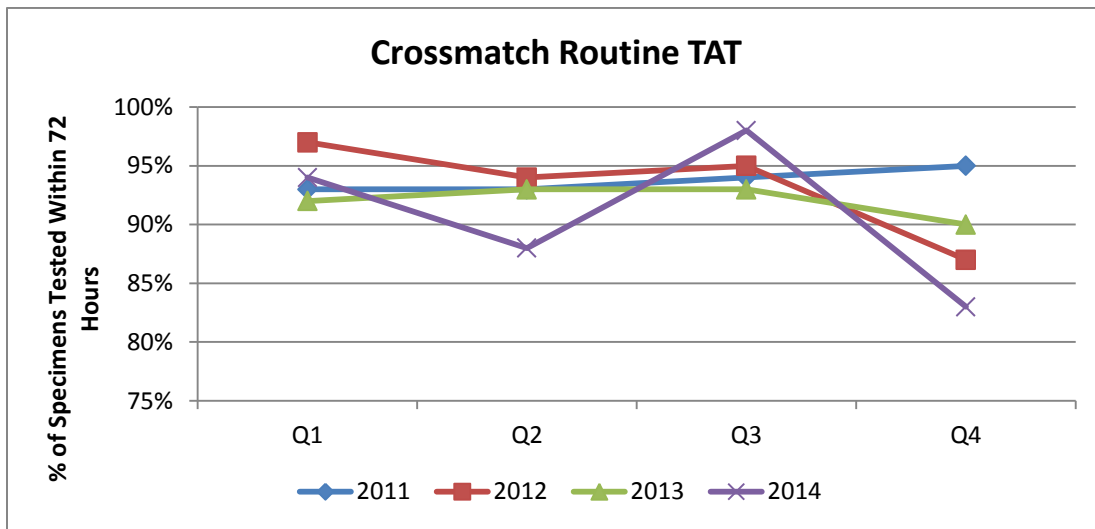
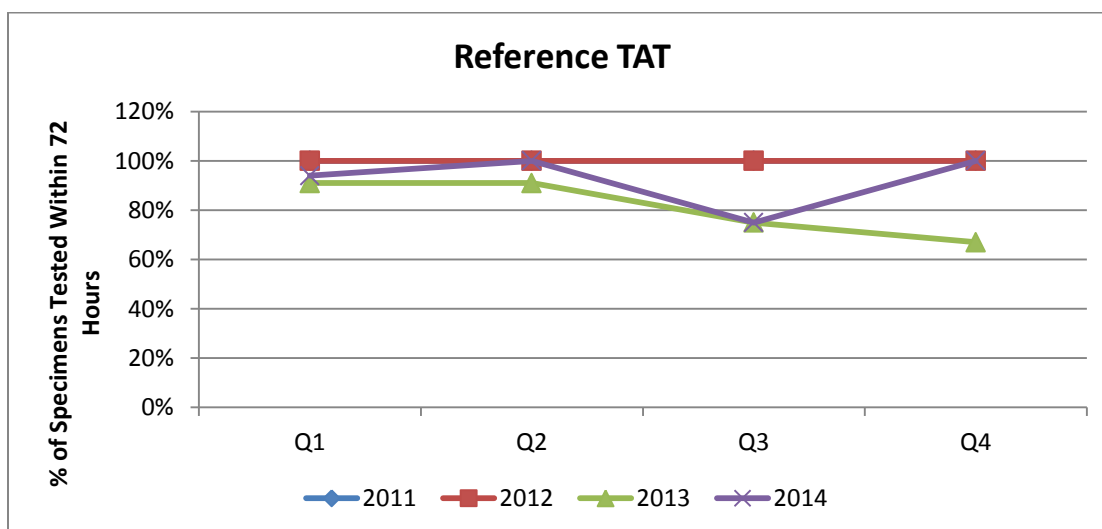


Table 10: Turnaround Time – Routine Crossmatch Specimens

Turnaround Time (TAT)	2011	2012	2013	2014
% of Specimens Tested within 72 hours	93.75%	93.25%	92%	90.75%
% of Specimens Tested > 72 hours	6.25%	6.75%	8%	9.25%

Figure 9: Turnaround Time – Reference Specimens



**Table 11: Reference TAT**

Turnaround Time (TAT)	2011	2012	2013	2014
% of Specimens Tested within 72 hours	100%	100%	81%	92.25%
% of Specimens Tested > 72 hours	0%	0%	19%	7.75%

**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 13*, the reasons for rejecting specimens in the Perinatal Laboratory are distributed similarly between problems with requisitions and discrepancies between the requisition and the specimen. Also, a number of samples fell outside of the testing criteria, having been tested within the current pregnancy (Other category). Average rejection rates have continued to decrease from 2.6% in 2012 to 1.75% in 2013 to 1.75% in 2014 which correlates with increased efforts to contact customers and educate them on acceptable labelling criteria.

*Table 14* describes the reasons for rejecting specimens in the Crossmatch Laboratory. The majority are due to test cancellation (Other category). Problems with requisition and specimen labelling are rare occurrences.

**Table 12: Quarterly Rejection Rates – Perinatal Specimens**

Rejection Category	Q1	Q2	Q3	Q4
Requisition	21	13	9	31
Specimen	60	10	10	15
Discrepancies Between Requisition & Specimen	18	20	20	28
Discrepancies Between Current Requisition & Historical Records	2	10	1	8
Other	26	13	37	15
Total # specimens rejected	127	66	77	97
Total # specimens received	5480	5235	5127	5164
<b>Rejections as a % of total</b>	<b>2.3%</b>	<b>1.3%</b>	<b>1.5%</b>	<b>1.9%</b>

Figure 10: Perinatal Rejection Reasons

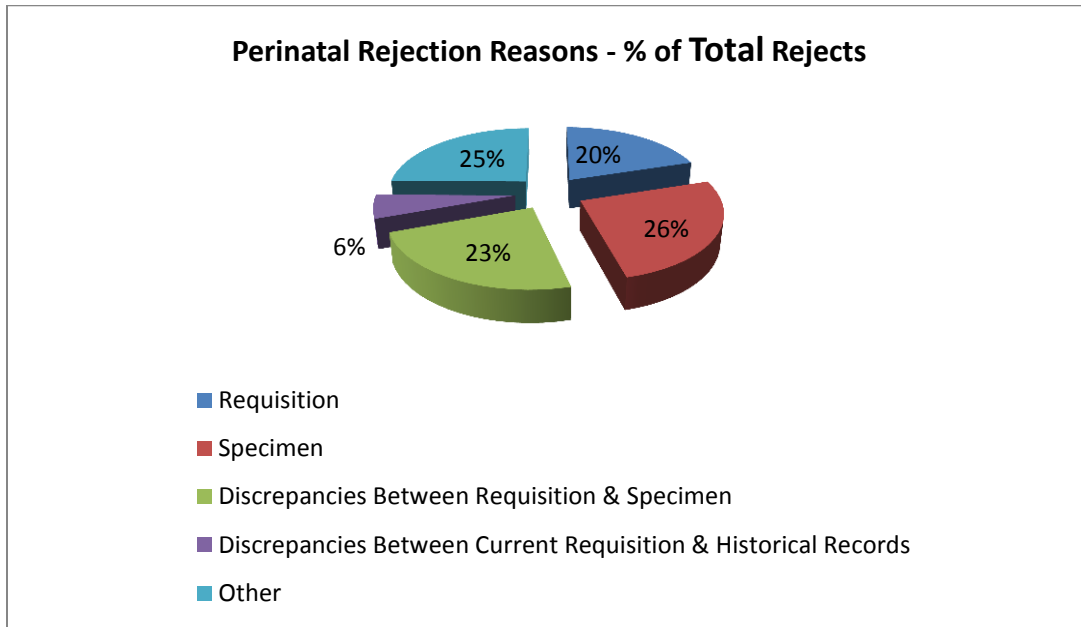
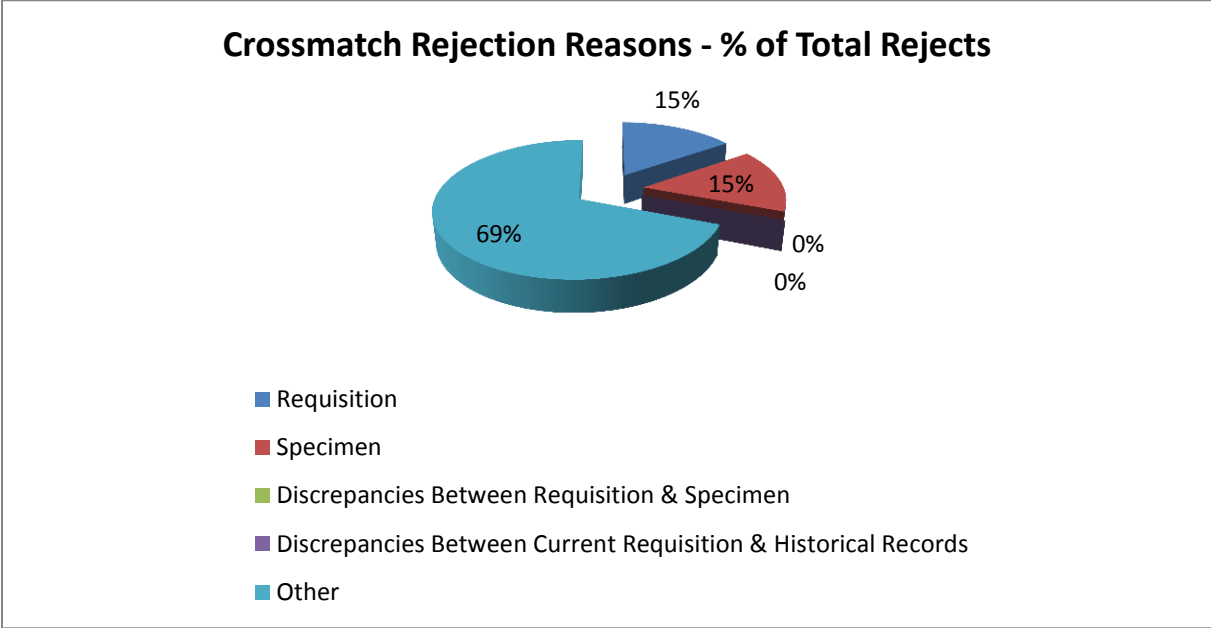


Table 13: Quarterly Rejection Rates – Crossmatch Specimens

Rejection Category	Q1	Q2	Q3	Q4
Requisition	0	0	1	1
Specimen	0	1	0	1
Discrepancies Between Requisition & Specimen	0	0	0	0
Discrepancies Between Current Requisition & Historical Records	0	0	0	0
Other	1	3	3	2
Total # specimens rejected	1	4	4	4
Total # specimens received	123	144	119	127
<b>Rejections as a % of total</b>	<b>0.8%</b>	<b>2.8%</b>	<b>3.4%</b>	<b>3.1%</b>

Figure 11: Crossmatch Rejection Reasons



## ACCOMPLISHMENTS IN 2014

### A. Automated Testing Instrument Upgrade

In 2013 the Diagnostic Services Red Cell Serology sites (Vancouver, Edmonton, Regina and Winnipeg) upgraded the Galileo instruments to the second generation Galileo NEO. This instrument is used for ABO/Rh typing, antibody screening and antibody identification for perinatal samples. Regina's instrument was validated and implemented in the Diagnostic Services Laboratory in May of 2013.

### B. Genotyping – Red Cell

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

### C. Perinatal Advisory Committee

The PNAC held their annual meeting on April 29 and 30, 2015 in Edmonton. Attendees included the Director, Testing, the Associate Director, Diagnostic Services and the Associate Medical Director, Clinical Services for CBS. The Medical Officers and Managers for the CBS Diagnostic Services Laboratories across the country and representatives from the CBS National Reference Laboratory (NIRL) in Ottawa as well as guests from user hospitals were also in attendance. The meeting included an overview of Diagnostic Services activities over the past year, and discussion of procedures and quality issues affecting these laboratories.

Highlights of the two day meeting include the following:

- Human platelet antigen and antibody testing has been consolidated in the CBS Platelet Immunology Laboratory in Winnipeg and subsequent to this, an increase in test volumes has been observed. This laboratory has obtained College of American Pathologists (CAP) accreditation.
- Roll-out of the Trace Line hospital module has been completed in Manitoba.
- All testing services operating under the CBS umbrella have been consolidated into a single management structure.
- Genotyping using the Immucor BioArray BeadChip system was implemented in June 2014. Discussion occurred around the reporting and management of patients with weak D types 4.0, 4.1 and 4.3 in the context of a recent article by S. G. Sandler on behalf of the AABB/CAP Working Group on RHD Genotyping (Sandler SG et al. Transfusion March 2015; 55:680-689).
- Discussion occurred around expanding availability of testing for fetal DNA using maternal blood samples to provinces outside Alberta where this process is already in place.
- Report comments for anti-M in pregnancy was discussed in light of a recent article suggesting that this antibody rarely causes severe hemolytic disease of the fetus and newborn (HDFN) and/or delayed anemia in affected infants, particularly with patients of Asian extraction (Yasuda H et al. Transfusion Medicine Reviews 2014; 28: 1-6).

## GOALS FOR 2015

### **A. Automated Antibody Screen Investigation Algorithm**

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

### **B. Perinatal Advisory Committee (PNAC)**

Continue to participate in the Canadian Blood Services PNAC in order to identify and implement “best practices” in perinatal laboratory testing.

### **C. Saskatchewan Laboratory Result Repository (SLRR)**

Continue discussions around the process of downloading Canadian Blood Services test results directly into SLRR.

### **D. Talent Management**

Continue the Talent Management review in order to perform succession planning.

### **E. Continuing Education**

Support continuing education by providing presentations at Provincial symposiums and conferences.

### **F. Restructure Laboratory Services**

Participate with MOH, 3S Health and Regional Health Authorities in discussions related to restructuring provincial laboratory services. Discussions will include transfer of the crossmatch services to RHAs and potential relocation of the perinatal testing program.

### **G. DNA Testing**

Work with MOH and MSM physicians to introduce maternal fetal DNA testing for selected high risk pregnancies.