Canadian Blood Services
Société canadienne du sang

DIAGNOSTIC SERVICES

Alberta

YEAR IN REVIEW

JANUARY – DECEMBER 2015

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

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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
- 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)

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 three to four weeks for the duration of the pregnancy depending 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 or the specimen is too old to test by the routine rosette method used for fetal bleed screening.

Newborns (Cords) Cord blood or neonatal specimens must be submitted with the mother's specimen as noted above. ABO/Rh testing is performed on all cord and neonatal specimens submitted. 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.

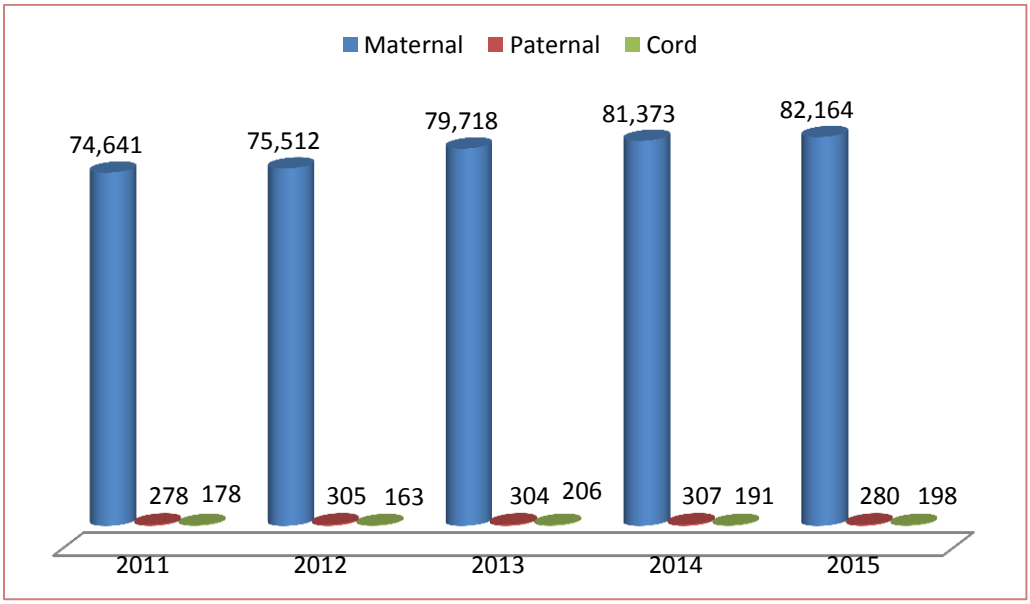
C. Specimens Tested

The data includes all women tested, including referrals.

Table 1: Perinatal Specimens Tested

Specimen Type	Test Type	2011	2012	2013	2014	2015
Maternal	Type and Screen	74,641	75,512	79,718	81,373	82,164
Paternal	ABO/Rh	278	305	304	307	280
Cord	ABO/Rh	178	163	206	191	198
Total # of Specimens Tested		**75,097**	**75,980**	**80,228**	**81,871**	**82,719**
Total # of Patients Tested		**N/Av**	**63,277**	**68,877**	**67,618**	**68,657**

Figure 1: Total Perinatal Specimens Tested



D. Antibodies Identified

In 2015, a total of 400 antibodies were reported (see *Table 2*). This is lower than 2014. Three hundred and forty-eight (348) women had antibodies identified during their pregnancies, and of these, forty-five (45) 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-D, anti-K, anti-c and anti-Jka which together represented 75.9% of the total antibodies identified.

Titres for 23 of the clinically significant antibodies increased from non-critical to critical levels during the pregnancy with a total of 43 antibody titres at critical levels (see *Table 3*). Recommendations were made for all patients with a critical titre level (current or previous pregnancy including all Kell system antibodies) to be referred to a Maternal-Fetal Medicine Clinic for further follow-up and monitoring during pregnancy.

Table 2: Total Number of Perinatal Antibodies Detected

Maternal Antibodies Identified (Including Passive D)					
Clinically Significant Antibodies - Antibody	**2011**	**2012**	**2013**	**2014**	**2015**
Anti-D	53	48	66	67	49
Passive Anti-D	648	702	791	1,119	633
Anti-C	11	0	30	31	17
Anti-Cw	2	1	3	1	2
Anti-Ce	3	0	0	0	0
Anti-c	39	45	70	59	41
Anti-E	112	80	134	117	91
Anti-e	9	10	15	15	13
Anti-f	0	0	0	0	0
Anti-G		0	3	2	3
Anti-K	65	50	77	65	46
Anti-S	11	10	17	16	14
Anti-s	2	0	1	1	3
Anti-U	1	0	0	1	1
Anti-Fya	10	9	10	11	18
Anti-Fyb	2	1	0	3	2
Anti-Jka	35	28	41	50	34
Anti-Jkb	6	5	10	6	4
Anti-JK3	0	0	0	1	1
Anti-Lua	1	3	3	2	0
Anti-Lub	4	3	4	1	1
Anti-V	1	0	1	1	0
Anti-Vw	0	0	1	0	0
Anti-Dia	1	0	0	1	1
Anti-Kpa	0	0	1	1	1
Anti-Wra	1	0	11	9	2
Total	**1017**	**995**	**1289**	**1580**	**977**

Clinically Insignificant Antibodies - Antibody	**2011**	**2012**	**2013**	**2014**	**2015**
Anti-A1	10	6	3	9	8
Anti-Lea	19	12	15	20	6
Anti-Leb	2	1	6	1	1
Anti-M	42	33	40	44	37
Anti-N	1	0	0	2	1
Anti-P1	1	1	0	0	3
Total	**75**	**53**	**64**	**76**	**56**

Table 3: Perinatal Patient Antibody Titres

Antibody	Critical Level	Non-Critical Level	Non-Critical to Critical
Anti-D	22	49	12
Anti-C	0	23	0
Anti-E	9	85	3
Anti-c	4	51	4
Anti-e	0	13	0
Anti-DC	0	0	0
Anti-DE	0	0	0
Anti-Ec	0	0	0
Anti-Ce	0	3	0
Anti-G	0	2	0
Anti-K	1	2	0
Anti-Fya	4	9	2
Anti-Fyb	0	2	0
Anti-Jka	1	45	1
Anti-Jkb	0	6	0
Anti-M	1	33	0
Anti-S	1	15	1
Anti-s	0	1	0

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

Figure 2: Total Number of Perinatal Antibodies

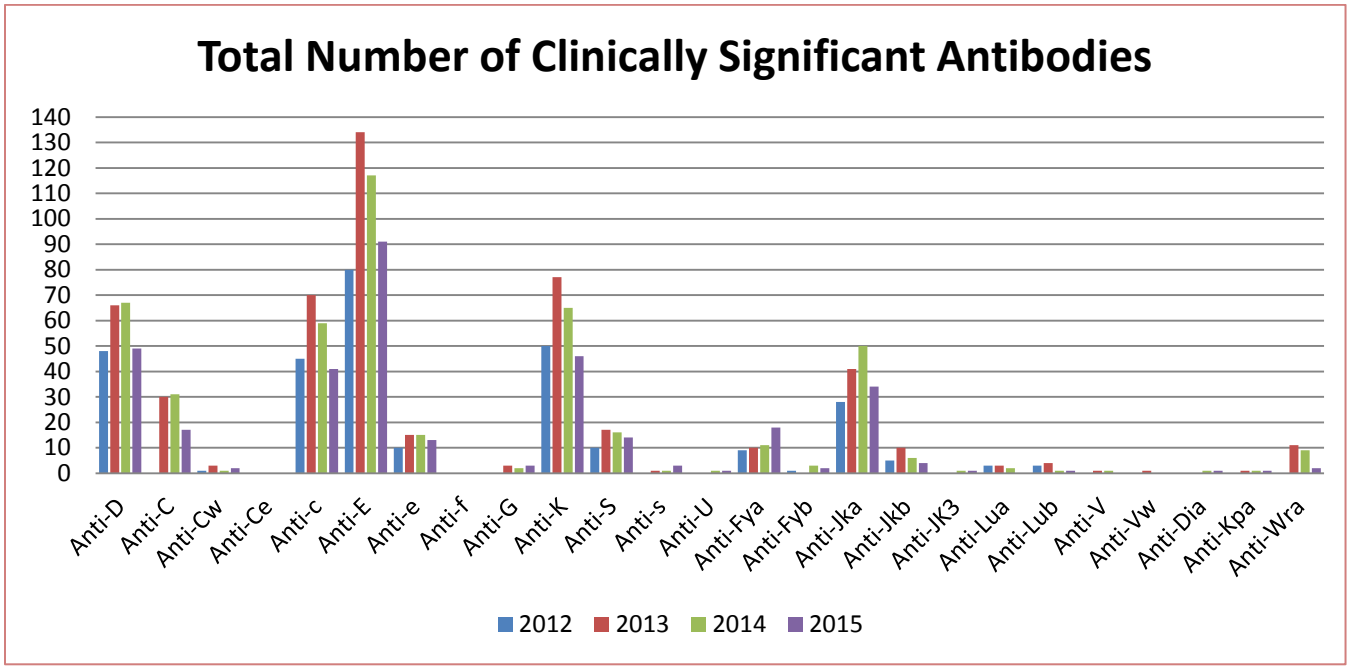


Figure 3: Frequency of Clinically Significant Antibodies

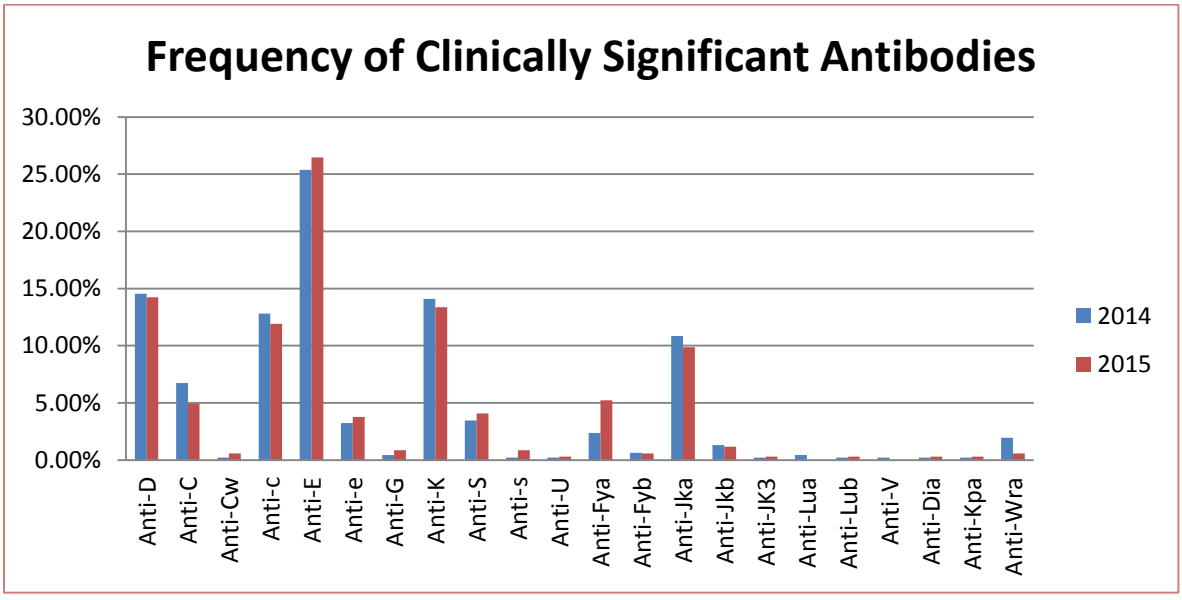


Table 4: Combination Antibodies

Antibodies	Number in 2015
Anti-c Anti-Cw Anti-E	1
Anit-c Anti-Cw Anti-K	1
Anti-C Anti-D	5
Anti-C Anti-D Anti-Dia	1
Anti-C Anti-D Anti-Fya	2
Anti-C Anti-D Anti-G	1
Anti-C Anti-e	2
Anti-c Anti-E	10
Anti-C Anti-G	2
Anti-c Anti-Jka	1
Anti-c Anti-K	1
Anti-D Anti-Jka	1
Anti-D Anti-Wra	1
Anti-E Anti-Jka	3
Anti-E Anti-K	1
Anti-E Anti-S	2
Anti-E Anti-Wra	1
Anti-Fya Anti-Jka	1
Anti-Fyb Anti-Jka	1
Anti-Jka Anti-E	1
Anti-Jka Anti-s	2
Anti-Jkb Anti-S	1
Anti-K Anti-Kpa	1
Anti-K Anti-Lea	1
Anti-K Anti-M	1

CROSSMATCH / REFERENCE LABORATORY

The Crossmatch/Reference Laboratory within Diagnostic Services at Canadian Blood Services provides transfusion medicine services (Crossmatch) for 24 hospitals in northern Alberta, 2 in the Northwest Territories and 1 in Nunavut that currently do not routinely perform these tests. Antibody investigation (Reference) services are provided for hospitals in Alberta, Northwest Territories, northeastern British Columbia and Lloydminster, Saskatchewan. Specimens from these sites are submitted for antibody identification, blood group discrepancy resolution, direct antiglobulin testing, fetal bleed screening and other serological testing.

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 Adsorption
- Cold Agglutinin Screen

Antibody Screening is routinely performed by solid phase testing. A combination of solid phase testing and indirect antiglobulin tube testing using PEG IAT for enhancement is the primary antibody identification method. 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 that receive all of their transfusion medicine services from Canadian Blood Services. As a reference laboratory, the crossmatch laboratory performs complex antibody investigations and directs the distribution of crossmatch compatible (or least incompatible) red cell units through the Canadian Blood Services Product Distribution area.

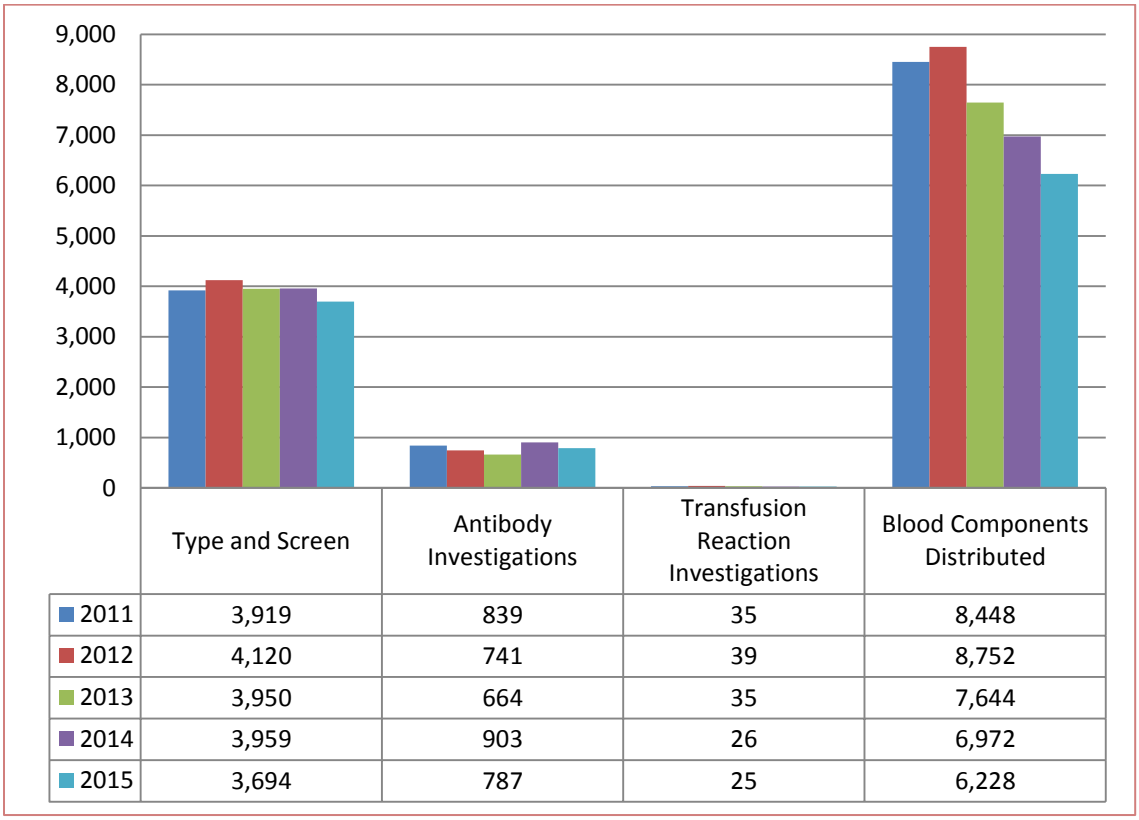
B. **Specimens Tested**

The data in this report reflects a calendar year period to enable better correlation to other government statistical data. The total number of specimens tested has remained relatively stable with fluctuations within 8% year over year as illustrated in *Table 5* below. There has been a steady decrease in the number of components distributed since 2012. Whether the decrease is due to better redistribution of components on the part of our customers, ordering units directly from the Product Distribution area or better blood utilization strategies is unknown.

Table 5: Crossmatch/Reference Specimens Tested

Specimen Type	Test Type	2011	2012	2013	2014	2015
Crossmatch/Reference	Type and Screen	3,919	4,120	3,950	3,959	3,694
	Antibody Investigations	839	741	664	903	787
	Transfusion Reaction Investigations	35	39	35	26	25
	Blood Components Distributed	8,448	8,752	7,644	6,972	6,228
Test Totals (excluding components distributed)		4,793	4,900	4,649	4,888	4,506
Number of Patients Tested		**2,362**	**2,437**	**2,349**	**2,345**	**2,115**

Figure 4: Total Crossmatch Specimens Tested



	Type and Screen	Antibody Investigations	Transfusion Reaction Investigations	Blood Components Distributed
2011	3,919	839	35	8,448
2012	4,120	741	39	8,752
2013	3,950	664	35	7,644
2014	3,959	903	26	6,972
2015	3,694	787	25	6,228

C. Antibodies Identified

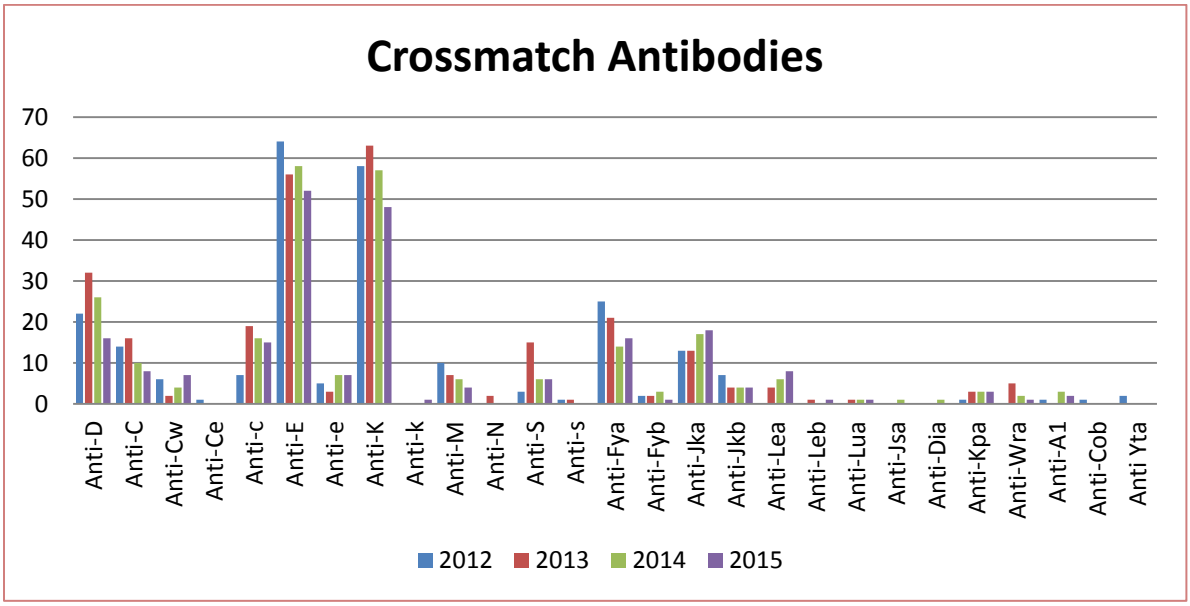
In 2015, a total of 219 antibodies were reported (see *Table 6*). The total number of antibodies detected is 10.6% lower than in 2014, but the distribution of the most common antibodies remains consistent. One hundred and seventy-six (176) patients had antibodies identified, and of these, thirty-two (32) patients had multiple antibodies.

Antibodies identified were considered to be clinically significant if they have been reported to cause acute or delayed hemolytic transfusion reactions. The most common clinically significant antibodies identified were anti-E, anti-K, anti-Jk^{a}, anti-D, anti-Fy^{a} and anti-c (see *Figure 5*) which together represented 75.3% of the total antibodies identified.

Table 6: Total Number of Crossmatch Antibodies Detected

Antibody	2012	2013	2014	2015
Anti-D	22	32	26	16
Anti-C	14	16	10	8
Anti-C^{w}	6	2	4	7
Anti-Ce	1	0	0	0
Anti-c	7	19	16	15
Anti-E	64	56	58	52
Anti-e	5	3	7	7
Anti-K	58	63	57	48
Anti-k	0	0	0	1
Anti-M	10	7	6	4
Anti-N	0	2	0	0
Anti-S	3	15	6	6
Anti-s	1	1	0	0
Anti-Fy^{a}	25	21	14	16
Anti-Fy^{b}	2	2	3	1
Anti-Jk^{a}	13	13	17	18
Anti-Jk^{b}	7	4	4	4
Anti-Le^{a}	0	4	6	8
Anti-Le^{b}	0	1	0	1
Anti-Lu^{a}	0	1	1	1
Anti-Js^{a}	0	0	1	0
Anti-Di^{a}	0	0	1	0
Anti-Kp^{a}	1	3	3	3
Anti-Wr^{a}	0	5	2	1
Anti-A_1	1	0	3	2
Anti-Co^{b}	1	0	0	0
Anti Yt^{a}	2	0	0	0
Total	**243**	**270**	**245**	**219**

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. Since March 2013, we have referred maternal blood specimens to the International Blood Group Reference Laboratory (NHS) in Bristol, England, for genotyping of fetal DNA in maternal plasma. Analysis of cell-free fetal DNA (cffDNA) in maternal plasma is significantly less risky for the fetus. Occasionally, a follow-up sample is requested, specifically if fetal DNA is not detected or if there is a negative result when detecting genes in the Kell system. As follow-up is routinely required when Kell genotyping is performed earlier in pregnancy, we are now recommending that samples for Kell testing be submitted after 28 weeks gestation.

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 amniocyte DNA testing ranged between two and eight specimens in recent years. In 2015, one specimen was sent to the Blood Center of Wisconsin for fetal genotyping by amniocyte DNA testing.

A total of 20 maternal samples from 17 patients were sent for cffDNA analysis in 2015 compared to twenty-four (24) samples from eighteen (18) patients in 2014 (see *Table 7*). This year, three samples were submitted for re-analysis, one due to undetectable DNA and two because shipping delays caused sample integrity to be questioned. Of the total 17 patients tested in 2015, Maternal-Fetal Medicine Clinic (MFM) follow-up of the current pregnancy was not required in 4 cases (see *Table 8*) because the fetus did not inherit the gene(s) for the antigen against which the maternal antibody was directed. In 2015, the most commonly probed antibodies were anti-D and Anti-E (see *Figure 6*). The number of samples sent for RHD genotyping has doubled since 2013 while the number of K antigen investigations has steadily declined.

Table 7: Fetal Genotyping Results Summary

	2013	2014	2015
Total samples sent	18	24	20
# patients tested	15	18	17
# patients not requiring MFM follow-up	6	10	4

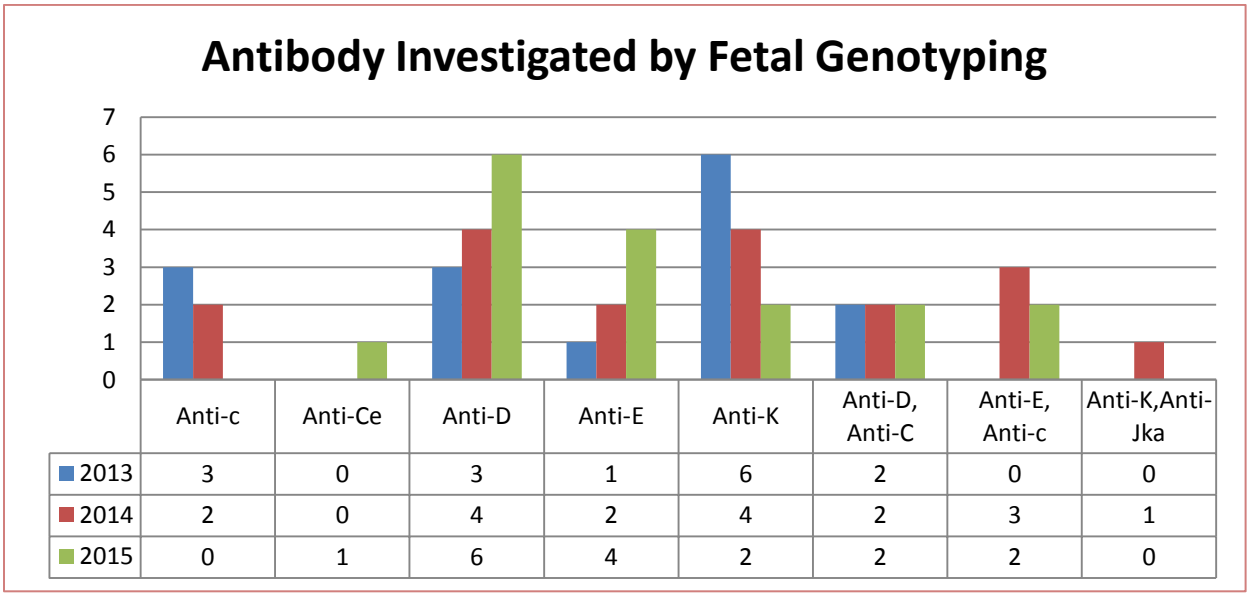
Table 8: Fetal Genotyping Results Summary

Patient	Maternal Antibody	Predicted Fetal Phenotype	Follow-up required?
1	Anti-D	RhD Pos	Yes
2	Anti-E	RhE Pos	Yes
3	Anti-E	RhE Pos	Yes
4	Anti-D, Anti-C, Anti-E not detected	RhD Pos, RhC Pos	Yes
5	Anti-E, Anti-c	RhE Neg, Rhc Neg	No
6	Anti-D	RhD Pos	Yes
7	Anti-E	RhE Pos	Yes
8	Anti-Ce	RhC Pos	Yes*
9	Anti-D	RhD Pos	Yes
10	Anti-D	RhD Pos	Yes
11	Anti-K	K Neg	No
12	Anti-K	Unable to type	Yes
13	Anti-D, Anti-C	RhD Pos	Yes**
14	Anti-D	RhD Neg	No
15	Anti-D	RhD Pos	Yes
16	Anti-E	RhE Neg	No
17	Anti-E Anti-c	Inconclusive	Yes

*MFM monitoring required for Anti-C.

**MFM monitoring required for Anti-D.

Figure 6: Total Number of Antibodies Probed by Fetal Genotyping



RED CELL GENOTYPING

Diagnostic Services Edmonton embarked on a pilot project for red cell genotyping in October 2013. Process validation and parallel testing began in December 2013 for both the RHD and Human Erythrocyte Antigen (HEA) systems. A process for referral of perinatal and pre-transfusion specimens for genotyping was developed and implemented. The laboratory began genotype testing on June 1st, 2014 for Alberta hospital customers and Canadian Blood Services - Diagnostic Services BC & Yukon. Prior to June, samples requiring genotyping were sent to the Canadian Blood Services National Immunohematology Reference Laboratory (NIRL) in Ottawa for investigation. Throughout the pilot, the demand for RHD genotype testing has been higher than HEA testing. Pilot testing determined that it was more economical to perform testing for identification of non-ABO/non-RHD alleles on the Progenika genotyping system in use at NIRL. Therefore, effective April 2015, all samples submitted to Canadian Blood Services across Canada had RHD testing performed by the Diagnostic Services Laboratory in Edmonton while genotyping for other alleles was performed at NIRL.

Specimens submitted directly to the Diagnostic Services Edmonton laboratory are accepted for RHD testing if they meet the following criteria:

- Patients have discrepant, weak or inconclusive serological RhD testing results where RHD genotyping may modify their blood product or RhIG requirements.
- Patients with an anti-D who appear serologically D positive.

Based on the following testing algorithm (see *Figure 7*) patients with serologically variable RhD typing results undergo RHD genotyping performed on the BioArray platform (for 2015 results see *Figure 8*). The number of samples sent for genotyping has steadily increased since testing began in 2011 (see *Table 9).* Testing volumes increased significantly (188%) from 2014 to 2015. A total of 375 samples were tested in 2015 compared to 130 in the previous year. Approximately 47% of patients were recommended to be treated as Rh Negative and 53% were recommended to be treated as Rh positive after molecular testing (see *Figure 9).* Patients with weak D types 1, 2, and 3 were treated as RhD positive for purposes of RhIG prophylaxis and transfusion management. This approach decreased the number of patients receiving RhIG and Rh negative blood products by 200.

Figure 7: Rh D Testing Algorithm

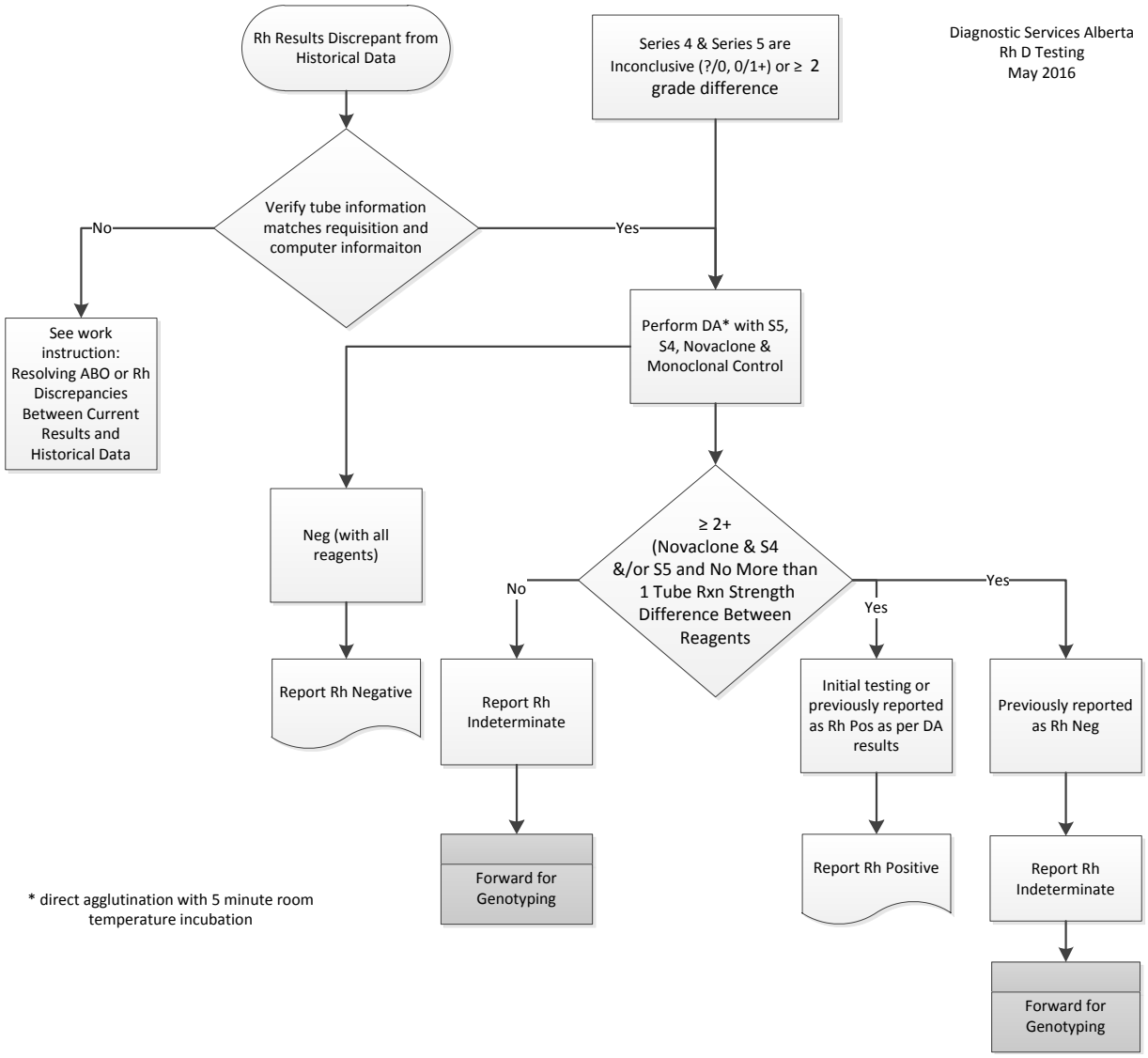


Figure 8: Number of RHD Genotyping Alleles Detected

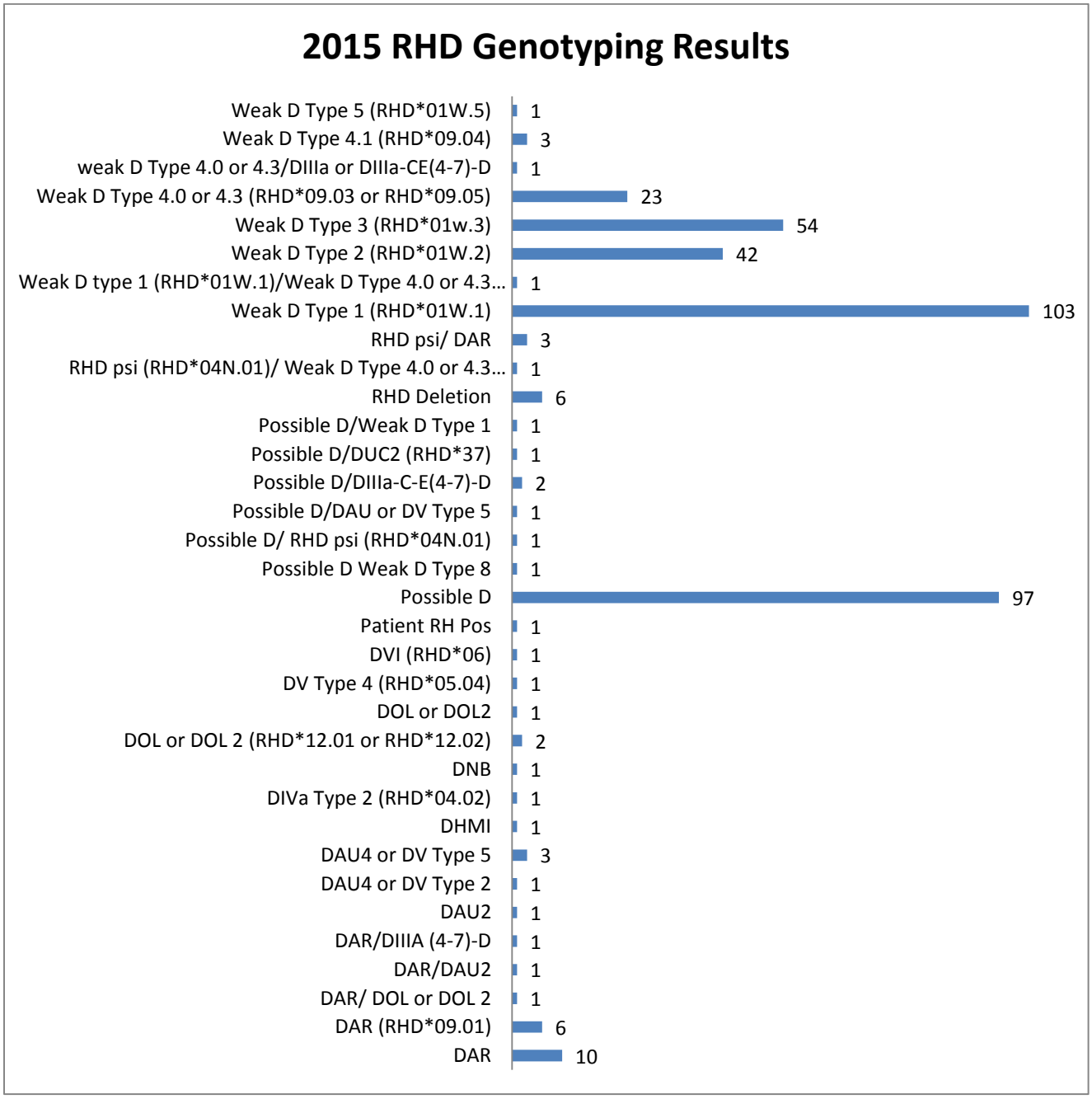
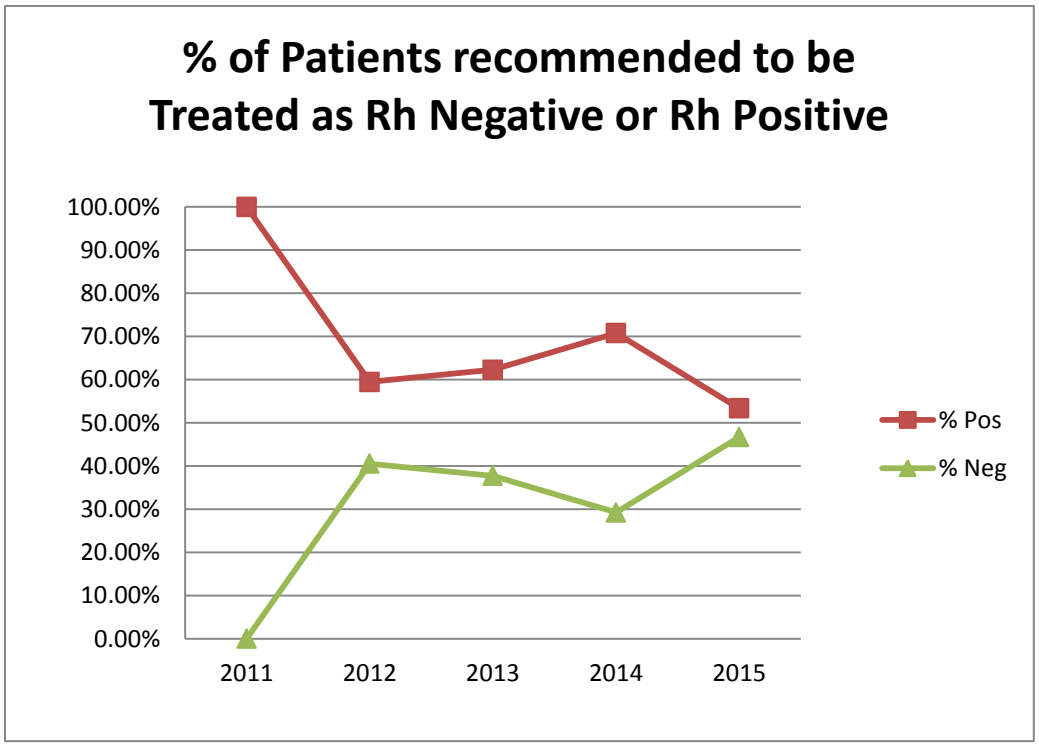


Table 9: RHD Genotyping – Number of Rh Negative and Rh Positive predicted phenotypes

	2011	2012	2013	2014	2015
Rh Positive	5	22	33	92	200
Rh Negative	0	15	20	38	175
Total # samples tested	**5**	**37**	**53**	**130**	**375**

Figure 9: RHD Genotyping - % of Patients recommended to be Treated as Rh Negative or Rh 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 Edmonton 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.

A change in the perinatal testing schedule occurred on January 2013. The shift to next day testing resulted in longer turnaround times (*see Figure 10)* but no change to report delivery times. Results continue to be delivered to physicians' offices and loaded into the Alberta Netcare portal (*see Table 11*) at the same time and exceeding set percentage targets (*see Table 10*).

Table 10: Turnaround Time – Routine Criteria by Specimen Type

Specimen Type	Expected Turnaround Time	Expected % of Specimens to Meet or Exceed Expected TAT
Routine Perinatal	72 hours	85%
Routine Crossmatch	24 hours	85%
Reference Testing	72 hours	85%

Figure 10: Perinatal Routine TAT

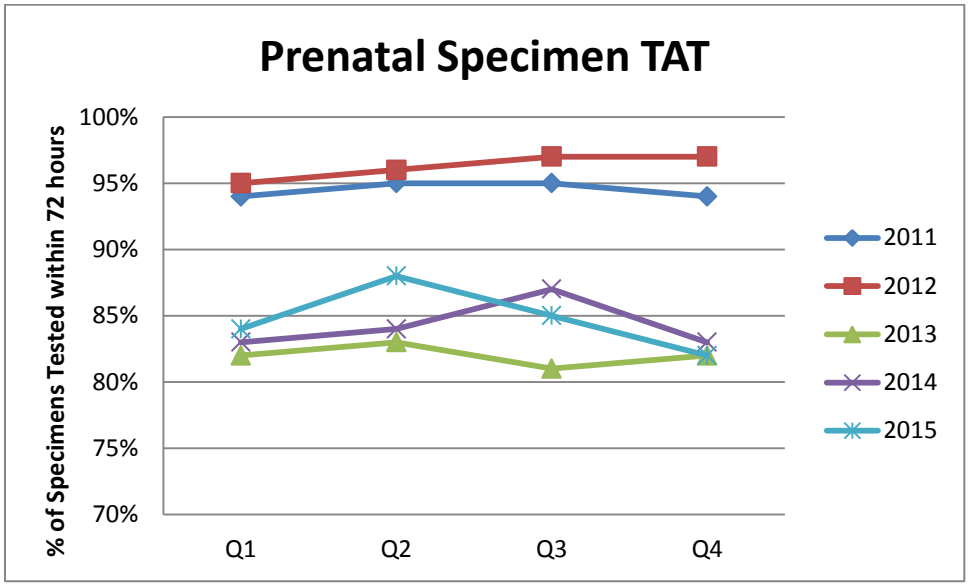


Table 11: Turnaround Time – Routine Perinatal Specimens

Turnaround Time	2011	2012	2103	2014	2015
% of Specimens Tested within 72 hours	95%	96%	82%	84%	85%
% of Specimens Tested > 72 hours	6%	4%	17%	16%	15%

Figure 11: Crossmatch Routine TAT

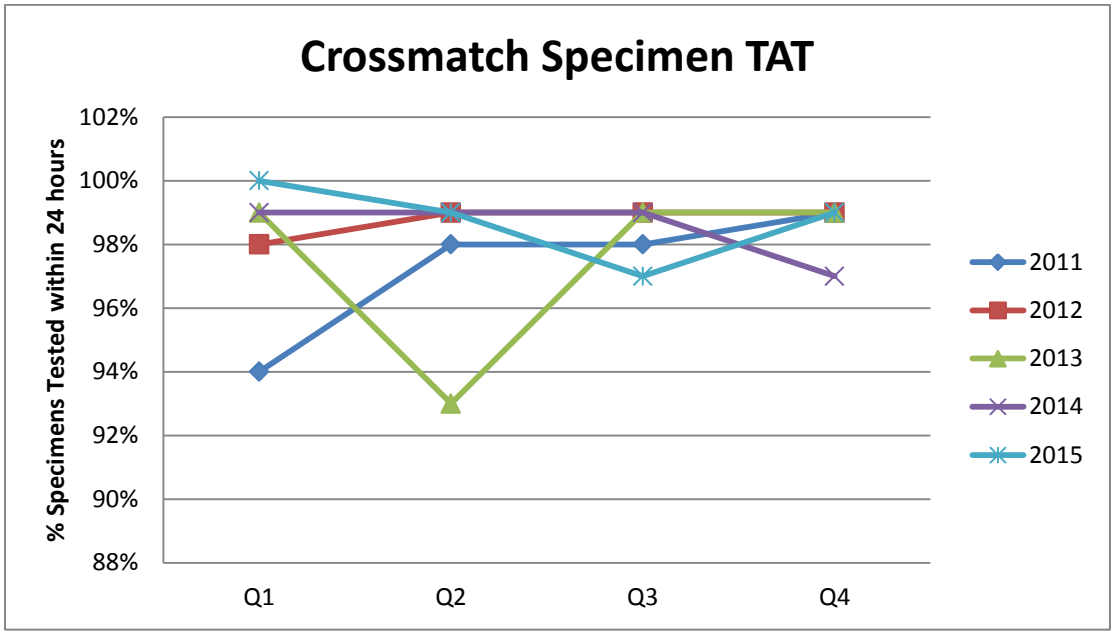


Table 12: Turnaround Time – Routine Crossmatch Specimens

Turnaround Time	2011	2012	2103	2014	2015
% of Specimens Tested within 24 hours	97%	99%	98%	99%	99%
% of Specimens Tested > 24 hours	3%	1%	3%	2%	1%

Table 13: Reference TAT

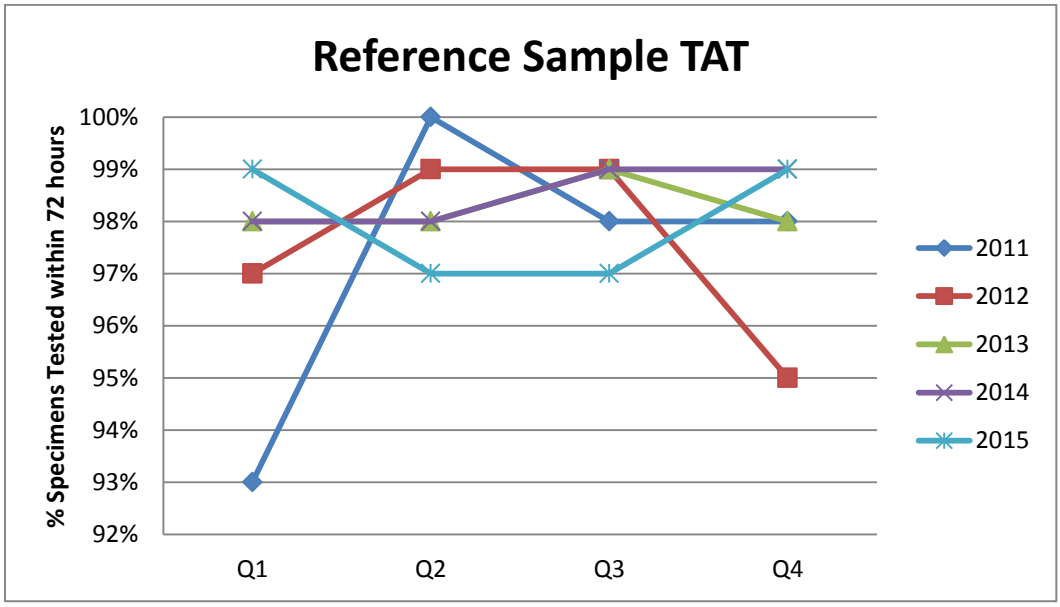


Figure 12: Turnaround Time – Reference Specimens

Turnaround Time	2011	2012	2103	2014	2015
% of Specimens Tested within 72 hours	97%	98%	98%	99%	98%
% of Specimens Tested > 72 hours	3%	4%	2%	2%	2%

B. Rejected Specimens

Each time a specimen is rejected, a reason for rejection is entered into our Laboratory Information System. This data is then retrieved and analysed on a quarterly basis. The number of rejected specimens is quite low for crossmatch/reference samples which are coming from hospitals and for perinatal samples which are primarily collected at community collection sites. The Diagnostic Services laboratory is following the provincial specimen rejection guidelines for Alberta.

The reasons for rejecting specimens in the crossmatch/reference and the perinatal laboratories are somewhat different. More crossmatch specimens are rejected because of problems with the requisition missing critical information such as the blood bank identification number, PHN or phlebotomist signature.

For perinatal specimens, the most common reason for rejecting a sample is that the sample is a duplicate. Samples are rejected if another sample from the patient was tested within the previous 96 hours. Often a duplicate sample is collected when the patient has seen their family physician and then sees their obstetrician shortly after. We do ensure that the report from the initial testing is sent to the second physician making the request. Health care professionals can access Canadian Blood Services reports for Alberta patients on Netcare, Alberta's Electronic Health Record.

Table 14: Quarterly Rejection Rates – Perinatal Specimens

Rejection Category	Q1	Q2	Q3	Q4
Requisition	28	26	26	11
Specimen	33	19	39	30
Discrepancies Between Requisition & Specimen	15	20	12	12
Discrepancies Between Current Requisition & Historical Records	0	0	0	0
Other	21	25	4	16
Total # specimens rejected	97	90	81	69
Total # specimens received	21,611	20,395	20,228	20,822
Rejections as a % of total	**0.4%**	**0.4%**	**0.4%**	**0.3%**

Figure 13: Perinatal Rejection Reasons

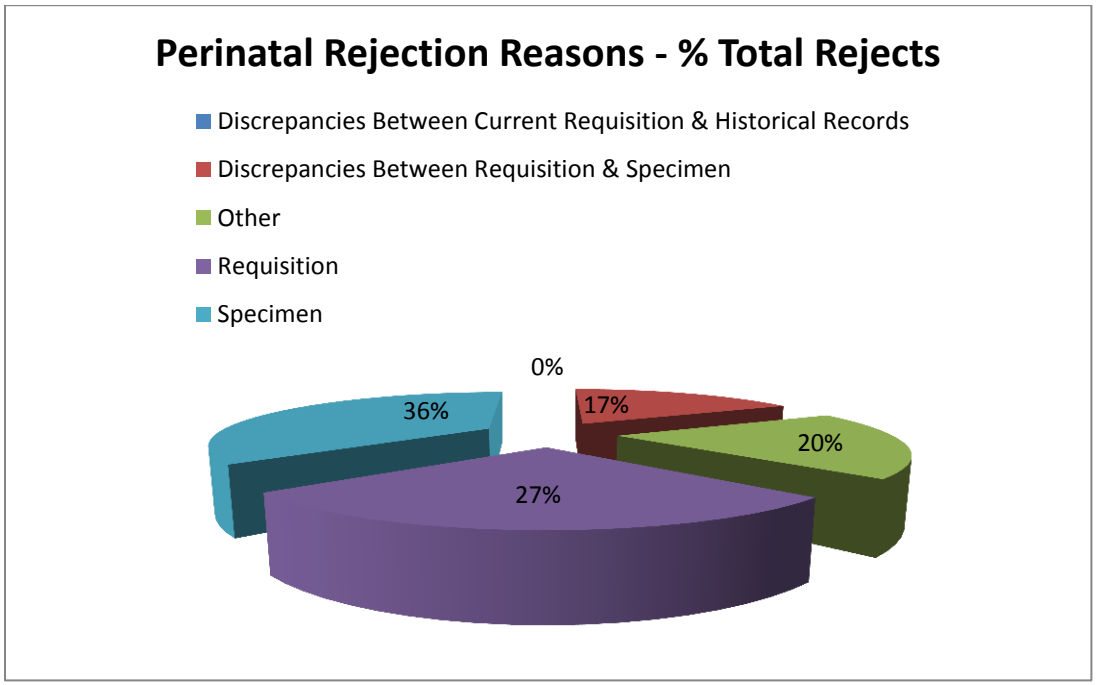
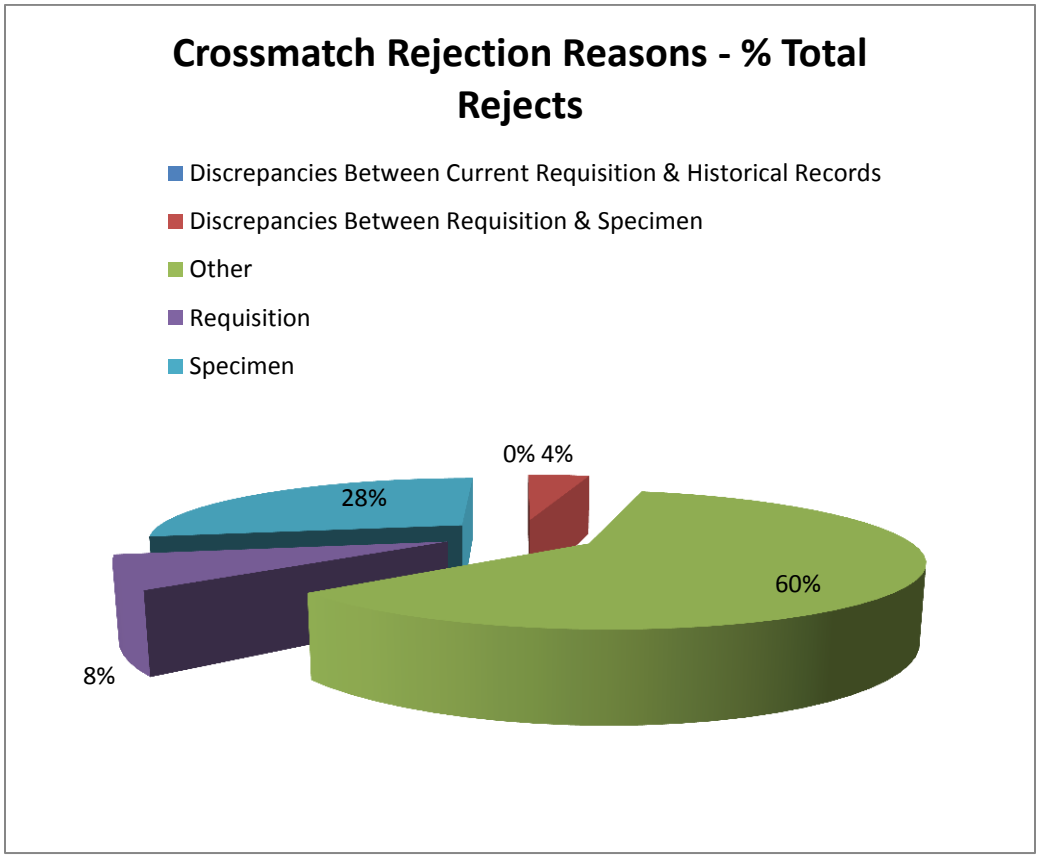


Table 15: Quarterly Rejection Rates – Crossmatch Specimens

Rejection Category	Q1	Q2	Q3	Q4
Requisition	0	1	0	1
Specimen	4	1	2	0
Discrepancies Between Requisition & Specimen	0	0	1	0
Discrepancies Between Current Requisition & Historical Records	0	0	0	0
Other	1	7	1	6
Total # specimens rejected	5	9	4	7
Total # specimens received	1052	1089	1080	1209
Rejections as a % of total	**0.5%**	**0.8%**	**0.4%**	**0.6%**

Figure 14: Crossmatch Rejection Reasons



ACCOMPLISHMENTS IN 2015

A. Automated Testing Instrument Upgrade

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

The sites also completed the validation and implementation of the Windows 7 software upgrade on the Galileo Neo test system.

B. Business Continuity Planning

Canadian Blood Services continues to refine the business continuity plans for all sites. Edmonton Diagnostic Services plan is under revision. Discussions are ongoing with internal and external stakeholders to ensure the Diagnostic Services plan continues to mesh seamlessly with other plans.

C. Genotyping – Red Cell

RHD genotype testing was offered to all eligible perinatal and pre-transfusion patients across Canada. A process for referral of samples and minimum labeling guidelines was established and communicated to hospital customers and the laboratory LIS (Trace Line) was upgraded to improve the reporting process.

The BioArray™ RHD BeadChip™ system received Health Canada licensure in 2015. In the fall of 2015, Edmonton Diagnostic Services lead the development of a plan to complete the validation and implementation of the licensed test system. Implementation of the licensed test is planned for January 2016.

D. Cell Free Fetal DNA (cffDNA) Testing Quality Assurance

In conjunction with local hospitals, Maternal-Fetal Medicine Clinics and the International Blood Group Reference Laboratory (NHS) in Bristol, U.K., a process to collect neonatal red cell serology results was implemented to assist in validating the accuracy of cffDNA testing results. Information gathered will allow correlation of genotyping predictions with neonatal phenotype.

E. Mis-Transfusion Risk Reduction Strategy

To reduce the risk of mis-transfusion of ABO incompatible red cell components due to misidentification of the intended recipient, Edmonton Diagnostic Services implemented a strategy in late 2015 to provide group O red cells to patients who do not have a historical ABO blood group.

This was part of a national strategy for all Canadian Blood Services Diagnostic Services Laboratories to comply with College of American Pathologists (CAP) accreditation requirements spearheaded by Diagnostic Services Manitoba. The national mitigation measure is scheduled to be completed April 2016.

F. Perinatal Advisory Committee

The annual Perinatal Advisory Committee meeting for 2016 will be held June 13 and 14, 2016 in Winnipeg MB. Attendees include Laboratory Directors, Associate Directors and Managers as well as perinatal supervisory staff and laboratory physicians who oversee perinatal testing. We also welcome some hospital colleagues, both technologists and physicians, who are involved with perinatal testing

laboratories. Ongoing work on standardization amongst the Canadian Blood Services Perinatal laboratories is a theme for this year. Our meeting plan and ongoing work plan for the remainder of 2016 will include:

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

GOALS FOR 2016

A. RHD Genotyping

Implement the licensed RHD testing platform in January 2016. Perform post implementation reviews to continue to improve and refine the reporting process.

B. Mis-Transfusion Risk Reduction Strategy

Implementation of the mis-transfusion risk reduction strategy in April 2016

C. New provincial perinatal testing requisition

The perinatal laboratory will review and engage provincial stakeholders to revise the perinatal testing requisition

D. Restructure Laboratory Services

Participate with AHW and AHS in discussions related to the repatriation of crossmatch services with a focus on a smooth transition with minimal impact to patient care.

Participate in discussions related to the National Facilities Redevelopment Plan Phase II for testing services that are to remain in Edmonton.

E. Testing Standardization

Support initiatives to standardize work instructions across Canadian Blood Services Testing laboratories.