

DIAGNOSTIC SERVICES Alberta YEAR IN REVIEW

JANUARY – DECEMBER 2017

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

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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
- Antibody Titre
- Phenotyping
- Fetal Bleed Screening Test
- Kleihauer-Betke Test for quantitation of fetal-maternal hemorrhage
- Postnatal Testing

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 monthly in the first and second trimester and every two weeks in the last trimester. 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 neonatal specimens must be submitted with the mother's specimen as noted above. ABO/Rh and direct antiglobulin testing is performed on cord or neonatal specimens submitted to Canadian Blood Services.

<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.

Table 1: Perinatal Specimens Tested

Specimen Type	Test Type	2013	2014	2015	2016	2017
Maternal	Type and Screen	79,718	81,373	82,164	79,693	76262
Paternal	ABO/Rh	304	307	280	304	338
Cord	ABO/Rh	206	191	198	172	147
Total # of Specimens Tested		80,228	81,871	82,642	80,169	76,747
Total # of Patients Tested		68,877	67,618	68,657	66,287	63,958

Figure 1: Total Perinatal Specimens Tested



D. Antibodies Identified

In 2017, a total of 437 antibodies were reported (see *Table 2*). This is higher than 2016 where 360 antibodies were reported. Of 437 antibodies identified in 2017, fifty-four (54) 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-D, anti-c, anti-K, anti-M (IgG), (see *Figure 2*) which together represented 81% of the total antibodies identified. IgG Anti-M can be considered clinically significant as it may cause HDFN and/or delayed anemia in rare cases.

Titres for 14 of the clinically significant antibodies increased from non-critical to critical levels during the pregnancy with a total of 29 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.

Maternal Clinically Significant Antibodies Identified-2017							
Clinically <u>Significant</u> Antibodies	2013	2014	2015	2016	2017		
Anti-D	66	67	49	58	56		
Anti-C	30	31	17	13	20		
Anti-Cw	3	1	2	1	0		
Anti-Ce	0	0	0	0	0		
Anti-c	70	59	41	43	43		
Anti-E	134	117	91	106	108		
Anti-e	15	15	13	6	10		
Anti-f	0	0	0	0	0		
Anti-G	3	2	3	1	6		
Anti-K	77	65	46	53	59		
Anti-M*	40	44	37	29	40		
Anti-S	17	16	14	7	11		
Anti-s	1	1	3	1	1		
Anti-U	0	1	1	0	0		
Anti-Fya	10	11	18	12	18		
Anti-Fyb	0	3	2	0	1		
Anti-Jka	41	50	34	18	30		
Anti-Jkb	10	6	4	1	2		
Anti-JK3	0	1	1	0	0		
Anti-Lua	3	2	0	2	0		
Anti-Lub	4	1	1	1	0		
Anti-V	1	1	0	0	0		
Anti-Vw	1	0	0	0	0		
Anti-Dia	0	1	1	0	0		
Anti-Kpa	1	1	1	0	0		
Anti-Wra	11	9	2	5	2		
Anti-Jsa	0	0	0	0	1		
Anti-Mia	0	0	0	0	2		
TOTAL: Clinically Significant Antibodies	538	505	381	348	410		

Table 2: Total Number of Perinatal Antibodies Detected

*Anti-M – IgG antibody component detected

Clinically <u>Insignificant</u> Antibodies	2013	2014	2015	2016	2017
Anti-A1	3	9	8	1	11
Anti-Lea	15	20	6	8	12
Anti-Leb	6	1	1	1	1
Anti-N	0	2	1	1	2
Anti-P1	0	0	3	0	1
Anti-VS	0	0	0	1	0
Passive Anti-D (not included in total)	791	1119	633	497	680
TOTAL: Clinically <u>In</u> significant Antibodies	24	32	19	12	27

Table 3: Perinatal Patient Antibody Titres

Antibody	Critical Level	Non-Critical Level	Non-Critical to Critical
Anti-D	9	24	6
Anti-C	2	12	0
Anti-E	11	80	7
Anti-c	7	23	5
Anti-e	2	6	0
Anti-DC	4	3	1
Ant-DE	0	1	0
Anti-Ec	7	12	1
Anti-Ce	0	2	0
Anti-G	0	3	0
Anti-DG	1	1	1
Anti-CG	0	1	0
Anti-Fya	5	12	5
Anti-Fyb	1	1	1
Anti-Jka	1	30	0
Anti-Jkb	0	7	0
Anti-M	3	36	1
Anti-S	1	7	0
Anti-s	1	1	1





Figure 3: Frequency of Clinically Significant Antibodies



Table 4: Combination Antibodies

Antibodies	Number in 2017
Anti-C, Anti-D	9
Anti-c, Anti-E	13
Anti-C, Anti-e	1
Anti-C, Anti-E	1
Anti-C, Anti-e, Anti-Jkb	1
Anti-c Anti-E Anti-Jkb Anti- S	1
Anti-C, Anti-G	3
Anti-c, Anti-Jka	1
Anti-c, Anti-Jka, Anti-K	1
Anti-c, Anti-Mia	1
Anti-c, Anti-N	1
Anti-D, Anti-E	1
Anti-D, Anti-Fya, Anti-G	1
Anti-D, Anti-G	1
Anti-D, Anti-Wra	1
Anti-E, Anti-Jka	5
Anti-E, Anti-Jkb	1
Anti-E, Anti-K	2
Anti-E, Anti-Lea	1
Anti-E, Anti-S	1
Anti-Fya, Anti-Jka	2
Anti-Jsa, Anti-Mia	1
Anti-K, Anti-Jka	1
Anti-K, Anti-Lea	1
Anti-K, Anti-S	1
Anti-Lea, Anti-S	1

CROSSMATCH / REFERENCE LABORATORY

The Crossmatch/Reference Laboratory within Diagnostic Services provides transfusion medicine services (Crossmatch) for 24 hospitals in central / 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 Isohemagglutinin Titre 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. Combinations of solid phase testing and indirect antiglobulin tube testing using PEG for enhancement are 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 other blood components to those hospitals which receive all of their transfusion medicine services from Canadian Blood Services. As a Reference Laboratory, the Laboratory performs complex antibody investigations.

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 18% year over year as illustrated in *Table 5* below. There has been a steady decrease in the number of components distributed since 2012 but remained relatively the same.

Table 5: Crossmatch/Reference Specimens Tested

Specimen Type	Test Type	2013	2014	2015	2016	2017
Crossmatch/Reference	Type and Screen	3,950	3,959	3,694	4,360	3908
	Antibody Investigations	664	903	787	945	692
	Transfusion Reaction Investigations	35	26	25	32	16
	Blood Components Distributed	7,644	6,972	6,228	6,245	5352
Test Totals (excluding co	4,649	4,888	4,506	5,337	4616	
Number of Patients Test	2,349	2,345	2,115	2,092	1853	

Figure 4: Total Crossmatch Specimens Tested



C. Antibodies Identified

In 2017, a total of 212 antibodies were reported (see *Table 6*). The total number of antibodies detected is 13.6% lower than in 2016, but the distribution of the most common antibodies remains consistent. One hundred and sixty-three (163) patients had antibodies identified, and of these, twenty-nine (29) patients had multiple antibodies (18%).

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-D, anti-C, anti-E, anti-K and anti-Jk^a (see *Figure 5*) which together represented 77% of the total antibodies identified.

	2013	2014	2015	2016	2017
Anti-D	32	26	16	31	15
Anti-C	16	10	8	19	10
Anti-Cw	2	4	7	1	2
Anti-Ce	0	0	0	0	0
Anti-c	19	16	15	9	8
Anti-E	56	58	52	65	57
Anti-e	3	7	7	7	5
Anti-K	63	57	48	54	44
Anti-k	0	0	1	1	0
Anti-M	7	6	4	9	18
Anti-N	2	0	0	0	0
Anti-S	15	6	6	3	8
Anti-s	1	0	0	0	0
Anti-Fya	21	14	16	10	16
Anti-Fyb	2	3	1	1	1
Anti-Jka	13	17	18	13	16
Anti-Jkb	4	4	4	3	2
Anti-Lea	4	6	8	8	3
Anti-Leb	1	0	1	0	0
Anti-Lua	1	1	1	1	1
Anti-Lub	0	0	0	1	0
Anti-Jsa	0	1	0	0	0
Anti-Dia	0	1	0	0	0
Anti-Kpa	3	3	3	1	1
Anti-Wra	5	2	1	1	2
Anti-A1	0	3	2	2	2
Anti-P1	0	0	0	1	0
Anti-Cob	0	0	0	0	0
Anti Yta	0	0	0	0	1
Total	270	245	219	241	212

Table 6: Total Number of Crossmatch Antibodies Detected





FETAL GENOTYPING

Canadian Blood Services in Alberta refers specimens for fetal genotyping on maternal plasma to the International Blood Group Reference laboratory (IBGRL) of the National Health Services (NHS) in Bristol, United Kingdom. Amniotic fluid samples are rarely sent to the Blood Center of Wisconsin for fetal genotyping. Testing on maternal blood samples is preferred because sample collection does not represent a risk to the fetus.

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, <u>OR</u>
- 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 18 and 24 specimens in recent years.

Table 7: Fetal Genotyping Results Summary

	2013	2014	2015	2016	2017
Total samples sent	18	24	20	23	24
# of patients tested	15	18	17	22	24
# of patients not requiring MFM follow-up. (Tested negative for the corresponding antigen)	6	10	4	9	5

Table 8: Fetal Genotyping Results Summary

Patient	Maternal Antibody	Predicted Fetal Phenotype negative for the corresponding antigen	Follow-up required?
1	Anti-E	RhE Pos	Yes
2	Anti-c	Rhc Pos	Yes
3	Anti-K	K inconclusive	Yes
4	Anti-D	RhD Pos	Yes
5	Anti-E	RhE Pos	Yes
6	Anti-K	K neg	No
7	Anti-E	RhE Pos	Yes
8	Anti-K	K Pos	Yes
9	Anti-D / Anti-C	RhD Pos / RhC Pos	Yes
10	Anti-D	RhD Pos	Yes
11	Anti-D	RhD Pos	Yes
12	Anti-D	RhD neg	No
13	Anti-D / Anti-C	RhD Pos/ RhC Pos	Yes
14	Anti-K	K Neg	No
15	Anti-K	K Pos	Yes
16	Anti-E / Anti-c	RhE Pos	Yes
17	Anti-K	K Pos	Yes
18	Anti-D	RhD Pos	Yes
19	Anti-K	K Pos	Yes
20	Anti-D	RhD Pos	Yes
21	Anti-K	K Neg	No
22	Anti-E	RhE Neg	No
23	Anti-D	RhD Pos	Yes
24	Anti-D	RhD Pos	Yes



Figure 6: Total Number of Antibodies Investigated by Fetal Genotyping

RHD RED CELL GENOTYPING

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

Figure 7: RhD Testing Algorithm



Figure 8: Number of RHD Genotyping Alleles Detected

The results in Figure 8 were obtained with either of the two red cell genotyping platforms available at Canadian Blood Services: *BioArray* and *Progenika*.



	2012	2013	2014	2015	2016	2017
Rh Positive	22	33	92	200	292	309
Rh Negative	15	20	38	175	338	390
Total # samples tested	37	53	130	375	630	699

Table 9: RHD Genotyping – Number of Rh Negative and Rh Positive Predicted Phenotypes

Figure 9: RHD Genotyping – % Patients Recommended to be Treated as Rh Negative & 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 specimens are 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 perinatal specimens has been close to the predefined TAT threshold. The percentage of crossmatch/reference specimens has consistently met the predefined TAT threshold. Samples whose testing failed to meet expected TATs are usually those where clinically significant antibodies are detected or where difficulty in finding compatible blood is encountered.

Table 10: Turnaround Time – Routine Criteria by Specimen Type

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

Table 11: Turnaround Time – Perinatal Routine TAT

% of Specimens Tested within 72 hours	82%	84%	85%	84%	77.4
% of Specimens Tested > 72 hours	17%	16%	15%	16%	22.6

Figure 10: Perinatal Routine TAT



Table 12: Turnaround Time – Routine Crossmatch Specimens

Turnaround Time (TAT)	2013	2014	2015	2016	2017
% of Specimens Tested within 24 hours	98%	99%	99%	99%	99%
% of Specimens Tested > 24 hours	3%	2%	1%	1%	1%

Figure 11: Crossmatch Routine TAT



Table 13: Turnaround Time – Reference Specimens

% of Specimens Tested within 72 hours	98%	99%	98%	98%	99%
% of Specimens Tested > 72 hours	1%	1%	2%	2%	1%

Figure 12: Reference TAT



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 reasons for rejecting a sample for testing are patient identification labelling errors and duplicate requests for testing (duplicate specimens). Testing requests are rejected if another sample from the patient was tested within the previous 96 hours. Often a duplicate test request 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.

Rejection Category	Q1	Q2	Q3	Q4
Requisition	20	18	13	16
Specimen	42	55	54	82
Discrepancies Between Requisition & Specimen	10	15	12	13
Discrepancies Between Current Requisition & Historical Records	0	0	0	0
Other (Duplicates, etc.)	12	5	6	6
Total # specimens rejected	84	93	85	117
Total # specimens received	18369	18289	19166	20166
Rejections as a % of total	0.5%	0.5%	0.4%	0.6%

Table 14: Quarterly Rejection Rates – Perinatal Specimens

Figure 13: Perinatal Rejection Reasons



Table 15: Quarterly Rejection Rates – Crossmatch Specimens

Rejection Category	Q1	Q2	Q3	Q4
Requisition	6	0	2	1
Specimen	7	4	4	6
Discrepancies Between Requisition & Specimen	2	0	1	1
Discrepancies Between Current Requisition & Historical Records	2	0	0	1
Other (Duplicates, etc.)	0	9	12	8
Total # specimens rejected	5	13	19	17
Total # specimens received	1283	1016	1093	755
Rejections as a % of total	6	0	2	1

Figure 14: Crossmatch Rejection Reasons



ACCOMPLISHMENTS IN 2017

A. Perinatal Advisory Committee

The Perinatal Advisory Committee meeting for 2017 was held in Brampton, Ontario on November 20th. In addition to the Canadian Blood Services Testing group members, a few hospital colleagues with an interest in perinatal medicine attended the meeting.

The PNAC meeting included a discussion of plans for conversion and standardization of work instructions across all patient testing sites. A number of ongoing standardization initiatives were updated, including automated solid phase testing for detection of passive anti D, and an adjusted algorithm for RHD genotyping of prenatal patients. The process for implementation of new initiatives was outlined by the leadership group.

Commercially available software for cataloguing and tracking reagent red cells and antisera was presented. This software provides a searchable database of reagent cells that could be viewed from any Canadian Blood Services laboratory across the country, potentially enhancing complex antibody identification in prenatal or pre-transfusion patients.

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

B. Diagnostic Services Web Page Redesign

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

C. Crossmatch Re-patriation (Central Zone)- Crossmatch testing performed by Edmonton Diagnostic Services Laboratory for Central Zone non-testing sites was repatriated back Alberta Health Services on July 17, 2017. There was no impact to perinatal, referral or genotyping programs.

D. Presentations / Abstracts / Publications

- J. Hannon, G. Barr, T. Dolnik, L. Ciurcovich, T. Alport, G. Clarke. Summary of Cell-Free Fetal DNA (cffDNA) Testing in Pregnant Women in Western Canada. Poster/Abstract presented at CSTM (Canadian Society for Transfusion Medicine). April 20 – 23, 2017.
- J. Hannon, G. Barr, T. Dolnik, L. Ciurcovich, T. Alport, G. Clarke. An Approach to Ensuring Quality in Cell-Free Fetal DNA (cffDNA) Testing. Poster/Abstract presented at CSTM (Canadian Society for Transfusion Medicine). April 20 – 23, 2017.
- G. Barr, L. Ciurcovich, T. Dolnik, R. Fallis, L. Grabner, J. Hannon, T. Ison. *Anti-G Testing and Titration Strategy in Prenatal Patients.* Poster/Abstract presented at CSTM (Canadian Society for Transfusion Medicine). April 20 23, 2017.
- Chan B, Maguire A, Stepien J, To L, Nahirniak S, Hannon J, Lagrange C, Richardson T, Clarke G.
 Optimizing Phenotyped Blood Inventory in Alberta Rural Hospitals. Poster/Abstract presented at Labcon Annual Conference, Banff, Alberta May 26 28th, 2017.
- AB Diagnostic Services contributes to continuing technologist education at provincial or national transfusion medicine conferences.

GOALS FOR 2018

A. Crossmatch Re-patriation (North Zone, Cross Cancer Institute (CCI) and NWT non-testing sites)

Crossmatch testing performed by Edmonton Diagnostic Services Laboratory to be repatriated back to Alberta Health Services no later than March 31, 2018. Diagnostic Services Laboratory will no longer keep or manage blood component inventory. Daratumumab (DARA) clinic trial studies from CCI will be transferred to the University of Alberta Hospital. There will be no impact to perinatal, genotyping or referral testing programs.

B. Extended Red Cell Genotyping

To provide continuous service in the event that genotyping testing is disrupted at the National Immunohematology Reference Laboratory, Edmonton will validate and implement the HEA and RHCE genotyping tests.

C. Genotyping equipment

The computerized imaging system used for genotype testing will be upgraded to the newest version.

D. Work Instruction Conversion Project

Local Work Instructions (WI) will be converted to a new standardized template. AB and BC/Yukon Centres will standardize accessioning and manual testing procedures with the accompanying testing forms.