

DIAGNOSTIC SERVICES SASKATCHEWAN

YEAR IN REVIEW JANUARY – DECEMBER 2017

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

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TABLE of CONTENTS

SEN	IOR STAFF AND CONTACT INFORMATION
PER	NATAL LABORATORY
Α.	Testing Performed5
в.	Testing Frequency
C.	Specimens Tested
D.	Antibodies Identified6
CRO	SSMATCH / REFERENCE LABORATORY10
Α.	Testing Performed10
В.	Specimens Tested
C.	Antibodies Identified12
FET	AL GENOTYPING
QUA	LITY INDICATORS
Α.	Turnaround Times15
в.	Rejected Specimens
ACC	OMPLISHMENTS IN 2017
Α.	Perinatal Advisory Committee19
в.	Diagnostic Services Web Page Redesign
C.	Repatriation of Crossmatch Testing Services
D.	Saskatchewan Perinatal Testing
GO/	ALS FOR 2018
Α.	Perinatal Testing Transition

Figures

Figure 1:	Total Perinatal Specimens	Tested	6
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Figure 2: Total Number of Perinatal Antibodies	9
Figure 3: Frequency of Clinically Significant Antibodies	9
Figure 4: Total Crossmatch Specimens Tested	11
Figure 5: Total Number of Crossmatch Antibodies	13
Figure 6: Rh D Testing Algorithm	14
Figure 7: Perinatal Routine TAT	16
Figure 8: Crossmatch Routine TAT	16
Figure 9: Reference TAT	17
Figure 10: Perinatal Rejection Reasons (2017-2018 - Q1 and Q2)	18

Tables

Table 1: Perinatal Specimens Tested	6
Table 2: Total Number of Perinatal Antibodies Detected	7
Table 3: Perinatal Patient Antibody Titres	8
Table 4: Combination Antibodies	10
Table 5: Crossmatch/Reference Specimens Tested	11
Table 6: Total Number of Crossmatch Antibodies Detected	12
Table 7: Patient # - RHD Type/Result	15
Table 8: Turnaround Time – Routine Criteria by Specimen Type	15
Table 9: Turnaround Time – Routine Perinatal Specimens	15
Table 10: Turnaround Time – Routine Crossmatch Specimens	16
Table 11: Turnaround Time – Reference Specimens	17
Table 12: Quarterly Rejection Rates – Perinatal Specimens	18
Table 13: Quarterly Rejection Rates – Crossmatch Specimens	19

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. As of 2017-10-02, the Vancouver Diagnostic Services site provides Perinatal Testing Services for Saskatchewan.

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.

<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.

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).

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 referrals.

Table 1: Perinatal Specimens Tested

Specimen Type	Test Type	2013	2014	2015	2016	2017
Maternal	Type and Screen	20,074	20,707	21,117	21,598	21,448
Paternal	ABO/Rh	233	256	364	401	461
Cord	ABO/Rh	22	10	12	9	11
Total # of Specimens Tested		20,329	20,973	21,493	22,008	21,920
Total # of Patients Tested		16925	17,450	17,631	18,069	14,631

Figure 1: Total Perinatal Specimens Tested



D. Antibodies Identified

In 2017, a total of 123 antibodies were reported (see *Table 2*). This is slightly lower than 2016. One hundred and six women had antibodies identified during their pregnancies, of these; twenty-one 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-D, anti-E, anti-c, and anti-K which together represented 70% of the total antibodies identified.

Titres for 2 of the clinically significant antibodies increased from non-critical to critical levels during the pregnancy with a total of 19 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	9	16	10	8	7		
Anti-C	10	14	10	8	7		
Anti-E	33	39	38	28	33		
Anti-c	3	16	12	13	15		
Anti-e	2	3	5	6	1		
Anti-Cw	0	1	3	1	0		
Anti-K	17	24	30	37	21		
Anti-S	4	6	3	2	2		
Anti-s	0	1	1	1	0		
Anti-Fya	2	9	6	2	3		
Anti-Fyb	1	2	1	1	0		
Anti-Jka	10	6	8	10	7		
Anti-Jkb	1	4	3	1	2		
Anti-Lua	0	1	0	1	0		
Anti-Lub	0	0	0	0	0		
Anti-Kpa	0	2	0	1	1		
Anti-G	0	0	1	1	2		
Anti-Cob	0	0	1	0	0		
Anti-Wra	0	0	1	1	1		
Anti-V	0	0	0	1	0		
Anti-Mit	0	0	0	1	0		
Anti-Dantu	0	0	0	1	0		
TOTAL: Clinically Significant Antibodies	92	144	133	125	102		

Table 2: Total Number of Perinatal Antibodies Detected

Clinically <u>Insignificant</u> Antibodies	2013	2014	2015	2016	2017
Anti-Le ^a	10	12	14	9	7
Anti-Le ^b	1	2	2	1	1
Anti-N	2	1	0	1	1
Anti-A ₁	0	0	0	3	1
Anti-M	12	13	10	6	11
Passive Anti-D (not included in total)	123	156	178	217	158
TOTAL: Clinically <u>In</u> significant Antibodies	25	28	26	20	21

Table 3: Perinatal Patient Antibody Titres

Antibody	Critical Level	Non-Critical Level	Non-Critical to Critical
Anti-C	2	2	0
Anti-C Anti-G	0	1	0
Anti-c	0	4	0
Anti-D	4	1	0
Anti-D Anti-C	1	0	0
Anti-E	4	23	1
Anti-E Anti-c	1	4	0
Anti-Fya	1	0	0
Anti-G	0	1	0
Anti-Jka	0	6	0
Anti-Jkb	0	1	0
Anti-K	4	6	0
Anti-M	1	8	1
Anti-S	1	0	0





Figure 3: Frequency of Clinically Significant Antibodies



Table 4: Combination Antibodies

Antibodies	Number in 2017
Anti-C Anti-G	1
Anti-D Anti-C	2
Anti-C Anti-K	1
Anti-C Anti-S	1
Anti-E Anti-c	6
Anti-c Anti-Jka	2
Anti-D Anti-G	1
Anti-E Anti-Wra	1
Anti-e Anti-Lea	1
Anti-Jka Anti-Lea	1
Anti-K Anti-Kpa	1
Anti-C Anti-Fya Anti-S	1
Anti-D Anti-C Anti-Jkb	1
Anti-E Anti-K Anti-Wra	1

CROSSMATCH / REFERENCE LABORATORY

The Crossmatch/Reference Laboratory within Diagnostic Services provides transfusion medicine services and reference testing to 37 hospitals within 13 Health Regions in Saskatchewan. As of 2017-06-19, Crossmatching Services were repatriated from Canadian Blood Services to two Saskatchewan hospital sites.

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

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 marked decrease over this year because of the repatriation of the service by two Saskatchewan hospital sites.

Table 5: Crossmatch/Reference Specimens Tested

Specimen Type	Test Type	2013	2014	2015	2016	2017
Crossmatch/Reference	Type and Screen	590	497	413	416	152
	Antibody Investigations	257	232	196	217	77
	Transfusion Reaction Investigations	0	1	2	2	2
	Blood Components Distributed	1321	1096	919	772	303
Test Totals (excluding components distributed)			730	611	635	168
Number of Patients Tested			262	242	214	87

Figure 4: Total Crossmatch Specimens Tested



C. Antibodies Identified

In 2017, a total of 24 antibodies were reported (*see Table 6*). The total number of antibodies detected is lower than 2016 year because of the repatriation of the service by two Saskatchewan hospital sites. The distribution of the most common antibodies remains consistent.

Antibodies identified are 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, and anti-c (*see Figure 5*) which together represented 68% of the total antibodies identified.

Antibody	Number Detected 2013	Number Detected 2014	Number Detected 2015	Number Detected 2016	Number Detected 2017
Anti-D	6	3	6	2	1
Anti-C	7	4	5	5	0
Anti-Cw		1		3	0
Anti-c	2	7	5	7	4
Anti-E	16	18	19	19	7
Anti-e	1	1	2	2	1
Anti-f	0	2	0	0	0
Anti-G	0	0	1	0	0
Anti-K	15	14	21	14	6
Anti-k	1	0	0	0	0
Anti-M	3	0	2	0	0
Anti-S	3	2	2	2	1
Anti-s	0	0	0	1	0
Anti-Fya	4	6	12	3	1
Anti-Fyb	2	2	0	1	0
Anti-Jka	2	10	4	3	1
Anti-Jkb	3	0	0	2	1
Anti-Lea	2	2	1	4	0
Anti-Leb	0	0	0	1	0
Anti-Lua	1	0	0	0	0
Anti-Kpa	0	2	0	0	0
Anti-A1	0	1	3	1	0
Total	68	75	83	70	21

Table 6: Total Number of Crossmatch Antibodies Detected

Figure 5: Total Number of Crossmatch Antibodies



FETAL GENOTYPING

Canadian Blood Services in Saskatchewan has been coordinating specimen referrals for fetal genotyping with Edmonton Diagnostic Services. Samples are prepared by Edmonton for referral to the International Blood Group Reference Laboratory (NHS) in Bristol, England, for detection of fetal DNA in maternal plasma.

Specimens are accepted if they meet the following criteria:

- The mother has an antibody capable of causing hemolytic disease of the fetus/newborn (HDFN), <u>AND</u>
- The father is heterozygous for the corresponding antigen (or unknown), AND
- The antibody titre has reached a critical level, <u>OR</u>
- There has been a previous fetus/newborn affected by HDFN, OR
- The antibody is Rh and/or anti-K

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 2017, 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

Number of	RHD Genotype	Predicted	RHD Sequencing	Rh Group
Patients		Phenotype		
7	No RhD variants detected	N/A	No	Positive
2	Weak D Type 3 (RHD*01W.3)	Weak D	No	Positive
2	Weak D type 2 (RHD*01W.2)	Weak D	No	Positive
4	Weak D type 1 (RHD*01W.1)	Weak D	No	Positive
1	Weak D type 4.0 or 4.3 (RHD*09.03 or RHD*09.05)	Weak D	No	Negative
1	Weak D type 4.1 (RHD*09.04)	Weak D	No	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 Times

To ensure timely reporting of patient test results, Canadian Blood Services monitors turnaround time (TAT) from when the specimen is received at Canadian Blood Services in Winnipeg to the time when the results are available. Since monitoring of this quality indicator began in 2008, the percentage of specimens has consistently exceeded the predefined TAT threshold. Samples whose testing exceeds the expected TAT are usually those where clinically significant antibodies are detected or where difficulty in finding compatible blood is encountered.

Table 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	85%

Table 9: Turnaround Time – Routine Perinatal Specimens

Turnaround Time (TAT)	2013	2014	2015	2016	2017
% of Specimens Tested within 72 hours	88%	87%	90%	87%	85%
% of Specimens Tested > 72 hours	13%	13%	10%	13%	15%

Figure 7: Perinatal Routine TAT



Table 10: Turnaround Time – Routine Crossmatch Specimens

% of Specimens Tested within 24 hours	92%	91%	93%	90%	82%
% of Specimens Tested > 24 hours	8%	9%	7%	10%	18%

Figure 8: Crossmatch Routine TAT



Note: SK Diagnostic Services crossmatch services discontinued June 2017

Table 11: Turnaround Time – Reference Specimens

% of Specimens Tested within 24 hours	81%	92%	95%	93%	100%
% of Specimens Tested > 24 hours	2%	1%	5%	7%	0%

Figure 9: Reference TAT



Note: SK Diagnostic Services crossmatch services discontinued June 2017

B. Rejected Specimens

Each time a specimen is rejected, a reason for rejection is captured in the laboratory information system (LIS). This data is retrieved and analyzed on a quarterly basis.

As described in *Table 12*, the reasons for rejecting specimens in the Perinatal Laboratory are distributed similarly between problems with requisitions and discrepancies between the requisition and the specimens. Also, a number of samples fell outside of the testing criteria, having been tested within the current pregnancy (Other category). Rejection rates have consistently stayed 2 – 3% for each quarter. *Table 13* describes the reasons for rejecting specimens in the Crossmatch Laboratory.

Note: As of 2017-10-02, the Vancouver Diagnostic Services site provides Perinatal Testing Services for Saskatchewan. Specimen rejection rates are captured in Vancouver Diagnostic Services' Year in Review statistics.

Table 12: Quarterly Rejection Rates – Perinatal Specimens

Rejection Category	Q1 2017	Q2 2017	Q3 2017	Q4 2018
Requisition	26	33	N/A	N/A
Specimen	16	29	N/A	N/A
Discrepancies Between Requisition & Specimen	32	38	N/A	N/A
Discrepancies Between Current Requisition & Historical Records	0	3	N/A	N/A
Other (Duplicates, etc.)	48	32	N/A	N/A
Total # specimens rejected	122	135	N/A	N/A
Total # specimens received	5052	5278	N/A	N/A
Rejections as a % of total	2.4	2.6%	N/A	N/A

Figure 10: Perinatal Rejection Reasons (2017-2018 - Q1 and Q2)



Rejection Category	Q1 2017	Q2 2017	Q3 2017	Q4 2018
Requisition	0	N/A	N/A	N/A
Specimen	0	N/A	N/A	N/A
Discrepancies Between Requisition & Specimen	1	N/A	N/A	N/A
Discrepancies Between Current Requisition & Historical Records	0	N/A	N/A	N/A
Other (Duplicates, etc.)	0	N/A	N/A	N/A
Total # specimens rejected	1	N/A	N/A	N/A
Total # specimens received	46	N/A	N/A	N/A
Rejections as a % of total	2.2%	N/A	N/A	N/A

Table 13: Quarterly Rejection Rates – Crossmatch Specimens

ACCOMPLISHMENTS IN 2017

A. Perinatal Advisory Committee

The Perinatal Advisory Council meeting for 2017 was held in Brampton, Ontario on November 20th.

In addition to the Canadian Blood Services Testing group members, an invited hospital guest in 2017 was Dr. Oksana Prokopchuk- Gauk from the Saskatoon Health Region.

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

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

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

B. Diagnostic Services Web Page Redesign

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

C. Repatriation of Crossmatch Testing Services

Canadian Blood Services worked with the Saskatchewan Ministry of Health and their stakeholders to seamlessly the Crossmatch Testing Services from Canadian Blood Services to hospital facilities in Regina and Saskatoon. The transition was completed on 2017-06-19.

D. Saskatchewan Perinatal Testing

With the closure of the Saskatchewan (SK) Diagnostic Services in October 2017, BC and Yukon Diagnostic Services was assigned testing of SK perinatal patients samples to provide continuity of services to the healthcare providers of SK. Under the scope of the perinatal program, BC provides routine testing, antibody identification, titrations and report results to SK healthcare provider. The SK perinatal program will be reverted back to Saskatchewan under the direction of SK Health in the near future.

GOALS FOR 2018

A. Perinatal Testing Transition

Canadian Blood Services will continue to hold planning discussions with Saskatchewan Ministry of Health officials and stakeholders to ensure a smooth transition process of perinatal testing from the Vancouver Diagnostic Services laboratory to Saskatchewan hospital testing sites.