Canadian Blood Services
Société canadienne du sang

DIAGNOSTIC SERVICES

British Columbia / Yukon

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.

SENIOR STAFF AND CONTACT INFORMATION

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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

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 month followed by biweekly in the last trimester for the duration of the pregnancy dependant on the specificity of the antibody and the strength of the antibody titre.
For patients with titers of 16 or greater (and dependant on paternal phenotype) referral to Maternal Fetal Medicine clinic is recommended.
Refer to Fetal Genotyping (page 17) for additional 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).

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.

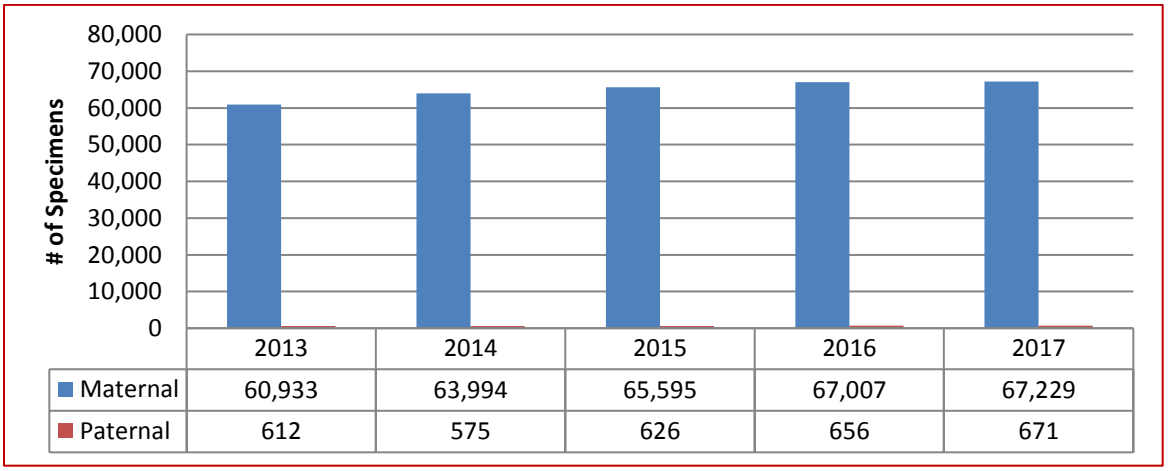
C. Specimens Tested

The data includes all women tested, including referrals.

Table 1: Perinatal Specimens Tested

Specimen Type	Test Type	2013	2014	2015	2016	2017
Maternal	Type and Screen	60,933	63,994	65,595	67,007	67,229
Paternal	ABO/Rh	612	575	626	656	671
Total # of Specimens Tested		**61,545**	**64,569**	**66,221**	**67,663**	67,899
Total # of Patients Tested		**53,800**	**55,052**	**55,869**	**57,089**	**62,063**

Figure 1: Total Perinatal Specimens Tested



D. Antibodies Identified

In 2017, a total of 389 antibodies were reported (see *Table 2*). This is slightly higher than 2016. Three hundred and forty nine women had antibodies identified during their pregnancies (increased from 285 women in 2016), of these; 312 women had clinically significant antibodies, 37 had clinically insignificant antibodies and 13 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-K, anti-M (IgG), (see *Figure 2*) which together represented 71% of the total antibodies identified. IgG Anti-M can be considered clinically significant as they 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 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

Maternal Clinically Significant Antibodies Identified– 2017					
Clinically Significant Antibodies	**2013**	**2014**	**2015**	**2016**	**2017**
Anti-D	44	44	46	38	52
Anti-C	11	12	8	5	7
Anti-C^{w}	4	1	2	2	1
Anti-Ce	2	0	1	0	0
Anti-c	25	23	14	11	30
Anti-E	102	92	85	80	101
Anti-e	10	8	3	3	2
Anti-G	5	2	1	2	4
Anti-K	37	43	41	33	41
Anti-Kp^{a}	0	0	0	0	1
Anti-Lu^{b}	0	1	1	0	0
Anti-M*	45	39	46	47	49
Anti-S	6	8	8	6	8
Anti-s	0	0	2	2	1
Anti-Fya	2	3	4	1	8
Anti-Fyb	3	3	1	1	1
Anti-Jka	17	18	12	15	23
Anti-Jkb	0	3	2	1	8
Anti-Jk3	0	0	0	1	0
Anti-Vw	1	2	0	0	0
Anti-Wra	2	9	3	3	3
Anti-Jra	1	0	1	0	0
Anti-Lub	2	0	0	1	0
Anti-Inb	0	0	0	0	0
Anti-Sc1	0	0	1	0	0
Anti-Lua	0	0	1	0	1
Anti-Cob	0	0	1	0	0
Anti-Dantu	0	1	1	0	0
Anti-Yta	0	0	1	0	1
Anti-V	0	0	0	0	1
TOTAL: Clinically Significant Antibodies	**319**	**312**	**286**	**252**	**343**

*Anti-M – IgG antibody component detected

Clinically Insignificant Antibodies	2013	2014	2015	2016	2017
Anti-A1	14	5	10	12	11
Anti-Lea	16	17	9	7	11
Anti-Leb	10	11	1	1	5
Anti-N			3	1	
Anti-P1	52	38	23	20	19
Anti-Sda	16		6		
Passive Anti-D (not included in totals)	469	514	651	681	726
TOTAL: Clinically Insignificant Antibodies	108	71	52	41	46

Table 3: Perinatal Patient Antibody Titres (2017)

Antibody	Critical Level	Non-Critical Level	Non-Critical to Critical
Anti-D	11	53	4
Anti-C	-	5	-
Anti-E	6	87	4
Anti-c	3	21	1
Anti-e	-	2	-
Anti-DC	1	-	-
Anti-DE	-	-	-
Anti-Ec	1	7	1
Anti-Ce	-	-	-
Anti-G	-	1	-
Anti-DG	1	-	-
Anti-CG	-	-	-
Anti-K	-	1*	-
Anti-Fya	2	7	1
Anti-Fyb	-	1	-
Anti-Jka	1	21	1
Anti-Jkb	-	7	-
Anti-M	1	44	1
Anti-S	-	6	-
Anti-s	1	1	1

*Titres are not normally performed on Kell system antibodies as these antibodies may be critical at any level. This titre was performed upon request of the physician.

Figure 2: Total Number of Perinatal Antibodies

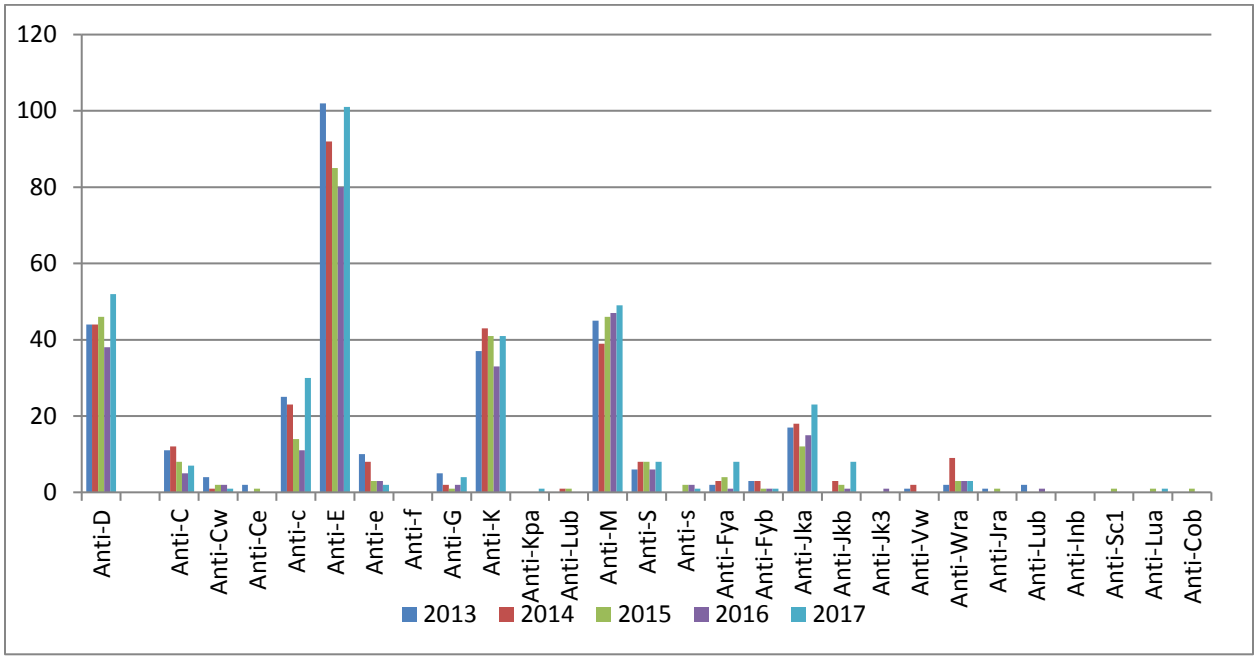


Figure 3: Frequency of Clinically Significant Antibodies

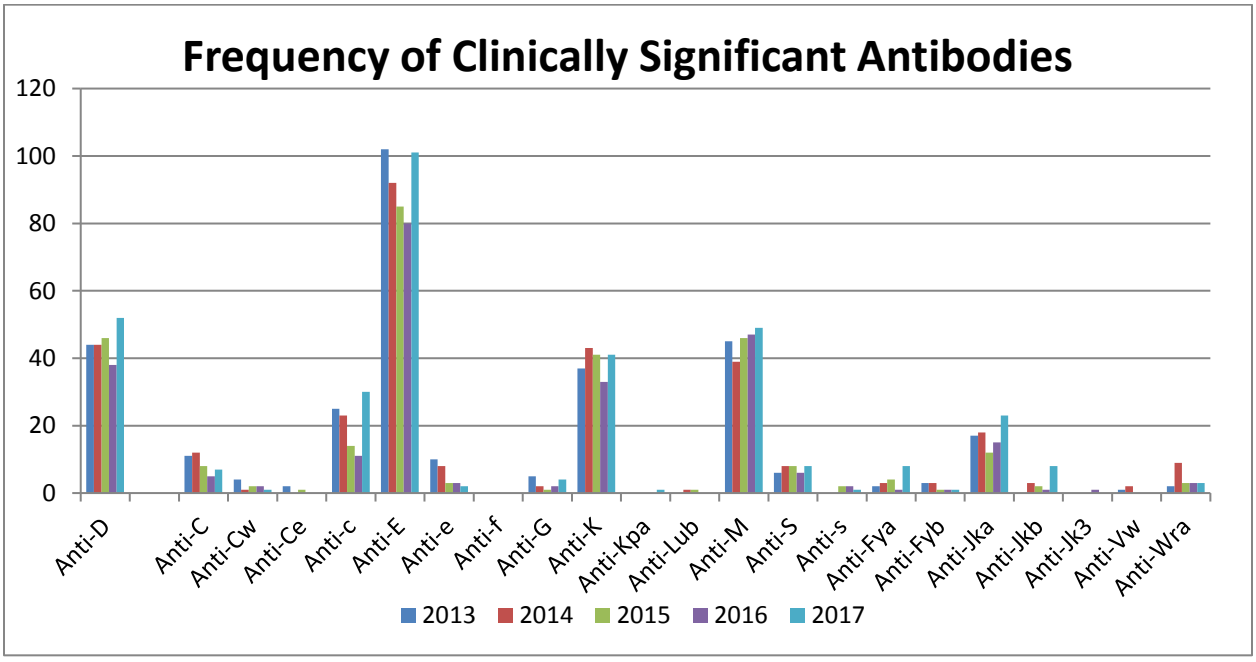


Table 4: Combination Antibodies

Antibodies	Number in 2017
Anti-Kpa Anti-Fya	1
Anti-D Anti-E	1
Anti-D Anti-K	1
Anti-D Anti-Lea	1
Anti-D Anti-G	2
Anti-E Anti-Wra	1
Anti-D Anti-C	2
Anti-D Anti-P1	1
Anti-D Anti-P1 Anti-Lea Anti-Leb Anti-V	1
Anti-M Anti-Fya	1
Anti-S Anti-D Anti-G	1

REFERENCE LABORATORY

The Reference Laboratory, Vancouver Diagnostic Services provides testing for hospital transfusion medicine laboratories. Hospital patients who are repeatedly transfused may develop red cell antibodies and as a result may have difficulty in tolerating transfusions. Diagnostic Services has specialized and experienced technologists that assist and provide consultation to hospital transfusion medicine laboratories (24 hours, 7 days per week). The Reference Laboratory identifies red cell antibodies and provides transfusion recommendations. Diagnostic Services has a varied selection of specialized procedures and rare reagents to resolve more difficult red cell antibody cases. Staff within our department have collaborated serological investigations with other reputable references laboratories such as the New York Blood Center and the National Immunohematology Reference laboratory (NIRL). BC Diagnostic Services contributes to continuing technologist education at provincial or national transfusion medicine conferences. (Refer to Accomplishments – page 23)

Diagnostic Services Red Cell Antibody Investigations

In 2017, hospitals have referred 412 requests for red cell antibody identification.

Diagnostic Services provides support for all BC and Yukon hospitals. Since hospitals have different capabilities and expertise in resolving red cell antibody investigations, Diagnostic Services has categorized hospitals into three levels based on their capabilities.

Level 1

Level 1 is defined by hospital transfusion medicine laboratories that do not have the resources for either antibody identification or phenotyping of patient and donor units prior to transfusion. Hospital transfusion medicine laboratories capabilities usually include the following methods:

Routine Services	Additional Methods:
ABO and Rh Antibody detection Crossmatch	Gel / SIAT / PEGIAT / LIAT / Solid Phase Pre-warm Saline replacement

Diagnostic Services Support Provided - Level 1 Hospitals

- Consultation.
- Identifying and/or excluding antibodies to the major blood group antigens.
- Providing compatible/antigen negative donor units if applicable.
- Forwarding an interim report followed by the final antibody report and patient antibody wallet card (where applicable) to the hospital Transfusion Service.

Level 2

Level 2 is defined by hospital transfusion medicine laboratories that have limited resources available for antibody identification. Level 2 hospitals generally have one in-date antibody panel and a small inventory of the common antisera to some of the major blood group antigens (eg. anti-C, -E, -c, -e, -K, -Fya, -Fyb, -Jka and -Jkb). Hospital Transfusion Service capabilities usually include the following methods:

Routine Services	Additional Methods
ABO and Rh Antibody detection Crossmatch Resolve antibody cases with exclusions of most single specificity antibodies base on an in-date panel Phenotype patient and donor units if antisera is available Resolve antibody cases with exclusions of most single specificity antibodies based on the in-date panel Phenotype patient and donor units if antisera available.	Gel/SIAT/PEGIAT/LIAT/ Solid Phase Pre-warm Saline replacements Differential DAT

Diagnostic Services Support Provided - Level 2 Hospitals

- Consultation.
- Identifying and excluding antibodies to the major blood group antigens.
- Providing antigen negative donor units if the corresponding antisera is not available at the hospital and if donor testing is not able to provide phenotyped inventory.
- Forwarding an interim report followed by the final antibody report and patient antibody wallet card (where applicable) to the hospital Transfusion Services. The hospital Transfusion Service should forward a copy of the report to the patient's physician (if indicated by hospital policy) as well as the antibody wallet card to the patient.

Level 3

Level 3 is defined by Hospital transfusion medicine laboratories that have the resources to resolve the majority of serological problems. Resources would include two or more in-date panels and antisera to the major blood group antigens. Hospital Transfusion Service capabilities usually include the following methods:

Routine Services	Additional Methods
ABO and Rh Antibody detection Crossmatch donor units SIAT/PEGIAT/LIAT// Solid Phase and/or Gel Identify or exclude most single/multiple/rare antibodies based on two or more in-date panels Phenotype patient/donor units as required Provide a written report to the patient's physician and an antibody wallet card to the patient.	Pre-warm Saline replacement Differential DAT Elution Auto/Alloadsorptions Inhibition/Neutralization

Diagnostic Services Support Provided - Level 3 Hospitals

- Consultation
- Identifying and excluding antibodies to the major blood group antigens
- Providing antigen negative donor units if the corresponding antisera is not routinely stocked at the hospital
- Forwarding an interim report followed by the final antibody report to the hospital Transfusion Service

A. Testing Performed

The Reference Laboratory routinely performs the following tests:

- ABO/Rh blood type
- Screen for red blood cell antibodies
- Antibody Identification
- Phenotyping (patient and donor units)
- Transfusion Reaction Investigation
- Direct Antiglobulin Test
- Elution and Allo and Auto Absorptions
- Neutralization Tests
- Referral Genotype Testing

Antibody Screening is routinely performed by solid phase testing. A combination of solid phase testing and indirect antiglobulin tube testing using PEG for enhancement is the primary antibody identification methods. PEG IAT is also the manual back-up method for antibody screening.

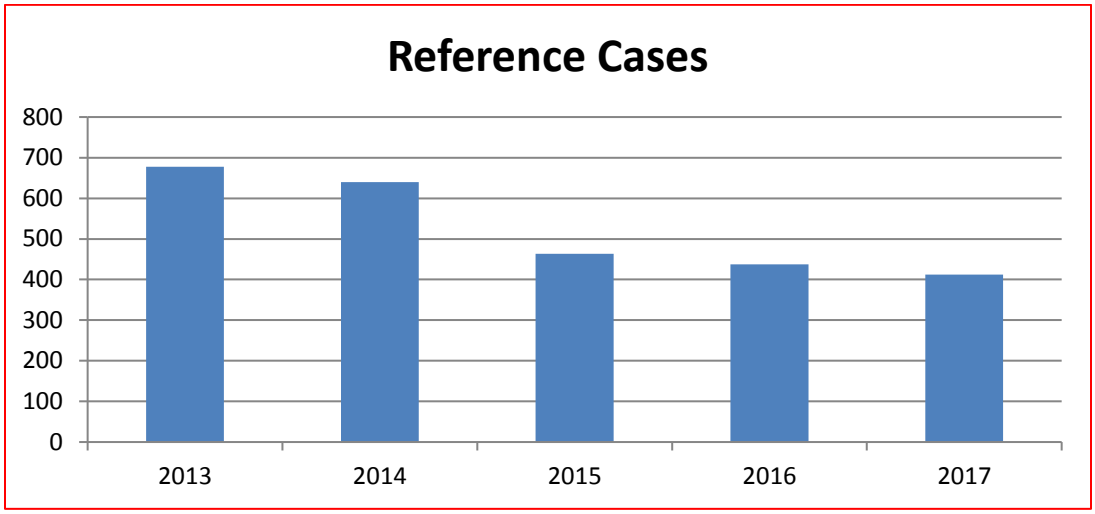
B. **Specimens Tested**

The data in this report reflects a calendar year period to enable better correlation to other government statistical data.

Table 5: Reference Specimens Tested

Specimen Type	2013	2014	2015	2016	2017
Total Reference Antibody Investigations	678	640	463	437	412

Figure 4: Total Reference Specimens Tested



C. Antibodies Identified

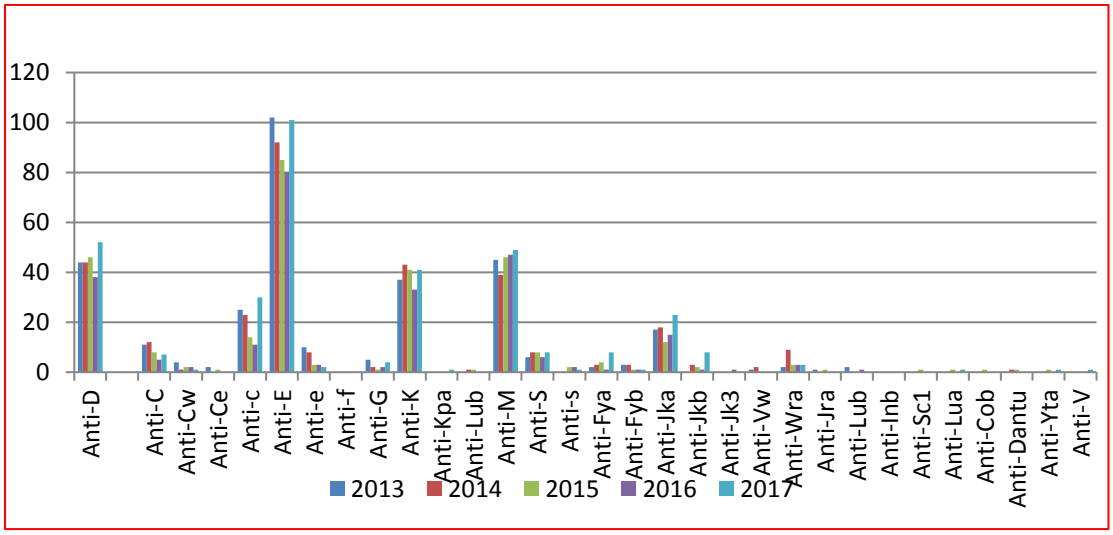
In 2017, a total of 412 antibodies were reported (see *Table 6*). The total number of antibodies detected is lower than in 2016, but the distribution of the most common antibodies remains consistent. Three hundred and twenty-three patients had antibodies identified; of these, ninety-five patients had 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-D, anti-M, anti-K, anti-c (see *Figure 5*) which together represented 80% of the total antibodies identified.

Table 6: Total Number of Reference Antibodies Detected

	2013	2014	2015	2016	2017
Anti-D	44	44	46	38	52
Anti-C	11	12	8	5	7
Anti-C^{w}	4	1	2	2	1
Anti-Ce	2		1		
Anti-c	25	23	14	11	30
Anti-E	102	92	85	80	101
Anti-e	10	8	3	3	2
Anti-f					
Anti-G	5	2	1	2	4
Anti-K	37	43	41	33	41
Anti-Kp^{a}					1

Anti-Lu^b		1	1		
Anti-M	45	39	46	47	49
Anti-S	6	8	8	6	8
Anti-s			2	2	1
Anti-Fya	2	3	4	1	8
Anti-Fyb	3	3	1	1	1
Anti-Jka	17	18	12	15	23
Anti-Jkb		3	2	1	8
Anti-Jk3				1	
Anti-Vw	1	2			
Anti-Wra	2	9	3	3	3
Anti-Jra	1		1		
Anti-Lub	2			1	
Anti-Inb					
Anti-Sc1			1		
Anti-Lua			1		1
Anti-Cob			1		
Anti-Dantu		1	1		
Anti-Yta			1		1
Anti-V					1

Figure 5: Total Number of Reference Antibodies



FETAL GENOTYPING

Canadian Blood Services in BC has been referring out specimens for fetal genotyping to the IBGRL (NHS) in Bristol, England as they can detect fetal DNA from maternal plasma.

Specimens are submitted through the Maternal Fetal Medicine clinics in BC 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, and
- 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.

Table 7: Fetal Genotyping Results Summary

Patient	Maternal Antibody	Paternal phenotype	Predicted Fetal Genotype	Follow-up Phenotype (on baby after delivery)
1	Anti-D	D+ C+ E- c+ e+	D-	D-
2	Anti-K	K+ k+	K-	K-
3	Anti-D and Anti-K	unknown	D+ / K-	D+ / K-
4	Anti-D	D+ C- E- c+ e+	D+	D+
5	Anti-E and anti-c	D+ C- E+ c+ e+	E-	E-
6	Anti-D	unknown	D+	D+
7	Anti-D	D+ C+ E- c+ e+	D+	D+
8	Anti-D	unknown	D-	D-
9	Anti-D	D+ C+ E+ c+ e+	D+	D+
10	Anti-D and Anti-G	D+ C+ E- c+ e+	D+	D+

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

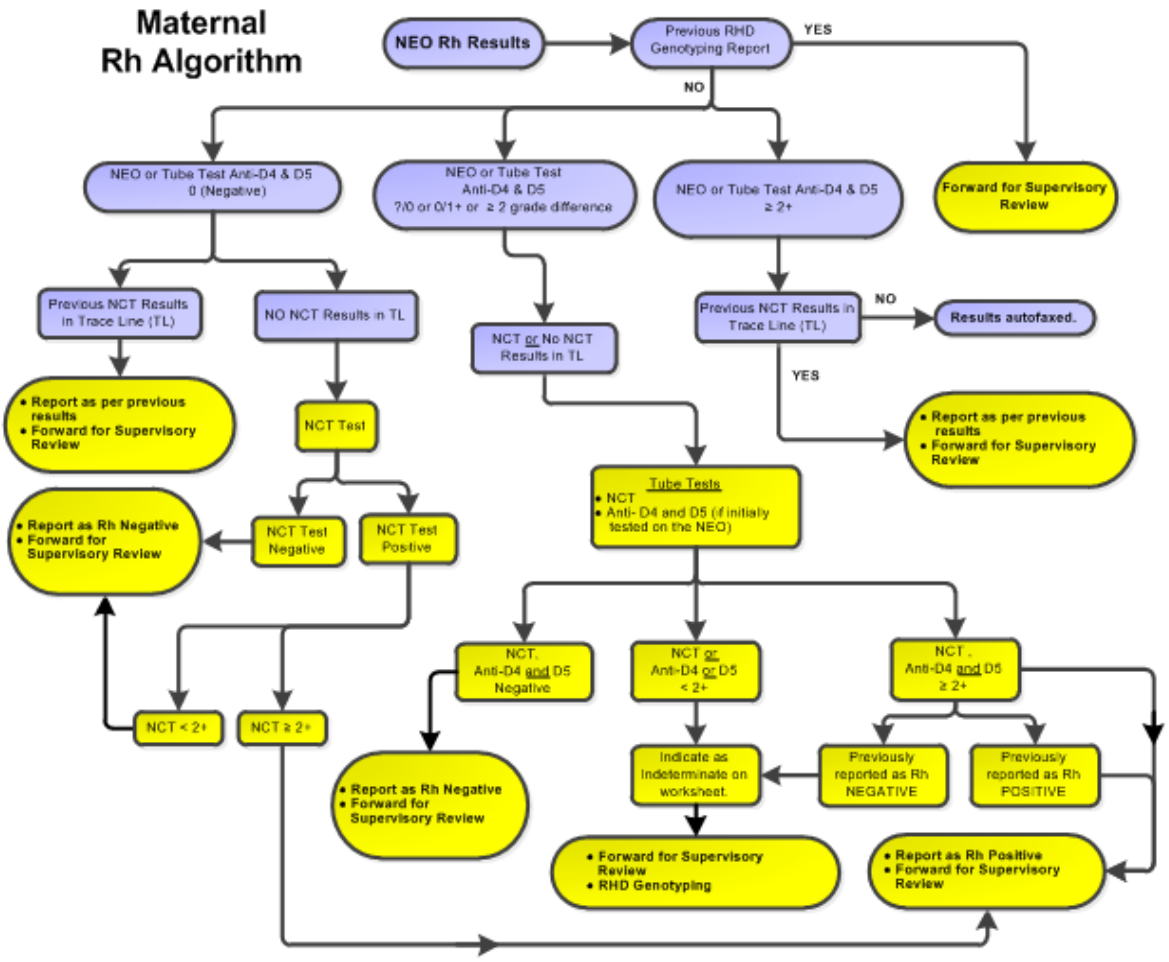


Table 8: Patient # - RHD Type/Result

# of Patients	RHD Genotype	Predicted Phenotype	RHD Sequencing	Rh(D) Group
4	DFR or DFR3	Partial D	NO	NEG
1	DOL or DOL 2	Partial D	NO	NEG
1	DVI	Partial D	NO	NEG
3	No RHD variants detected (Possible D)	D variant	NO	NEG
1	No RHD variants detected (Possible D)	D variant	NO	POS *
1	Normal RHD	Normal RHD	NO	POS
11	Possible D	D variant	NO	NEG
1	RHD deletion	Rh Negative	NO	NEG
2	RHD Deletion (possible rG)	RHD deletion	NO	NEG
21	weak D type 1	weak D	NO	POS
1	weak D type 14 or 40 or 51	weak D	NO	NEG
1	weak D type 2	weak D	NO	POS
48	weak D type 21	weak D	NO	NEG
1	weak D type 3	weak D	NO	POS
21	weak D type 4.0 or 4.3	weak D	NO	NEG
1	weak D type 4.1	weak D	NO	NEG
16	DFR or DFR3	Partial D	NO	NEG
10	DOL or DOL 2	Partial D	NO	NEG
1	DVI	Partial D	NO	NEG
146	**Total number tested**			

- CBS Medical Director decision to classify this patient as 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 Vancouver to the time when the results are available. Since monitoring of this quality indicator began in 2008, the percentage of specimens has consistently exceeded the predefined TAT threshold. Samples whose testing exceeds the expected TAT are usually those where clinically significant antibodies are detected or where difficulty in finding compatible blood is encountered.

Table 9: Turnaround Time – Routine Criteria by Specimen Type

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

Table 10: Turnaround Time – Routine Perinatal Specimens

% of Specimens Tested within 72 hours	91%	91%	89%	89%	91%
% of Specimens Tested > 72 hours	8%	8%	11%	11%	9%

Figure 7: Perinatal Routine TAT

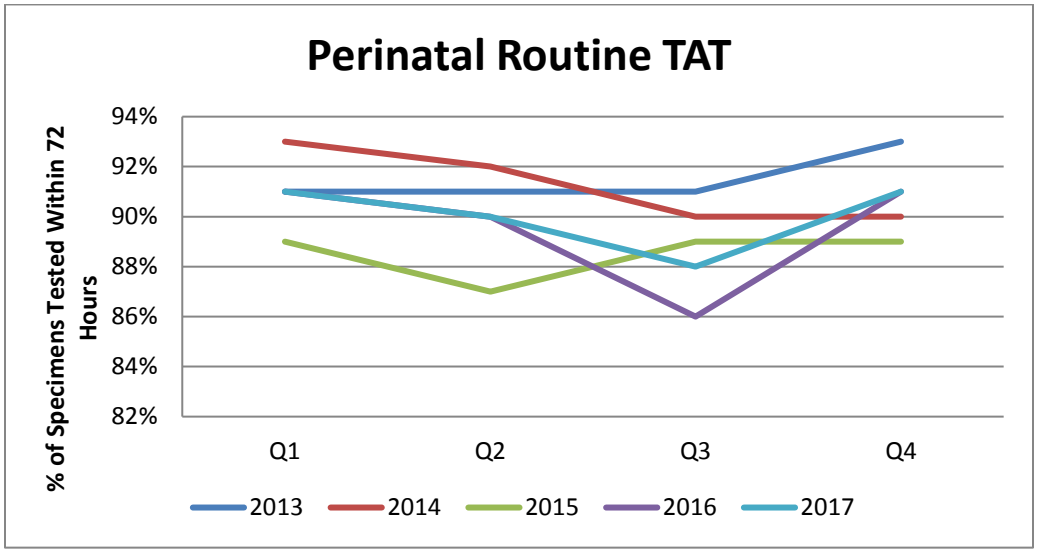
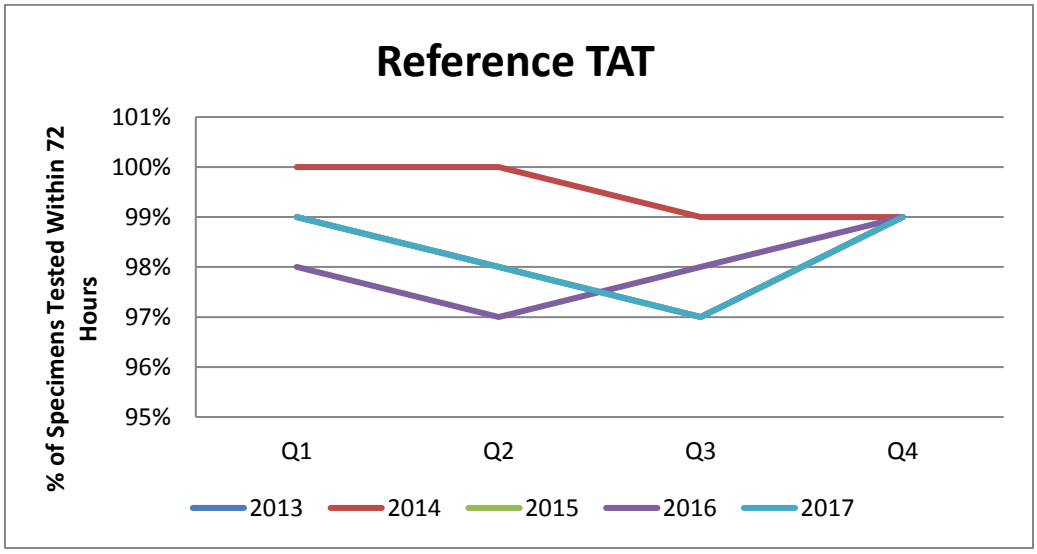


Table 11: Reference TAT

Turn Around Time (TAT)	2013	2014	2015	2016	2017
% of Specimens Tested within 72 hours	98%	99%	98%	98%	98%
% of Specimens Tested > 72 hours	2%	1%	2%	2%	2%

Figure 8: 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 analyzed on a quarterly basis. The number of rejected specimens is quite low for both perinatal and reference specimens. Reference specimens come from hospitals and perinatal samples are primarily collected at external collection sites.

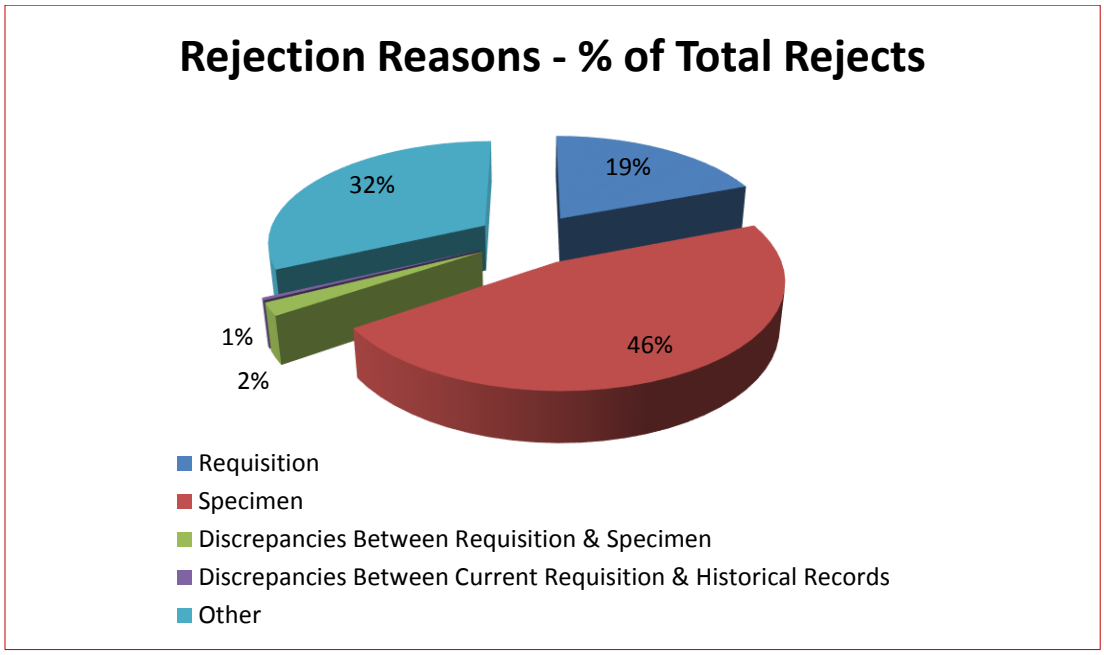
For perinatal specimens, the most common reason for rejecting a sample is that the sample is a duplicate. Samples are rejected if another sample from the patient was tested within the previous week. Often a duplicate sample is collected when the patient has seen their family physician and then sees their 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 BC patients on Care Connect (BC's Electronic Health Record).

Table 12: Quarterly Rejection Rates – Perinatal Specimens

Rejection Category	Q1	Q2	Q3	Q4
Requisition	0	2	26	20
Specimen	1	9	21	85
Discrepancies Between Requisition & Specimen	2	0	2	1
Discrepancies Between Current Requisition & Historical Records	0	0	1	0
Other (Duplicates, etc.)	33	32	65	117
Total # specimens rejected	36	32	65	117
Total # specimens received	16003	16325	23675	22275

Rejections as a % of total	**0.2%**	**0.2%**	**0.3%**	**0.5%**

Figure 9: Perinatal Rejection Reasons



ACCOMPLISHMENTS IN 2017

A. Cell Free Fetal DNA Testing (cff DNA)

Cell free fetal DNA testing is available by referral to the National Health Services (NHS) Laboratories in Bristol, UK. This testing would be performed on selected patients, referred by maternal fetal medicine physicians

B. 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.

C. 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.

D. Presentations / Abstracts / Publications

- ***How valuable is our time?*** (Mar 2017 Lunch and Learn) - Lhevinne Ciurcovich – Technical Supervisor BCY Diagnostic Services
- ***Management of Daratumumab (DARA) Patients by the Transfusion Medicine Laboratory*** - Kamloops BCSLS Sept 2017 – Lhevinne Ciurcovich – Technical Supervisor BCY Diagnostic Services
- ***It's always a horse and never a zebra! A perinatal case study***- Kamloops PBCO/CBS Education Session on Blood Transfusion Issues Sept 2017– Lhevinne Ciurcovich – Technical Supervisor BCY Diagnostic Services
- 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.

GOALS FOR 2018

A. Diagnostic Services Web Page Redesign

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

B. Update strategy for interpreting "Possible D" genotype reports.

Based on historical data, sequencing reports and information from other users of the genotyping assay, it is now considered that Individuals termed "Possible Anti-D" on the Bio-Array™ platform can be treated as RhD positive. They are at minimum risk of developing anti-D, and do not require RhIG prophylaxis. They can safely be transfused with RhD positive red cells. Further information to follow in the latter part of 2018.