DIAGNOSTIC SERVICES

MANITOBA

YEAR IN REVIEW

JANUARY – DECEMBER 2019

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

FIGURES

TABLES

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 Titration, 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)
- Bedside testing during fetal cordocentesis

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, maternal trauma, obstetrical procedure or suspected fetal hemorrhage).

Mothers – Antibody Present: If the antibody is known to cause HDFN, it is recommended that specimens be submitted every two 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. Less frequent sampling may also be recommended for antibodies that are unlikely to be clinically significant or in cases where clinical monitoring through fetal doppler ultrasound has commenced.

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 a Rh-negative woman delivers a Rh-positive baby. The Kleihauer-Betke assay is performed when the mother has a positive fetal bleed screening test.

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). This is especially important when the mother is Rh negative or when the mother has a clinically significant antibody. If the baby has unexpected anemia or jaundice, assessment of the cord blood sample for blood group and DAT may also be helpful.

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.

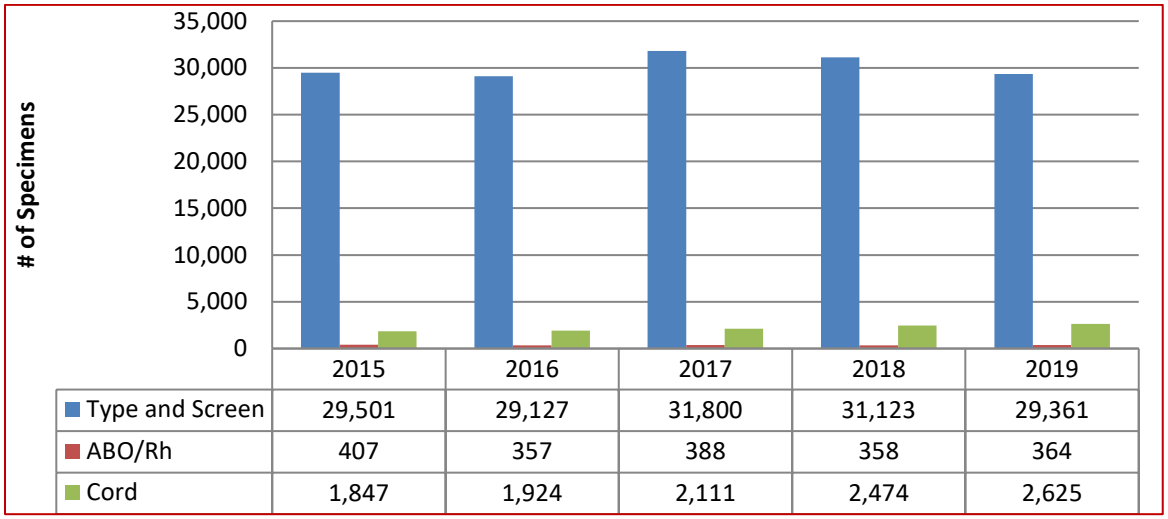
C. **Specimens Tested**

The data includes all women tested, including referral patients from other provincial jurisdictions. The total number of specimens tested has remained stable when compared to the last 4 years as seen in *Table 1* below.

Table 1: Perinatal Specimens Tested

Specimen Type	Test Type	2015	2016	2017	2018	2019
Maternal	Type and Screen	29,501	29,127	31,800	31,123	29,361
Paternal	ABO/Rh	407	357	388	358	364
Cord	ABO/Rh	1,847	1,924	2,111	2,474	2,625
Total # of Specimens Tested		31,755	31,408	34,299	33,955	32,350
Total # of Patients Tested		**24,005**	**23,980**	**24,248**	**24,079**	**23, 360**

Figure 1: Total Perinatal Specimens Tested



D. Antibodies Identified

In 2019, a total of 222 antibodies were reported (see *Table 2*). This is slightly lower than 2018 where 246 antibodies were reported. Two hundred and fifteen women had antibodies identified during their pregnancies (slightly decreased from 216 women in 2018). Breakdown of antibodies identified within the 215 women consisted of 206 clinically significant antibodies and 16 clinically insignificant antibodies. Thirty-eight women had multiple clinically significant antibodies. Passive anti-D data has been excluded from the preceding numbers.

Antibodies identified were considered clinically significant if they have been reported to cause HDFN. The most common clinically significant antibodies identified were: anti-E, anti-K, anti-Jk^{a}, anti-M (IgG), anti-D, and anti-c (see *Figure 3*) which together represented 84.4% of the total antibodies identified.

Titres for 6 of the clinically significant antibodies increased from non-critical to critical levels during the pregnancy with a total of 24 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 Antibodies Identified–2019					
Clinically Significant Antibodies	**2015**	**2016**	**2017**	**2018**	**2019**
Anti-D	10	12	11	11	16
Anti-C	18	10	9	10	6
Anti-C^{w}	1	2	2	0	0
Anti-Ce	0	0	0	0	0
Anti-ce	0	0	0	1	0
Anti-c	17	17	20	12	11
Anti-E	65	63	66	64	69
Anti-e	6	5	8	6	6
Anti-f	1	0	0	1	0
Anti-G	5	2	1	2	3
Anti-Ge3	0	0	0	1	0
Anti-K	57	47	56	58	51
Anti-Kp^{a}	1	1	1	0	1
Anti-Kp^{b}	0	1	1	0	0
Anti Lu^{a}	0	1	1	0	0
Anti-Lu^{b}	1	2	0	0	1
Anti-M*	12	9	18	16	14
Anti-S	7	6	6	7	6
Anti-s	1	1	2	0	1
Anti-Fy^{a}	5	4	4	4	2

Maternal Antibodies Identified–2019					
Clinically Significant Antibodies	**2015**	**2016**	**2017**	**2018**	**2019**
Anti-Fy^{b}	2	1	4	4	1
Anti-Jk^{a}	20	17	20	17	13
Anti-Jk^{b}	1	5	4	4	1
Anti-Jk^{3}	0	0	1	0	0
Anti-Di^{a}	1	0	0	1	1
Anti-Di^{b}	0	0	0	1	1
Anti Mi^{a}	0	0	0	1	0
Anti-V	0	1	1	1	0
Anti-Wr^{a}	2	2	2	1	2
Total	**233**	**209**	**238**	**223**	**206**

***Anti-M – IgG antibody detected**

Clinically Insignificant Antibodies	**2015**	**2016**	**2017**	**2018**	**2019**
Anti-A_1	0	0	1	0	0
Anti-He	0	0	1	0	0
Anti-JMH	0	0	1	1	1
Anti-Le^{a}	12	13	11	17	13
Anti-Le^{b}	1	2	2	2	1
Anti-N	0	0	2	1	1
Anti-P_1	0	0	3	2	0
Passive Anti-D (not included in totals)	892	738	813	763	665
TOTAL: Clinically Insignificant Antibodies	**13**	**15**	**21**	**23**	**16**

Figure 2: Total Number of Perinatal Antibodies

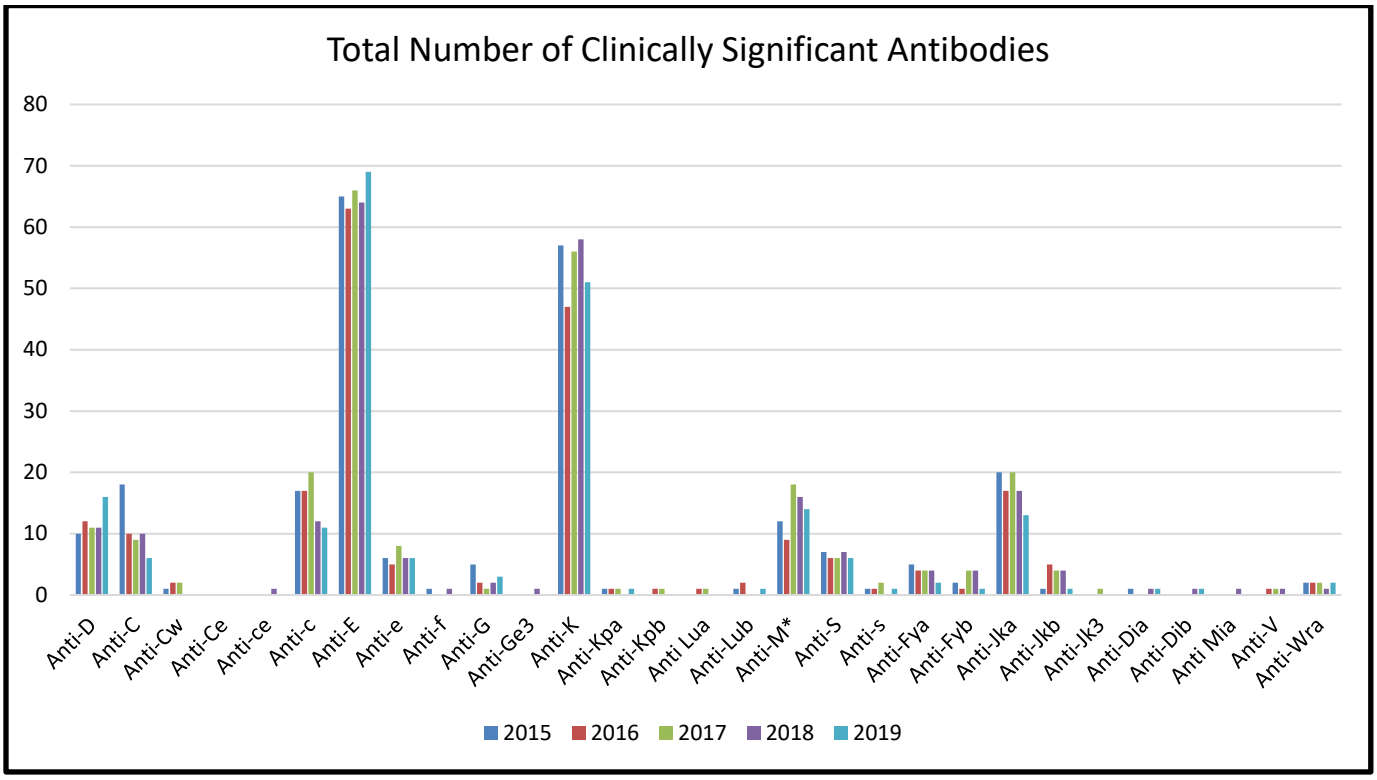


Figure 3: Frequency of Clinically Significant Antibodies

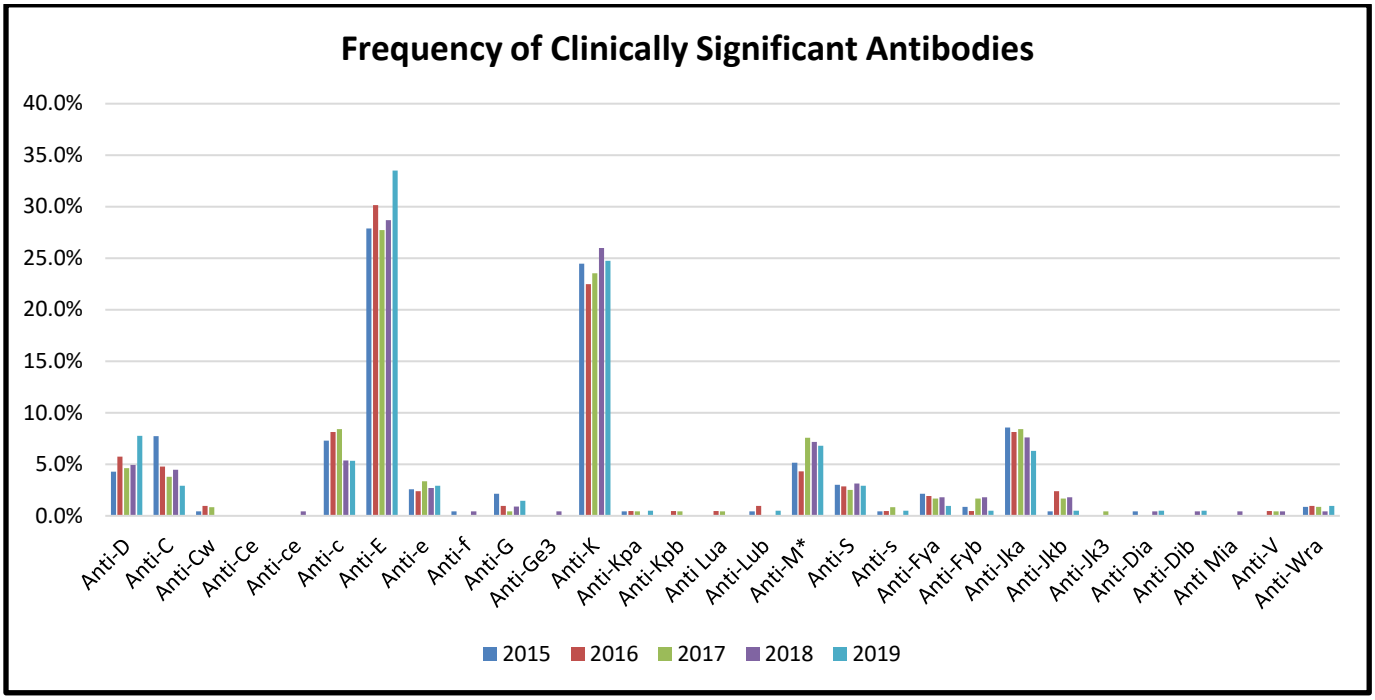


Table 3: Perinatal Patient Antibody Titres 2019

Antibody	Critical Level	Non-Critical Level	Non-Critical to Critical
Anti-D	7	9	3
Anti-C	1	3	0
Anti-E	5	39	2
Anti-c	1	8	0
Anti-e	1	0	0
Anti-DC	0	0	0
Anti-DE	0	1	0
Anti-Ec	4	1	1
Anti-Ce	0	1	0
Anti-G	0	0	0
Anti-DG	1	1	0
Anti-CG	0	1	0
Anti-K*	2	3	0
Anti-Fya	2	1	0
Anti-Fyb	0	1	0
Anti-Jka	0	8	0
Anti-Jkb	0	4	0
Anti-M	0	8	0
Anti-S	0	5	0
Anti-s	0	1	0

***Note:** Anti-K is considered critical at any titre. Antibody titres for Kell system antibodies may be performed in Manitoba after consultation with the Medical Officer.

Table 4: Perinatal Patient Combination Antibodies 2019

Combination Antibodies	Total
Anti-C, Anti-E	1
Anti-C, Anti-e	2
Anti-c, Anti-E, Anti-Jkb	1
Anti-c, Anti-Fya, Anti-Jkb	1
Anti-C, Anti-G	1
Anti-c, Anti-K	2
Anti-C, Anti-M	1
Anti-D, Anti-C	3
Anti-D, Anti-C, Anti-E	1
Anti-D, Anti-C, Anti-G	1
Anti-D, Anti-Fya	1
Anti-D, Anti-G	1
Anti-E, Anti-c	5
Anti-e, Anti-c, Anti-S	1
Anti-E, Anti-c, Anti-S, Anti-K, Anti-Kpa	1
Anti-E, Anti-c, Anti-Wra	1
Anti-E, Anti-Dib	1
Anti-E, Anti-Fya	1
Anti-E, Anti-Jkb	1
Anti-E, Anti-K	1
Anti-e, Anti-K	1
Anti-e, Anti-s	1
Anti-E, Anti-S	1
Anti-E, Anti-Wra	3
Anti-Fya, Anti-Jkb	1
Anti-Fyb, Anti-Dia	1
Anti-K, Anti-Lea	1
Anti-Lea, Anti-Leb	1
Total	38

CROSSMATCH / REFERENCE LABORATORY

The Crossmatch / Reference Laboratory Winnipeg Red Cell Serology, Diagnostic Services provides centralized transfusion medicine services and testing to 70 hospitals in Manitoba and eastern Nunavut that do not perform these tests. Reference services are provided for 4 rural hospitals with crossmatching laboratories in Manitoba and 12 hospitals in Northwest Ontario. 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 may collaborate with other references laboratories such as the National Immunohematology Reference laboratory (NIRL).

Diagnostic Services Red Cell Antibody Investigations

In 2019, hospitals have referred 232 requests for red cell antibody identification.

Referring hospitals have different capabilities and expertise in resolving red cell antibody investigations.

Canadian Blood Services, Diagnostic Services provides consultation and testing support including antibody investigation, advanced or alternative techniques where required, and recommendations for compatibility testing methods and selection of appropriate donor unit phenotypes if necessary.

Reporting may include interim, final and supplemental reports, depending on the urgency of the testing, the need for patient transfusion and the complexity of investigation. When a new antibody is identified by the Diagnostic Services laboratory a patient wallet card may be provided.

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 Absorption
- Cold Agglutinin Screen
- Thermal Amplitude
- Donath-Landsteiner Test

Antibody Screening is routinely performed by solid phase testing. A combination 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 platelet components to those hospitals which receive all of their transfusion medicine services from Canadian Blood Services.
The Crossmatch Laboratory performs complex antibody investigations and distributes crossmatch compatible (or least incompatible) red cell units.

B. Specimens Tested.

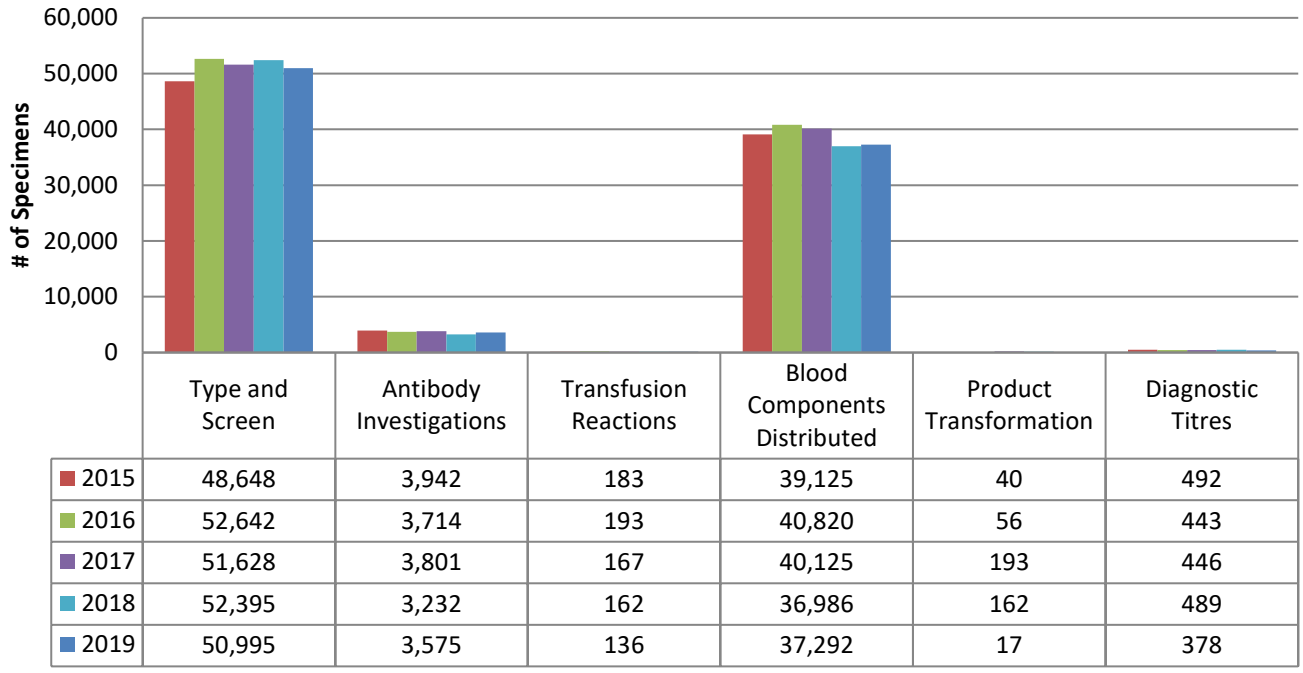
The data in this report reflects a calendar year period to enable better correlation to other government statistical data (Statistics Canada birth statistics).

The total number of crossmatch specimens tested has remained fairly consistent over the last 4 years as illustrated in *Table 5* below. The implementation of the Trace Line laboratory information system (LIS) was completed at 16 hospitals in Winnipeg and rural Manitoba in 2015. These hospitals now hold a stock inventory of red blood cell components and perform electronic crossmatch on demand; thus reducing the number of red blood cells issued and reserved for specific patients on hand in the hospital Blood Bank. The number of red blood cell components distributed has stabilized as hospitals appear to have adjusted inventories to optimal levels. As part of Choosing Wisely Canada, a “Just One” campaign that highlighted “Why give two when one will do?” was rolled out in late 2018 at the Winnipeg tertiary care facilities which may have contributed to the reduction in red blood cell utilization.

Table 5: Crossmatch/Reference Specimens Tested

Specimen Type	Test Type	2015	2016	2017	2018	2019
Crossmatch/Reference	Type and Screen	48,648	52,642	51,628	52,395	50,995
	Antibody Investigations	3,942	3,714	3,801	3,232	3,575
	Transfusion Reaction Investigations	183	193	167	162	136
	Blood Components Distributed	39,125	40,820	40,125	36,986	37,292
	Product Transformation	40	56	193	162	17
	Diagnostic Titres (Cold agglutinin, Isohemagglutinins)	492	443	446	489	378
Test Totals (excluding components distributed)		54,484	53,305	57,048	56,235	55,101
Number of Patients Tested		**29,219**	**31,200**	**30,553**	**31,025**	**29,528**

Figure 4: Total Crossmatch Specimens Tested



	Type and Screen	Antibody Investigations	Transfusion Reactions	Blood Components Distributed	Product Transformation	Diagnostic Titres
2015	48,648	3,942	183	39,125	40	492
2016	52,642	3,714	193	40,820	56	443
2017	51,628	3,801	167	40,125	193	446
2018	52,395	3,232	162	36,986	162	489
2019	50,995	3,575	136	37,292	17	378

C. Antibodies Identified

In 2019, total of 347 antibodies were reported (see *Table 6*). The distribution of the most common antibodies remains consistent. Two hundred and eighty-two patients had antibodies identified, of these; 55 patients had multiple antibodies.

Antibodies identified were considered clinically significant if they have been reported to cause acute or delayed hemolytic transfusion reactions. The most common clinically significant antibodies identified were: anti-K, anti-E, anti-D, anti-Jka, anti-c, anti-C, and anti-e, (see *Figure 5*) which together represented 85.0% of the total antibodies identified.

Figure 5: Total Number of Crossmatch Antibodies

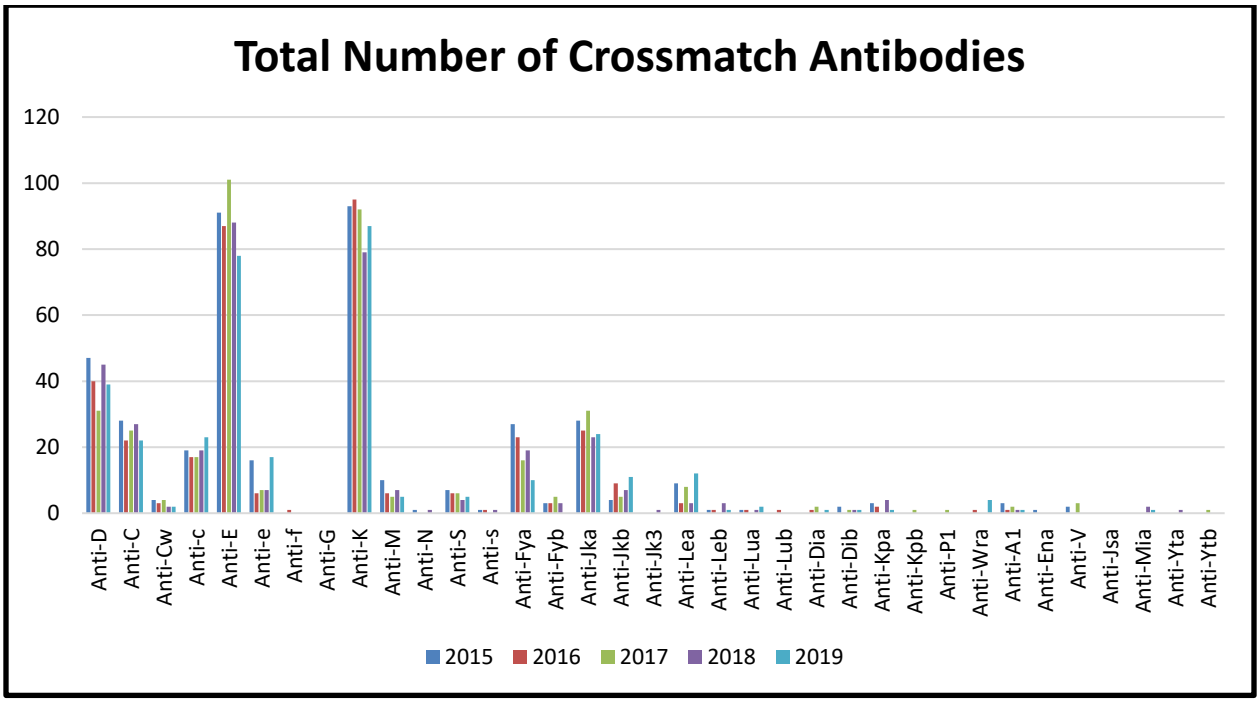
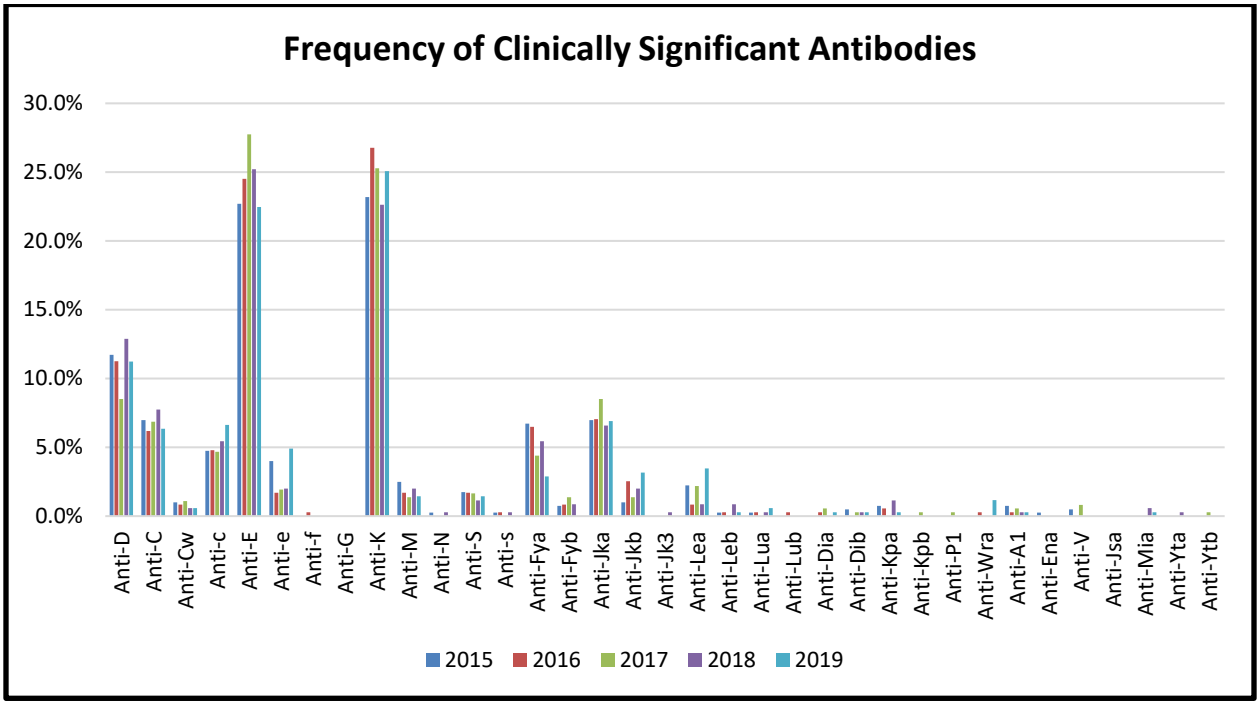


Table 6: Total Number of Crossmatch Antibodies Detected

Clinically Significant Antibodies	2015	2016	2017	2018	2019
Anti-D	47	40	31	45	39
Anti-C	28	22	25	27	22
Anti-C^w	4	3	4	2	2
Anti-c	19	17	17	19	23
Anti-E	91	87	101	88	78
Anti-e	16	6	7	7	17
Anti-f	0	1	0	0	0
Anti-G	0	0	0	0	0
Anti-K	93	95	92	79	87
Anti-M	10	6	5	7	5
Anti-N	1	0	0	1	0
Anti-S	7	6	6	4	5
Anti-s	1	1	0	1	0
Anti-Fy^a	27	23	16	19	10
Anti-Fy^b	3	3	5	3	0
Anti-Jk^a	28	25	31	23	24
Anti-Jk^b	4	9	5	7	11
Anti-Jk^3	0	0	0	1	0
Anti-Le^a	9	3	8	3	12
Anti-Le^b	1	1	0	3	1
Anti-Lu^a	1	1	0	1	2
Anti-Lu^b	0	1	0	0	0
Anti-Di^a	0	1	2	0	1
Anti-Di^b	2	0	1	1	1
Anti-Kp^a	3	2	0	4	1
Anti-Kp^b	0	0	1	0	0
Anti-P_1	0	0	1	0	0
Anti-Wr^a	0	1	0	0	4
Anti-A_1	3	1	2	1	1
Anti-En^a	1	0	0	0	0
Anti-V	2	0	3	0	0
Anti-Jsa	0	0	0	0	0
Anti-Mia	0	0	0	2	1
Anti-Yta	0	0	0	1	0
Anti-Ytb	0	0	1	0	0
Total	**401**	**355**	**364**	**349**	**347**

Figure 6: Frequency of Clinically Significant Antibodies 2019



PLATELET IMMUNOLOGY LABORATORY

The Platelet Immunology Laboratory within Diagnostic Services at Canadian Blood Services provides human leukocyte (HLA) and platelet specific (HPA) antigen typing and antibody investigation testing to assist health care providers in the management of thrombocytopenic patients who have become refractory to vital platelet transfusions, patients affected by neonatal alloimmune thrombocytopenia and autoimmune disorders and patients suspected to have had platelet antibody mediated adverse transfusion events such as post transfusion purpura (PTP). The Laboratory also performs testing on patients and donors for the investigation of Transfusion Related Acute Lung Injury (TRALI). The Laboratory provides service to all Manitoba hospitals and is a national reference lab for any hospital in Canada requiring these testing services.
In addition, the Laboratory also performs HLA and HPA typing on blood donors prior to being placed onto a national platelet donor registry. The registry is used to conduct searches to identify suitably compatible donors who can be used for patients that show no benefit from conventional platelet components.

A. Testing Performed

The Platelet Immunology Laboratory routinely performs the following tests:

- HLA Antigen Typing
- HLA Antibody Screen
- HLA Antibody Identification, if antibodies are detected
- HLA Antigen Typing for disease association
- HPA Typing
- HPA Screening
- HPA Antibody Identification, if antibodies are detected
- Platelet Crossmatch
- Selection of HLA/HPA Compatible Donors for Platelet Transfusion

HLA antibody screening and identification is performed using Luminex bead technology. Whereas HPA antibody screening, identification and crossmatching are performed using a solid phase platform, commercial ELISA kits and the MAIPA method.

A combination of Luminex® multiplex technology, Bioarray eMAP® (Elongation-mediated Multiplexed Analysis of Polymorphisms) technology and/or MicroSSP are the primary HLA and HPA genotyping methods utilized for genotyping both patients and donors.

Selection lists of HLA/HPA compatible donors for patients' requiring platelet transfusion support are generated by the Platelet Immunology Lab using the national platelet donor database.

B. Specimens Tested

Table 7 below illustrates the total number of Platelet Immunology specimens tested.

Table 7: Platelet Immunology Specimens Tested

Specimen Type		2015	2016	2017	2018	2019
Donor	HLA Antigen Typing	1,560	1,087	1,171	3,728	1,234
	HLA Antibody Screen/Identification	58	41	29	17	10
	HPA Antigen Typing	804	528	648	1918	615
	HPA Antibody Screen/Identification	19	10	79	9	31
Test Totals		**2,441**	**1,666**	**1,927**	**5,672**	**1,890**
Patient	HLA Antigen Typing	1,116	1,392	1,205	1,200	1,198
	HLA Antibody Screen/Identification	108	144	141	167	117
	HPA Antigen Typing	261	302	316	292	286
	HPA Antibody Screen/Identification	321	432	437	390	446
	Selection of HLA/HPA Selected Platelet Donors	307	369	395	333	289
Test Totals		**2,113**	**2,639**	**2,494**	**2,382**	**2,336**

Figure 7: Total Platelet Immunology Donor Specimens Tested

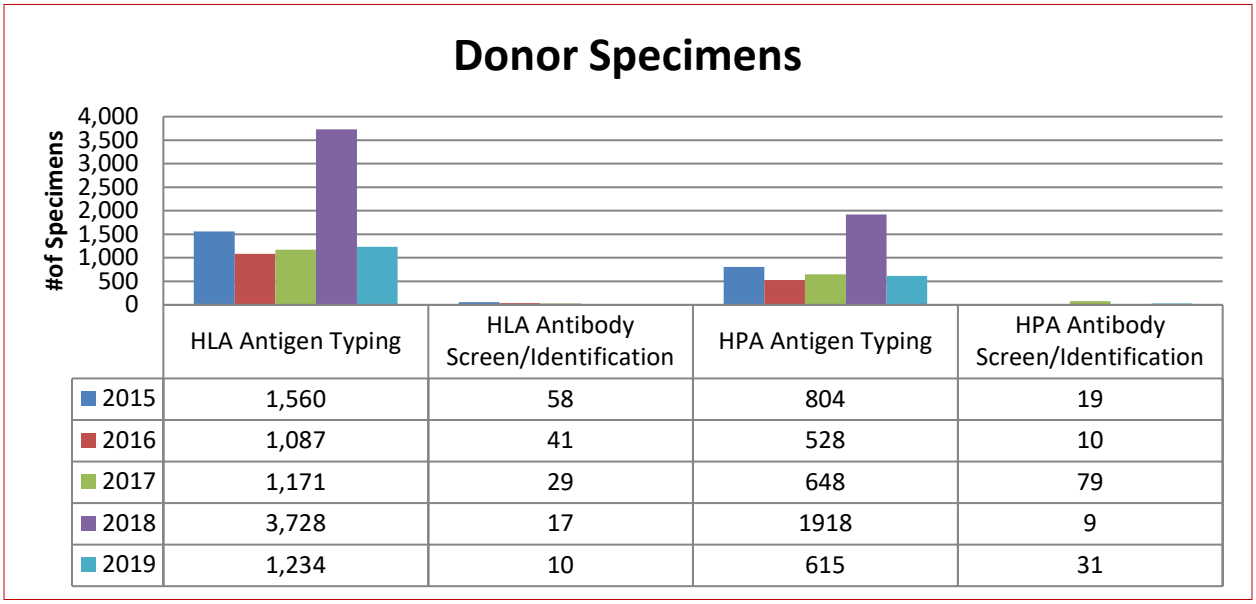
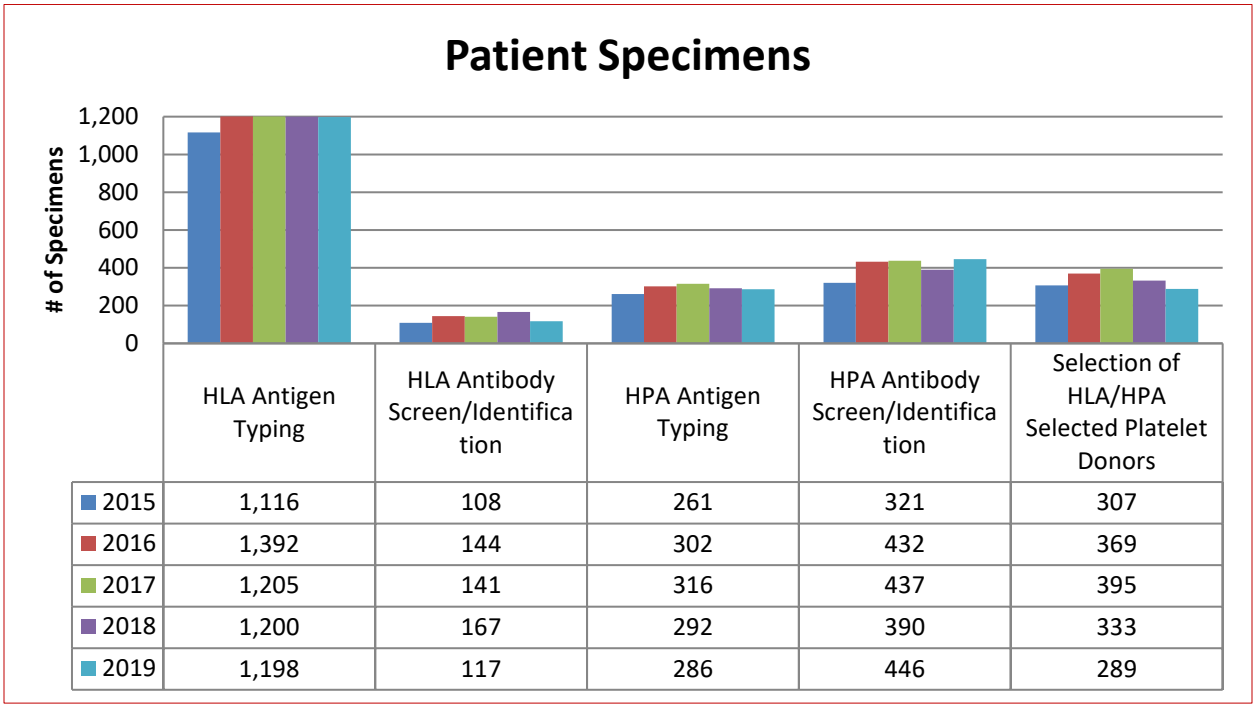


Figure 8: Total Platelet Immunology Patient Specimens Tested



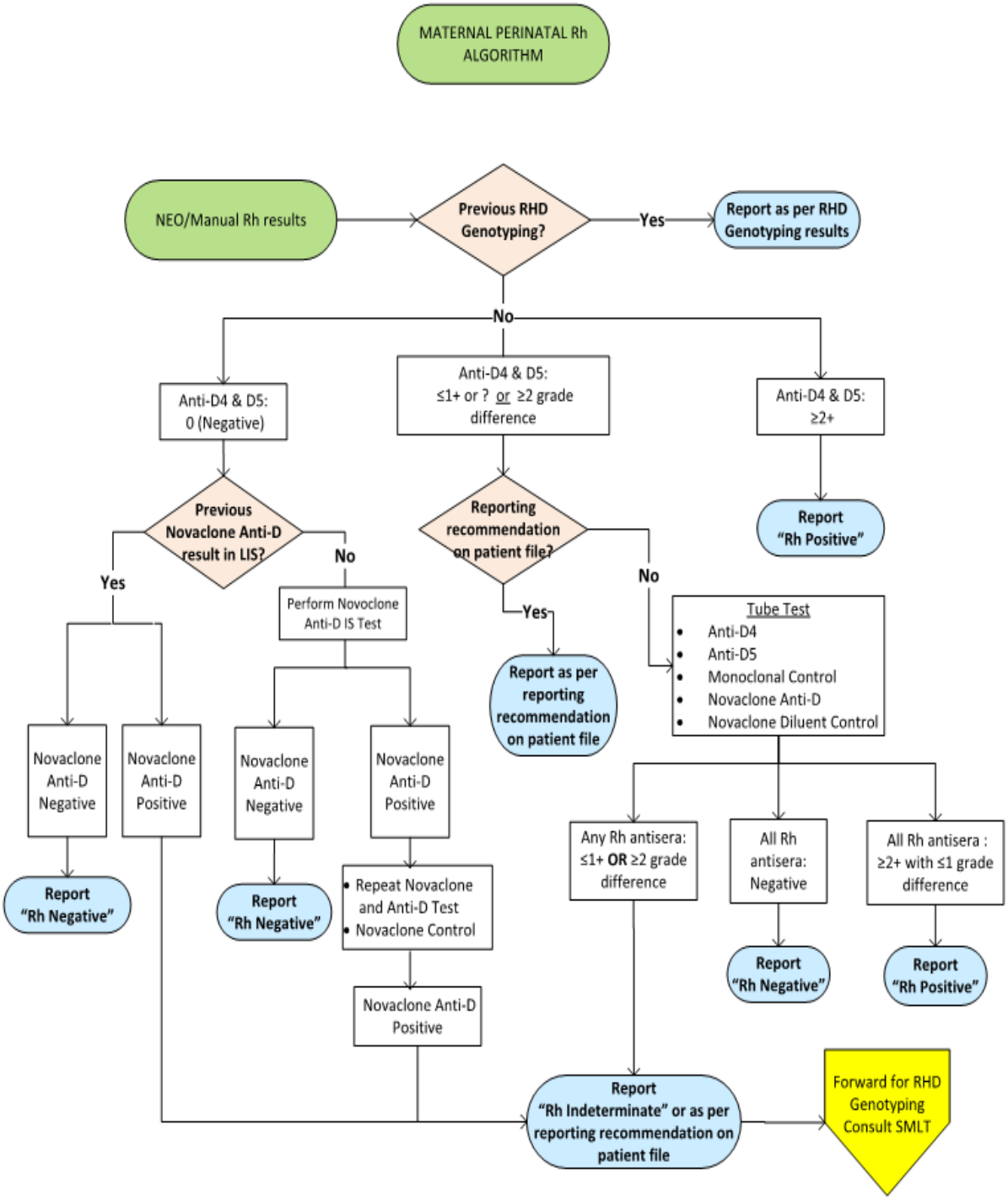
	HLA Antigen Typing	HLA Antibody Screen/Identification	HPA Antigen Typing	HPA Antibody Screen/Identification	Selection of HLA/HPA Selected Platelet Donors
2015	1,116	108	261	321	307
2016	1,392	144	302	432	369
2017	1,205	141	316	437	395
2018	1,200	167	292	390	333
2019	1,198	117	286	446	289

RED CELL GENOTYPING

Canadian Blood Services is able to provide red cell antigen genotyping services through our National Immunohematology Reference Laboratory (NIRL) and Edmonton Diagnostic Services Laboratory. This service is used to aid in resolving complex immunohematology cases. Molecular testing combined with hemagglutination testing can provide better resolution to serological problems and guide patient transfusion requirements in some circumstances especially for sickle cell patients and patients with chronic transfusion requirements and multiple or complex antibodies.

Based on the following testing algorithm patients with serologically variable Rh D typing results may require genetic testing for the RHD gene.

Figure 9: Rh D Testing Algorithm



For 2019, the following results were obtained in patients using one of the two red cell antigen genotyping platforms available at CBS:

Table 8: Patient # - RHD Type/Result 2019

Patient	RHD Genotype	Predicted Phenotype	RHD Sequencing	Rh(D) Group
1	Weak D type 1	Weak D	(not performed)	Positive
2	D positive			Positive
3	Weak D type 2	Weak D	RHD*O1W.2	Positive
4	Weak D type 2	Weak D	RHD*O1W.2	Positive
5	D Positive			Positive
6	Weak D type 1	Weak D	RHD*O1W.1	Positive
7	D positive			Positive
8	Weak D type 1	Weak D	RHD*01W.1	Positive
9	D positive			Positive
10	Weak D type 1	Weak D	RHD*01W.1	Positive
11	Weak D type 1	Weak D	RHD*01W.1	Positive
12	DaU4 or DV type 5	Partial D	RHD*10.04 or RHD*05.05	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 9: 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%
Perinatal Specimens with Antibodies	72 hours	85%
Routine Crossmatch Specimens	24 hours	90%
Reference Specimens	72 hours	85%
Routine Platelet Immunology Specimens (NAIT, PTP, Platelet alloimmunization)	14 days	90%
HLA Disease Association Specimens	28 days	90%
HLA B*5701 Specimens	28 days	90%
Donor HLA/HPA Typing Specimens	60 days	90%

Table 10: Turnaround Time – Routine Perinatal Specimens

Turnaround Time (TAT)	2015	2016	2017	2018	2019
% of Specimens Tested within 72 hours	93%	91%	94%	95%	92%
% of Specimens Tested > 72 hours	11%	9%	9%	11%	8%

Figure 10: Perinatal Routine TAT

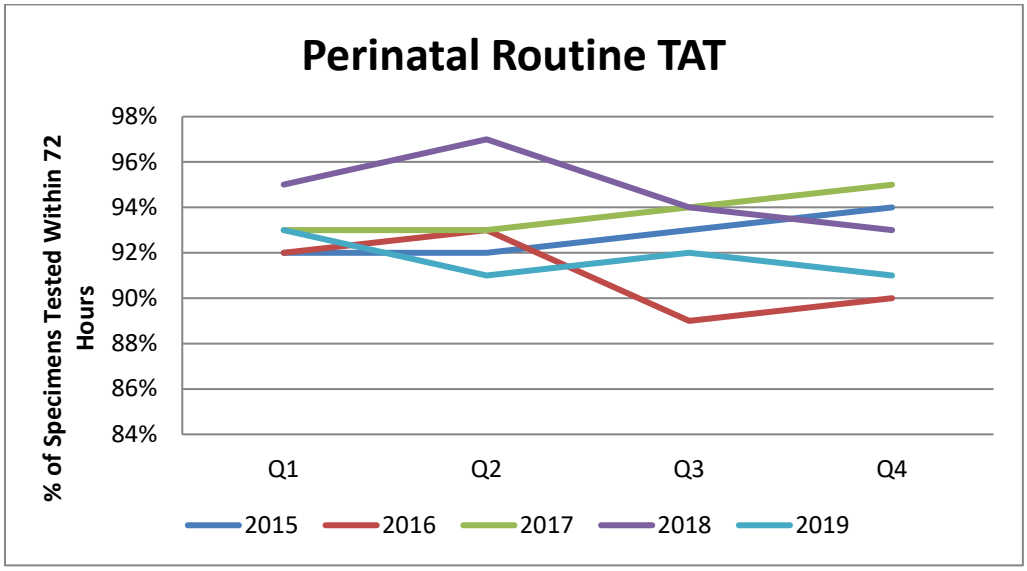


Table 11: Turnaround Time – Routine Crossmatch Specimens

Turnaround Time (TAT)	2015	2016	2017	2018	2019
% of Specimens Tested within 24 hours	99.80%	99.80%	99.80%	99.30%	99.30%
% of Specimens Tested > 24 hours	0.20%	0.20%	0.20%	0.70%	0.70%

Figure 11: Crossmatch Routine TAT

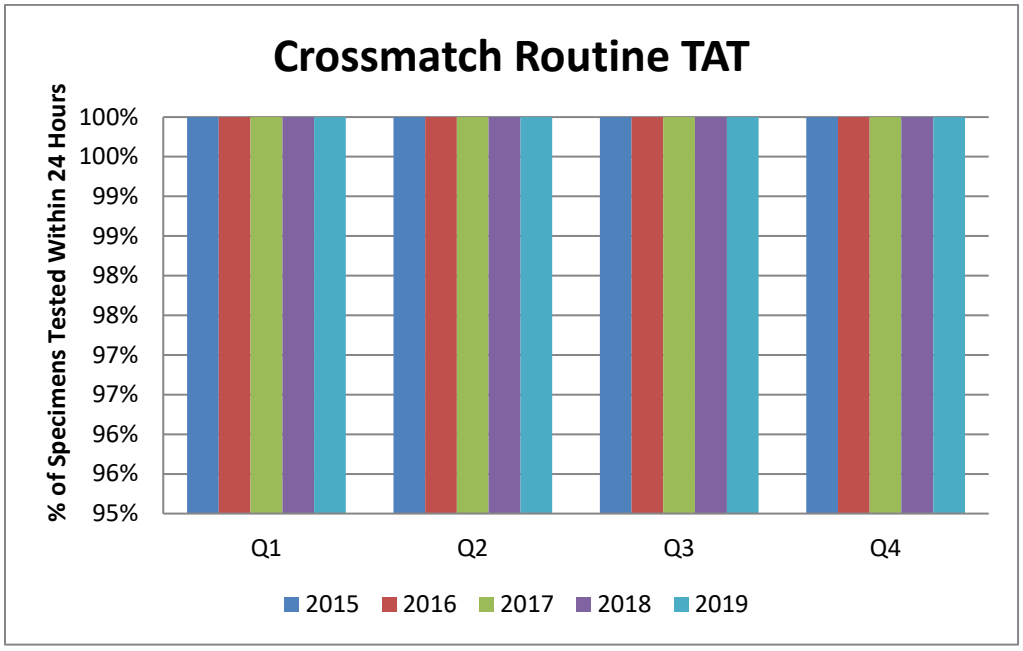


Table 12: Turnaround Time – Reference Specimens

Turnaround Time (TAT)	2015	2016	2017	2018	2019
% of Specimens Tested within 24 hours	99%	99%	99%	97%	97%
% of Specimens Tested > 24 hours	1%	2%	1%	3%	3%

Figure 12: Reference TAT

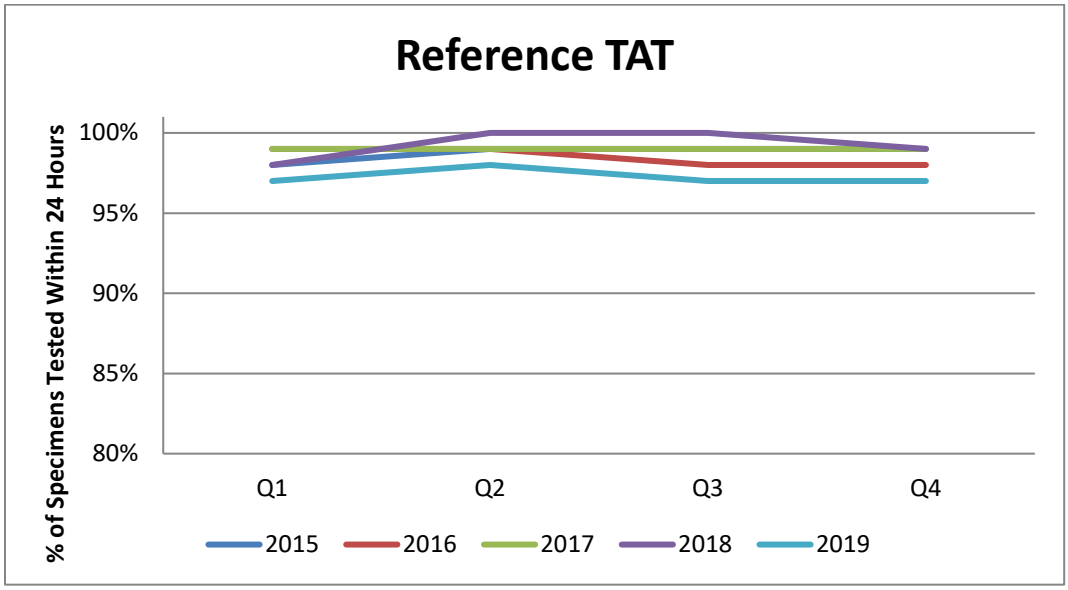
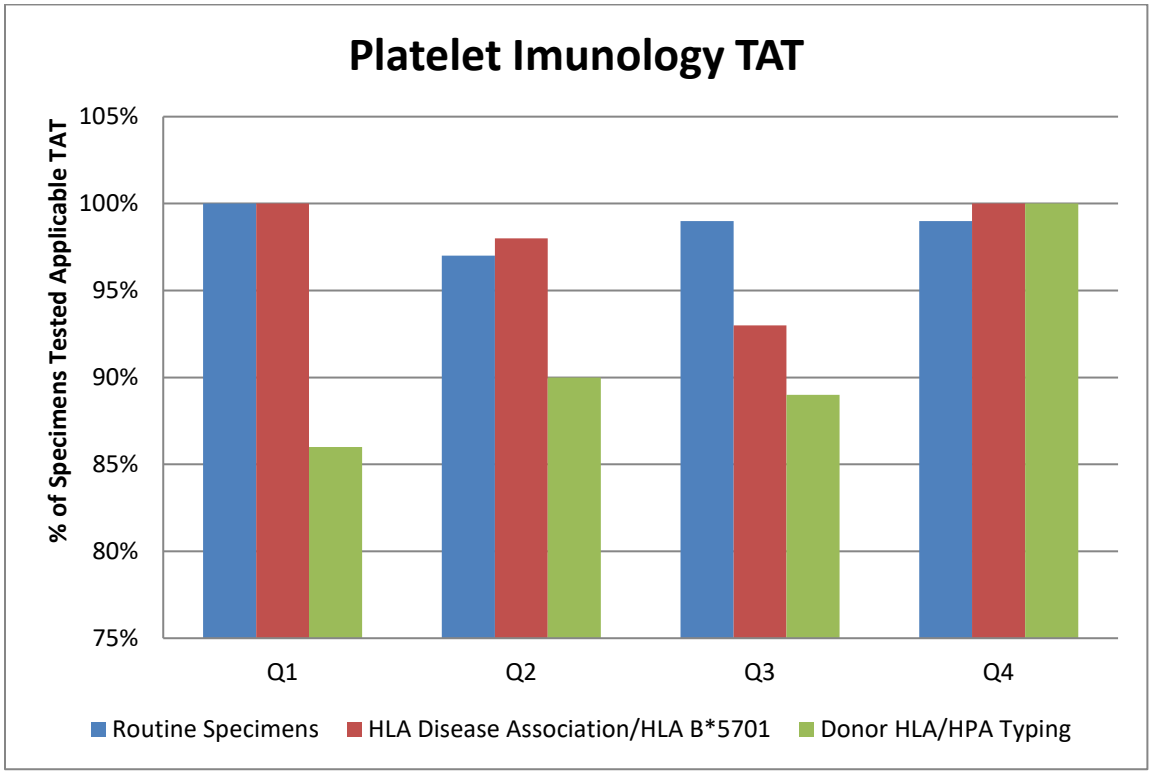


Table 13: Turnaround Time - Platelet Immunology Specimens

Turnaround Time (TAT)	2015	2016	2017	2018	2019
% of Specimens Tested within 14 days	94.50%	91.60%	85.3%*	97%	99%
% of Specimens Tested within 28 days	96.80%	94.00%	95.30%	94%	98%
% of Specimens Tested within 60 days	100%	95.00%	91%	99%	92%

* Preliminary results reported within 1-2 days of sample receipt.

Figure 13: Platelet Immunology TAT



B. Rejected Specimens

Each time a specimen is rejected, a reason for rejection is entered into our laboratory information system (LIS). This data is then retrieved and analyzed on a quarterly basis.

As described in ***Table 14 and Figure 14*****,** the reasons for rejecting specimens in the Perinatal Laboratory are primarily problems with requisitions, specimen labelling and discrepancies between the requisition and the specimen. Average rejection rates have decreased from a high of 4.4% in 2012 to 3.3% in 2019 which correlates with increased efforts to contact customers and educate them on acceptable labelling criteria.

Table 15 and Figure 15 describe the reasons for rejecting specimens in the Crossmatch Laboratory; the majority of which involve problems with specimens. Problems with specimen labelling and discrepancies between the requisition and the specimen tube label constitute the main reasons for specimen rejection. Missing or incorrect information on the label and discrepancies in the name, personal health number (PHN) or date of collection continue to be the most common specimen labelling errors seen. Specimens are also rejected if the sample is a duplicate. The rejection rate for crossmatch specimens continued to remain low throughout 2019. The average rejection rates have decreased from a high of 2.9% in 2012 to 12% in 9

The rejection rates for perinatal specimens are higher than for crossmatch (pre-transfusion) specimens. The collection process for crossmatch specimens is controlled with stringent best practices and standards that must be followed. Crossmatch specimens are usually collected in hospitals and are sent to Canadian Blood Services via the hospital blood banks where the samples are pre-screened to determine if there are discrepancies between the sample and requisition. Perinatal specimens are most often collected in clinics and community collection sites where the identification and labelling process may be more variable. Although there may be differences in the collection process all specimens are scrutinized using the same stringent acceptance criteria prior to testing at Canadian Blood Services.

Some specimens for crossmatch have already been rejected by the referring hospital laboratory and total numbers of these rejected specimens are not included in our data.

Table 16 and Figure 16 describe the reasons for rejecting specimens in the Platelet Immunology Laboratory; the majority of which involve specimens. Ninety-six percent of the specimens in this category were rejected because they were duplicate specimens that would not be tested; wrong tube type was the next most common reason. Efforts to educate hospital customers continued throughout 2018 and 2019. Average rejection rates have decreased from 9.6% in 2016 to 5.8%% in 2019.

Table 14: Quarterly Rejection Rates – Perinatal Specimens 2019

Rejection Category	Q1	Q2	Q3	Q4
Requisition	123	89	83	118
Specimen	91	139	117	93
Discrepancies Between Requisition & Specimen	59	37	82	57
Discrepancies Between Current Requisition & Historical Records	22	13	8	10
Other	4	8	23	14
Total # specimens rejected	299	286	313	292
Total # specimens received	8,762	8,992	8,636	8,799
Rejections as a % of total	3.4%	3.2%	3.6%	3.3%

Figure 14: Perinatal Rejection Reasons

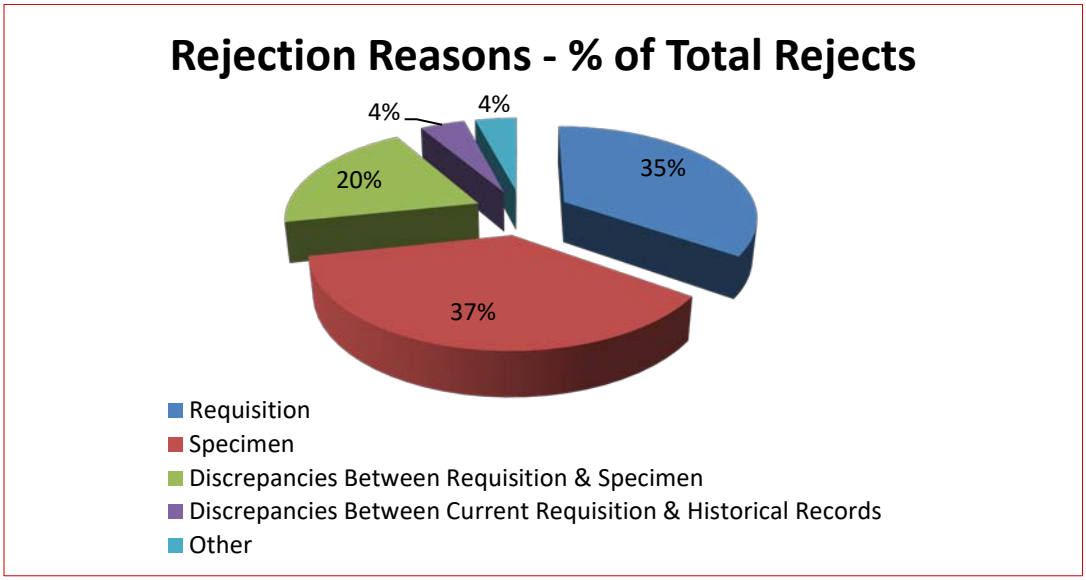


Table 15: Quarterly Rejection Rates – Crossmatch Specimens 2019

Rejection Category	Q1	Q2	Q3	Q4
Requisition	26	36	29	24
Specimen	94	66	73	85
Discrepancies Between Requisition & Specimen	85	68	81	64
Discrepancies Between Current Requisition & Historical Records	2	2	1	2
Other	23	10	9	6
Total # specimens rejected	230	182	193	181
Total # specimens received	13,959	14,469	13,526	14,725
Rejections as a % of total	1.6%	1.3%	1.4%	1.2%

Figure 15: Crossmatch Rejection Reasons 2019

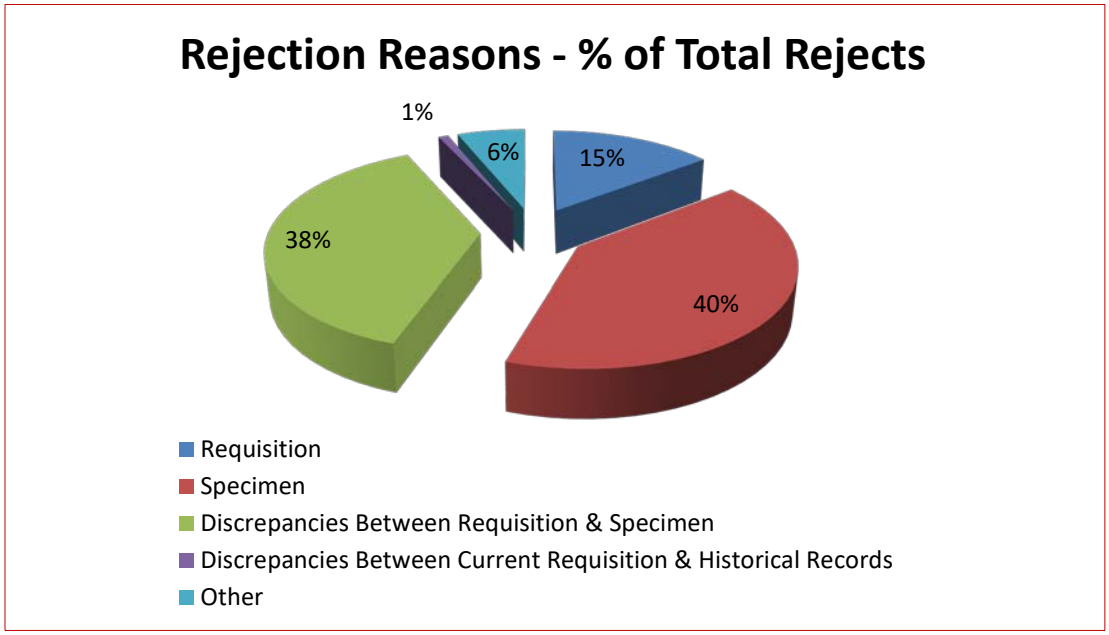
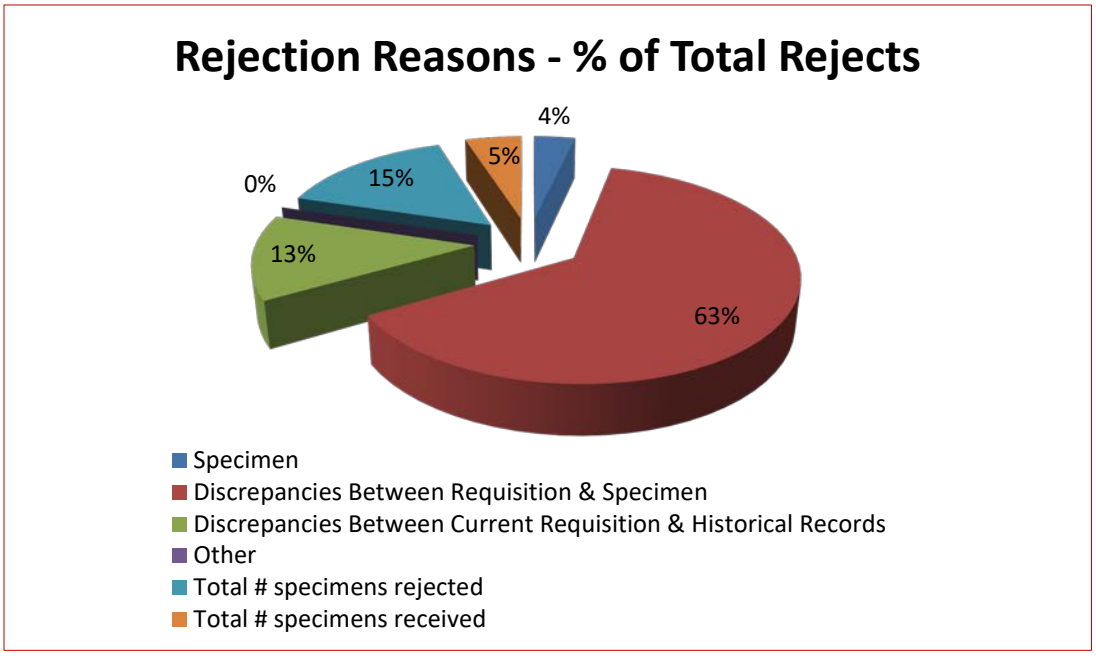


Table 16: Quarterly Rejection Rates – Platelet Immunology Specimens 2019

Rejection Category	Q1	Q2	Q3	Q4
Requisition	4	0	3	1
Specimen	24	53	38	25
Discrepancies Between Requisition & Specimen	8	10	6	5
Discrepancies Between Current Requisition & Historical Records	0	0	0	0
Unable to Enter Results in PROGESA	7	11	6	10
Other	7	3	1	0
Total # specimens rejected	50	77	54	41
Total # specimens received	584	1,290	1,108	709
Rejections as a % of total	8.6%	6.0%	4.9%	5.8%

Figure 16: Platelet Immunology Rejection Reasons 2019



DIAGNOSTIC SERVICES UPDATE 2019

Updates pertain to all Diagnostic Services sites within Canadian Blood Services: Vancouver, Edmonton, Winnipeg and Brampton

ALL CBS Diagnostic Services Sites	**Implementation of eTraceline Nov 2019**: eTraceline was implemented at all CBS reference laboratory sites in November 2019.
	Implementation of Antigen Plus April 2019 Antigen Plus, a program to allow development of panels from reagent cell collections was implemented along with a review and re organization of the reference lab inventory of rare reagent red cells and antisera.
	Perinatal Advisory Committee The PNAC continues to collaborate throughout the year and at an annual November meeting. The group reviewed and discussed an ongoing project related to the titration of multiple antibodies using cells with both antigens represented versus the standard method involving separate titrations of each antibody. An update of the plans for repatriation of Saskatchewan patient samples to a provincial hospital-based program was provided and a collaborative study to compare titer levels using the Saline IAT method at CBS vs the automated gel titration method in the Saskatchewan perinatal program was discussed. A review of the form used for notification of Intra uterine transfusion by the BC maternal fetal medicine group was provided Results of the recent Canada wide survey distributed to perinatal testing labs by the Canadian Obstetrical Perinatal network were reviewed and discussed. A project in the Manitoba Red Cell Serology lab involving development of a new process for preparing aliquots of red cell units for neonatal transfusion was described. New interpretive reporting comments for specimens with features suggesting Fetal /neonatal Alloimmune thrombocytopenia were discussed.

ALL CBS Diagnostic Services Sites	**DBL Novaclone Testing (NCT) on all Rh Negative Perinatal Patients Implemented 2019-01-29** CBS DS sites incorporated NCT testing into their prenatal RhD algorithm for all patients who test RhD negative on the NEO analyzer. NCT testing identifies a group of Rh prenatal patients not eligible for RhIG, who might have been typed as Rh negative based on initial NEO testing and results in a decrease in unnecessary RhIG prophylaxis.
	Critical Anti-M titre – Implemented 2019-11-04 Dithiothreitol (DTT) plasma treatment for critical anti-M titres was implemented at all Diagnostic Services Sites to determine if critical titre is due to IgG or IgM:2019-11-04 DTT is used to inhibit IgM antibody activity which allows for detection of underlying IgG antibodies. Procedure is performed on prenatal patients with a critical anti-M titre ($\geq$ 16) to determine the immunoglobulin class and the risk of HDFN. If the antibody is predominately IgG there is greater risk of HDFN and the mother is referred to the Maternal Fetal Medicine Clinic if the titre remains at $\geq$ 16 after the DTT plasma treatment.
Brampton	**Patient Genotype Testing Implemented 2019:** Reference lab testing of patients' samples for genotyping using the Grifols Progenika Core XT platform was implemented in the CBS Brampton reference laboratory in 2019.
	Transition of National Immunohematology Reference laboratory from Ottawa to Brampton site: The NIRL moved location from Ottawa to CBS Brampton
Vancouver /Edmonton	**Ortho MTS Gel Workstation and Pipettes Implemented 2019** Ortho MTS Gel workstations were implemented in the Vancouver and Edmonton Diagnostic Services Laboratories as a supplementary method to help complete antibody cases referred in from hospitals.
	Passive Anti-D Testing by NEO Cap-R Ready ID Implemented 2019-01-29 Vancouver and Edmonton Diagnostic Services Laboratories modified their Passive Anti-D testing platform from manual PEGIAT method to automated Capture R testing using the NEO analyzer. Automated testing provides a reduction in cost and decreased time to complete passive anti-D identification (which represents > 40% of perinatal antibody investigations), positive sample ID and reduces the risk of transcription errors.
Winnipeg	Collaboration with Shared Health Diagnostics to ensure the Diagnostic Services Business Continuity plan meshes seamlessly with other plans was a focus in 2019.

Winnipeg	**College of American Pathologists (CAP) Laboratory Accreditation** An on-site inspection of the Platelet Immunology Laboratory occurred with the lab successfully being granted accreditation. in the beginning of 2019.
	LEAN Continuous Improvement of Red Cell Serology Laboratories – Staff Cross Training Cross-training of staff to perform both pre-transfusion and perinatal testing continued in 2019. The goal is to more efficiently use people's talents.
	Preparation of Red Cell Aliquots for Neonatal and Pediatric Transfusion The project team for aliquoting smaller, patient appropriate doses of red cells for neonate and pediatric transfusion worked in 2019. The process was implemented on January 27, 2020.
	Process Change for the Distribution of Components in eTraceline In collaboration with Shared Health Diagnostics, the process for distribution of blood components to eTraceline facilities changed from using the Reserve/Transfer function to the Reserve/Issue function. This change was implemented on September 16, 2020. This change is a quality improvement initiative to reduce distribution errors by utilizing the broader functionality of the Issue program

Presentations / Abstracts / Publications Listing
D Lane, R Fallis, B Herdman, A Kabani, C Musuka, L Grabner. **Implementation of Electronic Solution to Reduce the Risk of Mistransfusion in a Regional Transfusion Service,** Poster/Abstract presented at AABB Meeting, San Diego, October 2017.
*Tammy Ison, Balkar Gill, Gwen Clarke, Carmela Pote, Melba Sarmiento***. Rare Donors Identified through Selective Genotype Testing using Voluntary Ethnic Donor Information,** CSTM abstract.
*L. Ciurcovich, H. Abukhadra, T. Dolnik, B. Gill, I. Resz, M. Yan, G. Clarke***. Maintaining an Inventory of Rare Reagent Red Cells and Antisera Across Multiple Reference Laboratories at Canadian Blood Services,** Poster Presentation at CSTM (Canadian Society for Transfusion Medicine), Calgary, Alberta, May 30 – June 2, 2019.
*Heba Abukhadra – Supervisor, BCY Diagnostic Services***. Transfusion Medicine Case Studies,** PBCO/CBS Education Session on Blood Transfusion Issues, October 3, 2019.
*Kirsten Hannaford, Supervisor EDM Diagnostic Services***. Monocyte Monolayer Assay Implementation**, Presentation for Immunohematology Working Group, May 07, 2019.
Hannon JL, Berardi P, Hannaford K. **Significance of "Possible D" Variant on BioArray BeadChip™ RHD Genotyping of Prenatal Patients, Abstract for** AABB, San Antonio, TX, October 19 – 22, 2019.

Presentations / Abstracts / Publications Listing
K Hannaford, M Yan, L Ciurcovich, J Hannon, G Clarke. **RHD Genotyping of patients with serological weak D: 2444 Patient samples with no anti D on follow up of 428 with a variant RHD,** Abstract for AABB, San Antonio, TX, October 19 – 22, 2019.
Matthew Yan, Medical Officer, CBS BC & Yukon Centre. **Anti-M: A Case of Hemolytic Disease of the Fetus and an Approach to Prenatal Management**, Abstract, Presentation at CSTM, Calgary, Alberta May 30 – June 2, 2019.
Vivian Stephens, Supervisor BCY Diagnostic Services. **Is it You?,** Lunch N Learn Presentation, June 11, 2019.
Brenda Caruk (Supervisor, EDM Diagnostic Services) and Lhevinne Ciurcovich (Technical Supervisor, BCY Diagnostic Services). **DARA and more... a Transfusion Medicine Case Study,** Lunch N Learn Presentation (EDM / BCY CBS Centres) April 3, 2019.