



Canadian Blood Services
it's in you to give

DIAGNOSTIC SERVICES BC & YUKON

YEAR IN REVIEW

JANUARY - DECEMBER 31, 2013

CANADIAN BLOOD SERVICES BC & YUKON DIAGNOSTIC SERVICES

SENIOR STAFF AND CONTACT INFORMATION

Associate Medical Director, West
Dr T Petraszko

(604) 707-3427
tanya.petraszko@blood.ca

Diagnostic Services Manager
Tony Dolnik

(604) 707-3481
tony.dolnik@blood.ca

Diagnostic Services Coordinator
Kathy O'Shea

(604) 707-3449
kathy.o'shea@blood.ca

Diagnostic Services Supervisor
Vivian Stephens

(604) 707-3483
vivian.stephens@blood.ca

Diagnostic Services Laboratory
Telephone
Fax

(604) 707-3434
(604) 874-6582

Website

www.blood.ca/diagnosticservices

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NOTE

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.

A. PERINATAL PROGRAM DESCRIPTION

Canadian Blood Services (CBS) provides testing of pregnant women for blood type and red blood cell antibodies under a program funded by BC Ministry of Health. This screening provides information to assist physicians, midwives and nurse practitioners in ensuring the appropriate management of a pregnancy for both the mother and baby.

1. Tests Performed

Canadian Blood Services, BC & Yukon, Diagnostic Services performs selected routine tests using the latest automated equipment for the appropriate management of hemolytic disease of the fetus and newborn (HDFN) and prevention of Rh(D) alloimmunization during pregnancy. The scope of this service includes the Province of British Columbia and Yukon Territory.

First Perinatal visit

All women, regardless of the results of tests performed elsewhere, should have blood drawn and forwarded to Canadian Blood Services – Diagnostic Services for routine serological testing as early as possible during each pregnancy. Routine tests include:

- ABO and Rh(D) typing – Automated Microplate
- Antibody Screen – Automated Solid Phase
- Antibody Identification (if antibodies are detected)
- Antibody Titre – if a clinically significant antibody is identified

Note: For Rh Negative patients, Rh testing does not include a test for Weak D

Subsequent Perinatal visits - Antibody Screen Negative

Initial Testing and testing at 24/26 weeks gestation

Rh Positive: First Pregnancy – Test at initial visit and re-test at 24/26 visit.

Rh Positive: Subsequent pregnancies – test at initial visit

Rh Negative: All pregnancies - Test at initial visit and re-test at 24/26 visit.

- ABO and Rh(D) typing
- Antibody Screen.

Samples should be submitted for testing for all perinatal patients at increased risk of alloimmunization as a result of previous transfusion, fetal trauma or procedure, IV drug use, regardless of Rh status.

Modified Antibody Screen

If the Perinatal requisition or the Perinatal database indicates that the patient has received an Rh Immune Globulin injection within the last three months, a routine Antibody Screen is omitted and a modified Antibody Screen is performed to:

- Exclude the presence of alloantibodies other than anti-D (passively acquired from a Rh Immune Globulin injection).

- Detect the presence of anti-D passively acquired from a recent Rh Immune Globulin injection. If the agglutination strength of the anti-D is greater than 2+, it is investigated as a possible active anti-D.

Subsequent Perinatal visits - Antibody Screen Positive

If the antibody screen is positive at any time during pregnancy, the antibody is identified. If the antibody identified is clinically insignificant, the following testing protocol is recommended:

- Rh Positive – Test the patient at a future pregnancy
- Rh Negative – Test the patient at 24/26 weeks tests and at future pregnancy.

If the antibody identified is clinically significant, the following testing protocol is recommended:

- Maternal specimens are requested monthly for antibody titration and exclusion of other clinically significant antibodies.
- Father's specimen for phenotyping is requested to predict the risk of hemolytic disease of the fetus and newborn (HDFN).
- If the antibody identified is anti-M the following tests are requested:

Anti-M titre is ≥ 4

- Father's specimen is requested for phenotyping.
- Maternal specimens are requested monthly for antibody titration.

Anti-M titre is < 4

- Maternal specimens are requested at 24/26 and 34 weeks for antibody confirmation and exclusion of other clinically significant antibodies.

2. Critical Titration Values

CBS Medical Consultants generally recommend that a referral to a high risk obstetric service be considered at a titer of 16 for all clinically significant antibodies (except anti-K). Referral to a high risk obstetric service is generally recommended for all patients having anti-K regardless of titer.

Once a critical value of 16 is reached or there is a significant rise in titer, the physician's office is notified by a report faxed immediately. The Diagnostic Services Medical Director also contacts the referring physician personally by phone.

- The detection and identification of anti-K is reported as "**Detection of anti-K is a critical result regardless of titre**".

- Once the titre result of any clinically significant antibody has reached '16', the detection and identification of the antibody is reported as **“A critical titre has been reached. It is not necessary to perform additional titres on this patient.”**

Since patients with a clinically significant antibody detected and identified are at a higher risk of developing further antibodies, monthly testing is recommended in order to monitor and detect the presence of any other developing antibodies.

3. Rh Immune Globulin Recommendations

Note: Rh Immune Globulin must be ordered by physicians, obtained at hospitals and used according to the manufacturer's recommendations and procedures. This is a human blood product and patient informed consent is required. Refer to the manufacturer's product insert prior to administration.

Perinatal

Rh Immune Globulin should be administered routinely to all patients who test Rh Negative (or test less than 2+ with monoclonal anti-D reagent) at the 28th week and who do not have an allo-anti-D antibody. Refer to the manufacturer's product insert for recommended dose at 28 weeks gestation.

- The physician should obtain the Rh Immune Globulin from his or her local hospital. CBS, BC & Yukon will not issue Rh Immune Globulin directly to physicians or patients.

Post Partum

Rh Immune Globulin administration is recommended for all patients who test Rh Negative (or test less than 2+ with monoclonal anti-D reagent) and who do not have an allo anti-D antibody following delivery of an Rh Positive or Weak D Positive baby. Recommended dose: refer to the manufacturer's product insert.

Rh Immune Globulin is recommended for the following events: (Prenatal patients who do not have an allo anti-D antibody and who test Rh Negative (or test less than 2+ with monoclonal anti-D reagent)).

- Spontaneous or therapeutic abortion
- Ectopic pregnancy
- Amniocentesis
- Chorionic Villus Sampling (CVS)
- Any Antepartum Uterine Bleeding
- Abdominal trauma

B. PERINATAL REPORTS

1. Turn Around Time:

Routine reports are available for “auto-faxing” within three working days from the date of specimen receipt (accessioning date). Perinatal antibody reports being “auto-faxed” may be delayed an additional working day depending on the complexity of the testing required to identify the antibody.

2. Reports Sent:

For Rh Positive and Rh Negative patients:

- All physicians, mid-wives, nurse practitioners and hospitals indicated on the requisition.
- Hospitals for delivery as indicted on the requisition.

For Perinatal antibody cases:

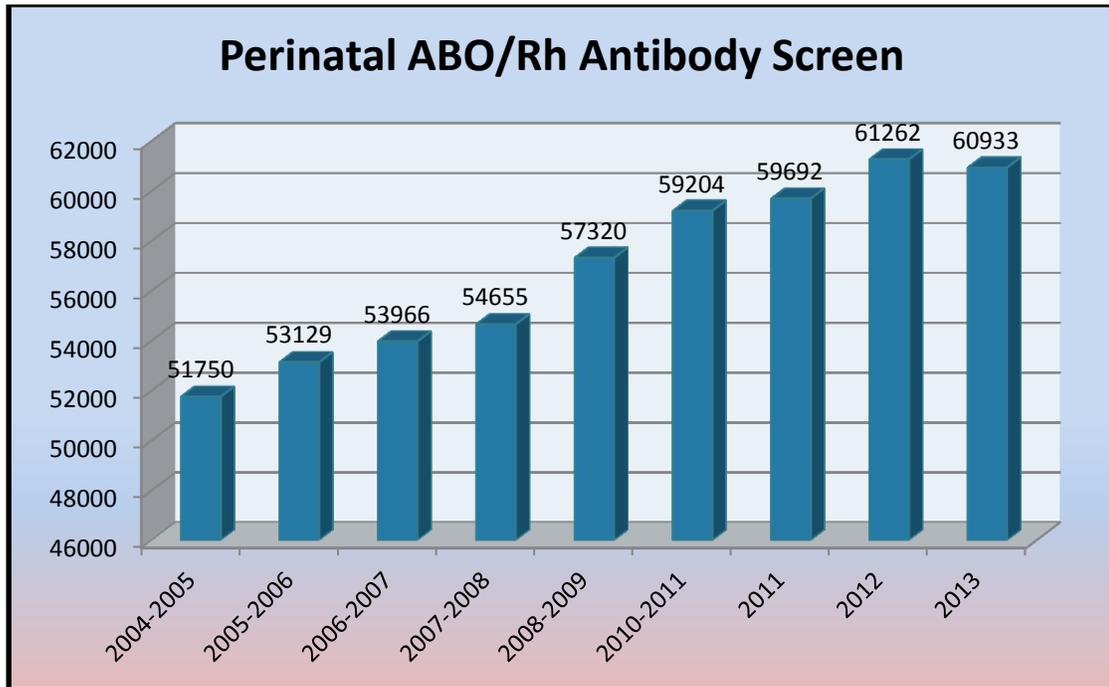
- All physicians indicated on the requisition.
- Hospitals for delivery as indicted on the requisition

C. PERINATAL SUMMARY OF TESTING PERFORMED

Table 1: Perinatal Specimens Tested (2013)

<i>Sample Source</i>	<i>Test Type</i>	<i>Number Tested</i>
Mothers	ABO/Rh, Antibody Screen	60,933
	Antibody Identification	1,894
	Titres	619
Fathers	ABO/Rh, Phenotype	612

Figure 1: Total Perinatal Specimens Tested – ABORh & Antibody Screen



1. Antibody Identification

In 2013 a total of 1894 antibody investigations were performed.

Of the antibodies identified, 323 were considered to be clinically significant (reported to cause hemolytic disease of the fetus/newborn (HDFN)). The most common clinically significant antibodies were anti-E, anti-M anti-D and anti-K. These 4 antibodies represented 71% of the clinically significant antibodies identified. The most common clinically insignificant antibodies were anti-P1 and cold agglutinins which represented 50% of total clinically insignificant antibodies identified. Inconclusive or unidentified antibodies are not reflected in this data. Inconclusive or unidentified antibodies require follow-up testing to determine whether they represent a clinically significant finding or are a transient testing phenomenon. Although Anti-M has been implicated in HDFN only on rare occasions, it is usually indicated as potentially clinically significant. If testing indicates that an identified anti-M may be potentially clinically significant, then it is monitored monthly as clinically significant.

Table 2: Perinatal Antibodies Identified (2013)

<i>Maternal Antibodies Identified – 2013</i>			
Clinically Insignificant Antibodies		Clinically Significant Antibodies	
Antibody		Antibody	
Anti-P1	52	Anti-D	44
Anti-Lea	16	Anti-C	11
Anti-Leb	10	Anti-E	102
Cold Agglutinin	30	Anti-c	25
HLA related	4	Anti-e	10
Anti-Sda	16	Anti-Ce	2
Anti- A1	14	Ant-Cw	4
Warm Auto	33	Anti-G	5
Passive-D	157	Anti-K	37
		Anti-M	45
		Anti-S	6
		Anti-Jka	17
		Anti-Fya	2
		Anti-Fyb	3
		Anti-Lub	2
		Anti-Lu14	1
		Anti-Vw	4
		Anti-Wra	2
		Anti-Jra	1

**Figure 2:
Frequency of Perinatal Clinically Significant Antibodies**

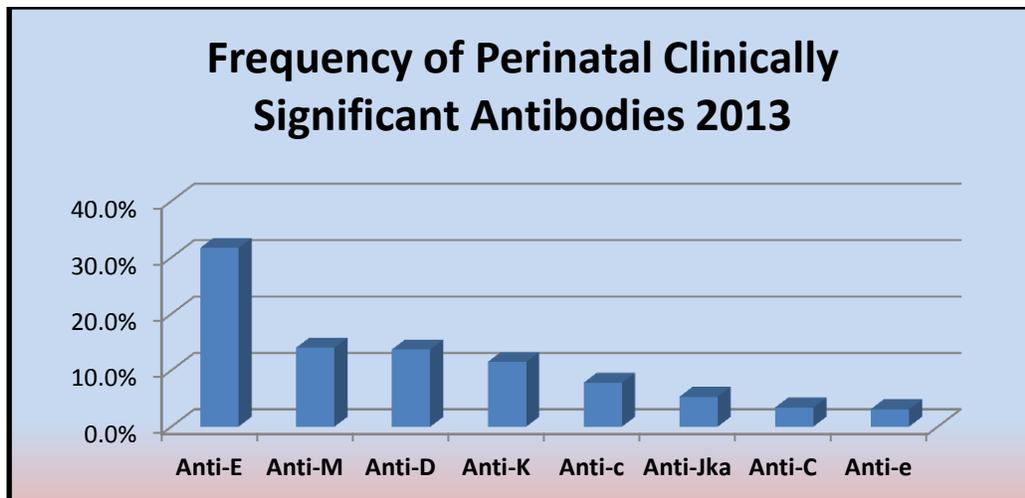


Table 3: Perinatal Antibodies Titrations (2013)

Antibody	Critical	Non-Critical	Non-critical to Critical
Anti-D	12	32	4
Anti-C	-	7	-
Anti-E	15	89	8
Anti-c	2	17	1
Anti-e	-	8	-
Anti-DC	-	-	-
Anti-DE	-	-	-
Anti-Ec	-	-	-
Anti-Ce	1	-	1
Anti-G	1	2	1
Anti-K	-	1	-
Anti-Fya	-	2	-
Anti-Fyb	-	2	-
Anti-Jka	-	14	-
Anti-Jkb	-	-	-
Anti-M	1	39	-
Anti-S	-	3	-
Anti-s	-	-	-
Total	32	216	15

Titres for 15 of the clinically significant antibodies increased from non-critical to critical levels during the pregnancy with a total of 32 antibody titres at critical levels. 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.

D. QUALITY INDICATORS

1. Rejected Samples

To ensure that the correct patient is being tested, samples and requisitions that are not clearly or correctly labelled are rejected. The reason for rejection is tracked in the laboratory information system (LIS).

Some of the common reasons that samples are rejected are:

- Illegible, incomplete or absence of patient information on the requisition
- Missing information on the specimen – specimens cannot be tested without the correct name and a unique numerical identifier (usually the Personal Health Number PHN)
- Incorrect information provided – occasionally key patient identifiers do not match with previous patient information in the CBS patient database.
- Wrong requisitions - use of an incorrect requisition (usually that of the health region or private laboratory) can lead to misdirected samples and may increase the Turn Around Time for the testing

Table 4: Perinatal Rejected Specimens (2013)

Rejection Category	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec
Requisition	4	6	10	17
Specimen	34	7	10	33
Discrepancies between Requisition and Specimen	3	6	4	3
Other	5	25	36	38
Total Specimens Rejected	46	44	60	91
Total Specimens Tested	15,182	15,747	15,230	15,607
Rejection as a % of Total	0.30%	0.28%	0.39%	0.58%

Figure 3: Perinatal Specimens Rejection Rate

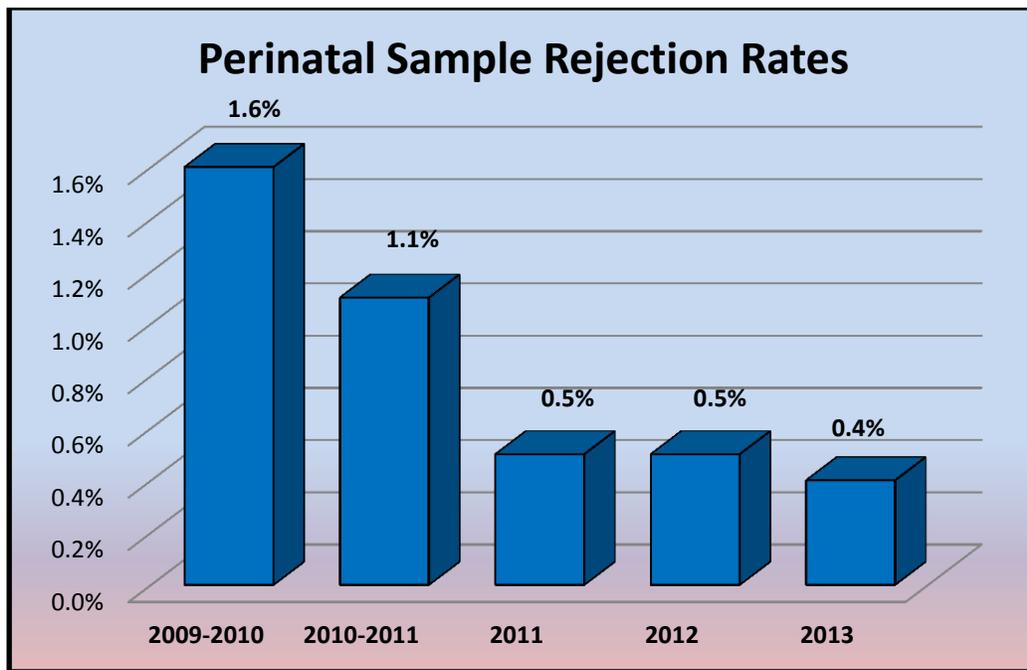
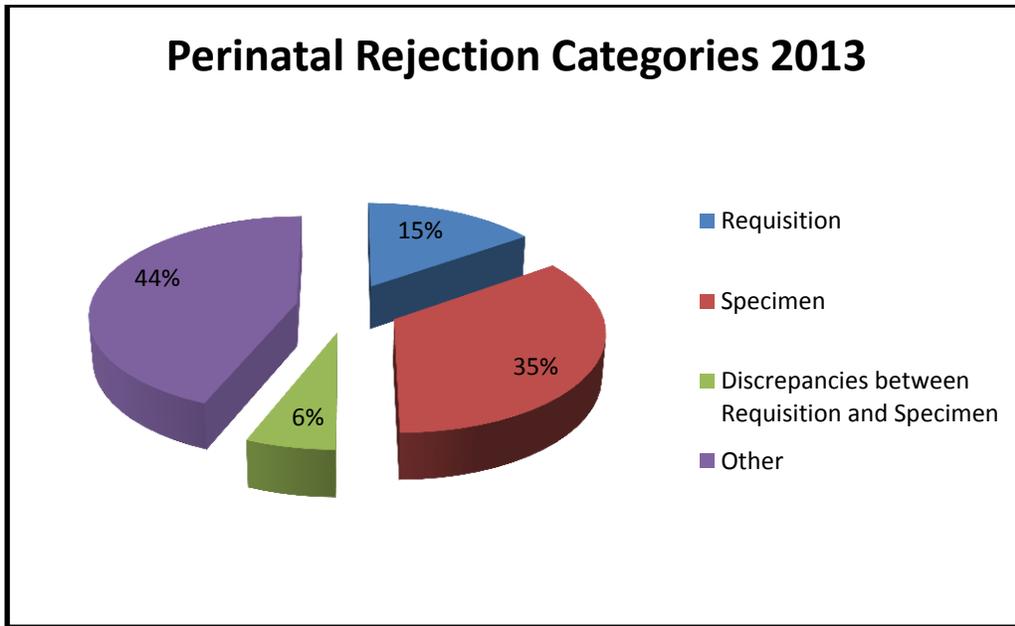


Figure 4: Perinatal Specimen Rejection Categories



2. Turn Around Time (TAT)

Turn Around Time for routine perinatal testing is three working days from sample receipt to when test results are available for sending.

For Perinatal specimens with antibodies, our goal is to ensure that 85% of these specimens meet a turn-around time of five working days or less (from date received at CBS to the date test report is available)

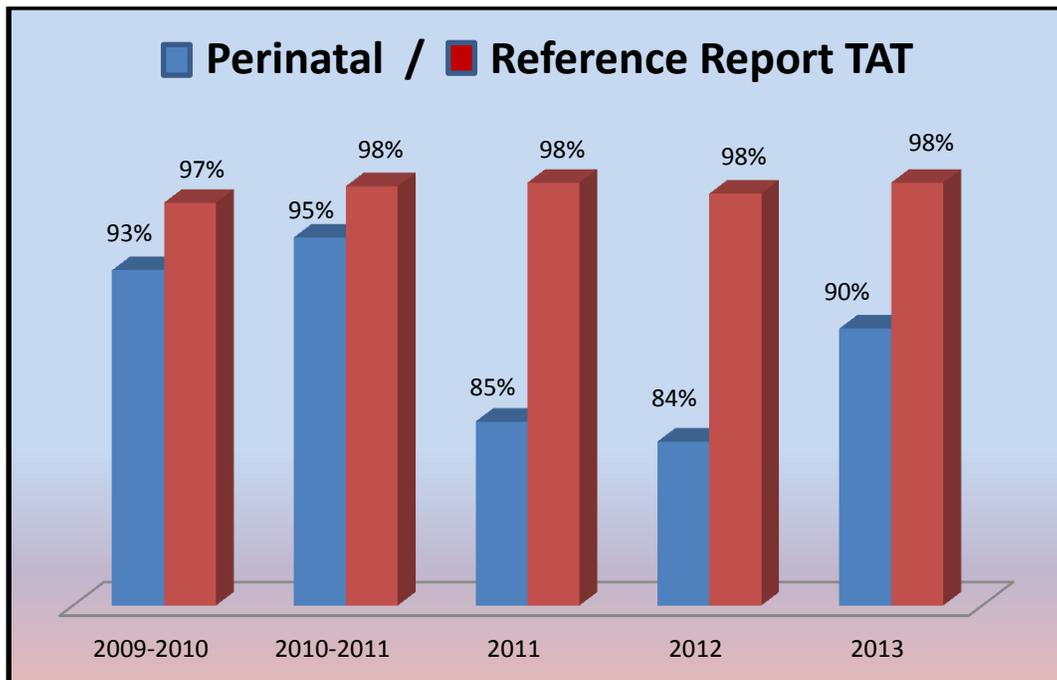
For reference specimens the turn-around time is three days from sample receipt to when the “interim report” is available.

Turn Around Time is determined from the date of receipt. If determined from the day of collection, the TAT would be extended. The reasons for this are collection facility delays in transporting samples and locations with limited transportation choices. Also some regions choose to send specimens in batches only once or twice per week.

Table 5: Turn Around Time (TAT) – Routine Testing Criteria

Specimen Type	Expected Turn-around Time	Expected % of specimens to meet or exceed TAT
Routine Perinatal	< 72 hours	≥ 85%
Reference Testing	< 72 hours	≥ 85%

Figure 5: Perinatal / Reference Turn Around Time



E. REFERENCE LABORATORY

1 Hospital Antibody Investigation Support

Hospital patients who are repeatedly transfused may develop red cell and platelet 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 blood banks (24 hours, 7 days per week). They identify red cell or platelet antibodies and give transfusion recommendations. Diagnostic Services has a varied selection of procedures and rare reagents that allow technologists to resolve more difficult red cell antibody cases. Diagnostic Services has an excellent reputation as a highly competent Reference Laboratory not only in the province but throughout Canada. Our area has published a number of papers, abstracts and posters and have collaborated with other reputable reference laboratories such as the New York Blood Center. Staff have also lectured at various conferences. Diagnostic Services plays an important role in providing continuing education for Hospital Transfusion Medicine laboratories, by organizing teleconferenced presentations.

This year, hospitals have referred 664 requests for red cell antibody identification.

Diagnostic Services provides support for all hospitals. Hospitals in the province have different capabilities and expertise in resolving red cell antibody investigations. Based on their capabilities, Diagnostic Services has categorized hospitals into three levels.

Level 1

Includes all 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 Service capabilities usually include the following methods:

Routine Services	Additional Methods:
<ul style="list-style-type: none">• ABO and Rh• Antibody detection• Crossmatch donor units	<ul style="list-style-type: none">• Gel / SIAT / PEGMAT / LIAT• Pre-warm• Saline replacement

Diagnostic Services Support - 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

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, -Fy^a, -Fy^b, -Jk^a and -Jk^a). Hospital Transfusion Service capabilities usually include the following methods:

Routine Services	Additional Methods
<ul style="list-style-type: none">• ABO and Rh• Antibody detection• Crossmatch donor units• 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.	<ul style="list-style-type: none">• Gel/SIAT/PEGMAT/LIAT• Pre-warm• Saline replacements• Differential DAT

Diagnostic Services Support - 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 routinely stocked at the hospital.
- 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

Includes 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
<ul style="list-style-type: none"> • ABO and Rh • Antibody detection • Crossmatch donor units • SIAT/PEGIAT/LIAT 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 and an antibody wallet card to the patient's physician. 	<ul style="list-style-type: none"> • Pre-warm • Saline replacement • Differential DAT • Elution • Auto/Alloadsorptions • Inhibition/Neutralization

Diagnostic Services Support - Level 3 Hospitals

CBS will provide additional testing only if the reagents, cells/serum or method(s) required to complete the case are unavailable at the hospital level.

CBS Technical support provided:

- 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

Figure 6: Number of Reference Antibody Investigations

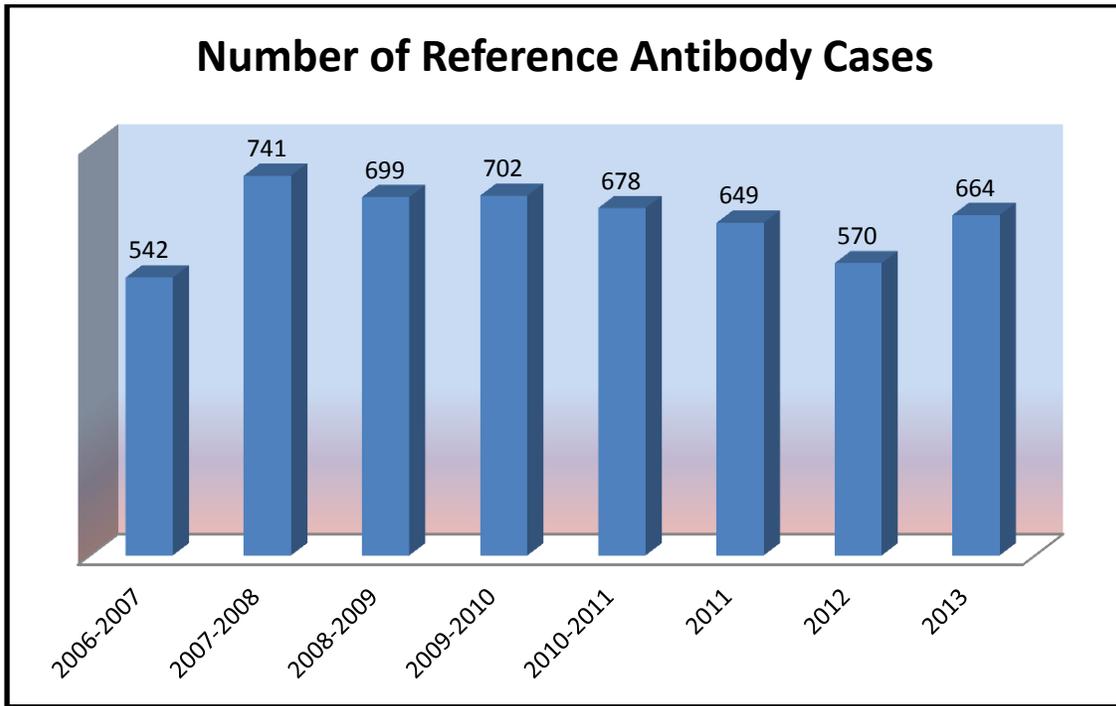


Figure 7: Frequency of Reference Clinically Significant Antibodies

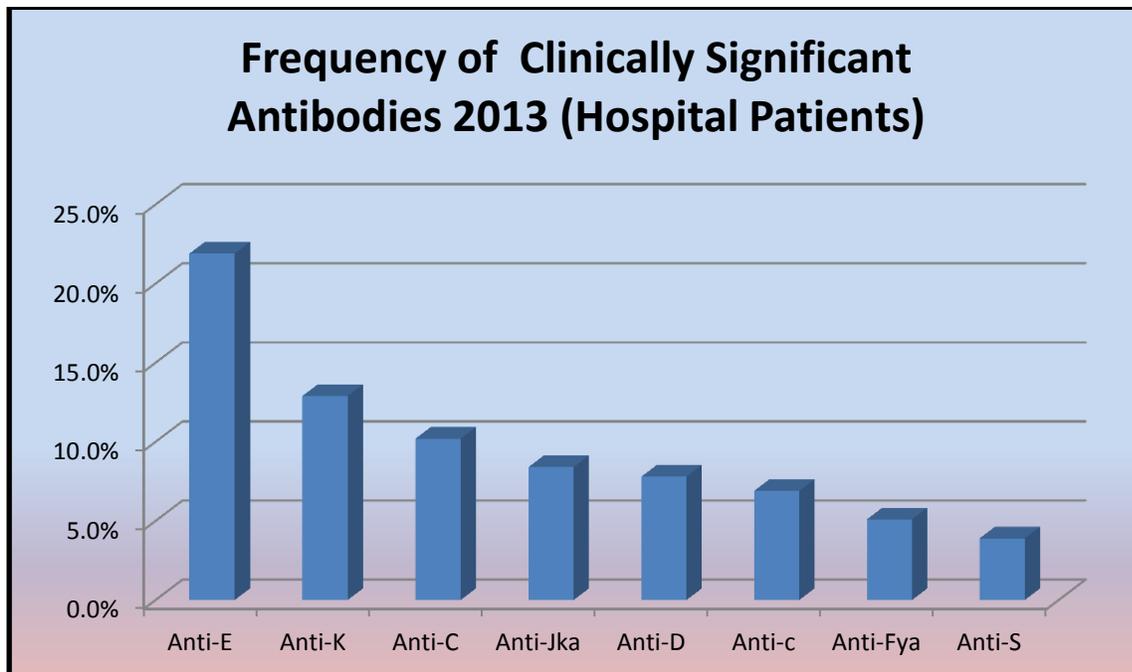


Table 7: Reference Red Cell Antibody Investigations – Case Complexity

<i>Red Cell Investigations - Hospital Referred Investigations – 2013</i>			
<i>Alloantibodies</i>	<i>No of cases</i>	<i>Warm auto antibodies</i>	<i>No of cases</i>
Single alloantibody	148	Warm auto antibody	130
Two alloantibodies	55	Warm auto antibody with one alloantibody	73
Three alloantibodies	16	Warm auto antibody with two alloantibodies	46
Four alloantibodies	6	Warm auto antibody with three alloantibodies	35
Five or more alloantibodies	4	Warm auto antibody with four or more alloantibodies	14

2. Platelet/HLA Immunology

Platelet antibody tests are performed for the following:

- Neonatal Alloimmune Thrombocytopenia (NAIT)
Platelet antibodies, usually anti-HPA-1a, in the plasma of a pregnant woman, may cause neonatal alloimmune thrombocytopenia, the platelet equivalent of hemolytic disease of the fetus and newborn (HDFN). It occurs with a frequency of 1 in 2000 to 3000 live births. Affected infants may be severely thrombocytopenic and at high risk, especially for intracranial bleeds.
CBS Winnipeg Centre maintains a list of available platelet apheresis donors who type as HPA 1b/1b (HPA-1a negative) and others such as HPA-5a negative.
- Post-Transfusion Purpura (PTP)
Post-transfusion purpura is a thrombocytopenia that develops after transfusion when platelet antibodies destroy autologous as well as transfused platelets. It is a rare complication characterized by acute thrombocytopenia occurring approximately 1 week after red cell transfusion. Most patients are multiparous women who have been sensitized to platelets through previous transfusions

Samples are tested by a Solid Phase ELISA method in Vancouver and by CBS Winnipeg. Diagnostic Services may refer samples to CBS Platelet Antibody Reference Laboratory in Winnipeg where more specific tests may be performed. Refer to Table 7 and Figure 10.

3. HLA Antibodies - HLA Typed Platelet Pheresis Units

Platelet refractoriness, which is characterized by the failure to gain adequate increments (within one hour post platelet transfusion) following at least two platelet transfusions from random donors, is a serious complication for transfusion-dependant donors and may be the result of anti-HLA antibodies.

HLA antibodies are found in approximately 50% of multi-transfused patients but only 30% of these patients are refractory to platelets. For these patients in whom non-immune causes have been excluded and HLA specific antibodies have been detected, HLA matched platelets may be indicated.

If patients require HLA typed platelet pheresis units, an HLA antibody screen is performed by BC & Yukon Diagnostic Services and, if positive, samples are forwarded to CBS Platelet/HLA Antibody Reference Laboratory in Winnipeg where more specific tests may be performed.

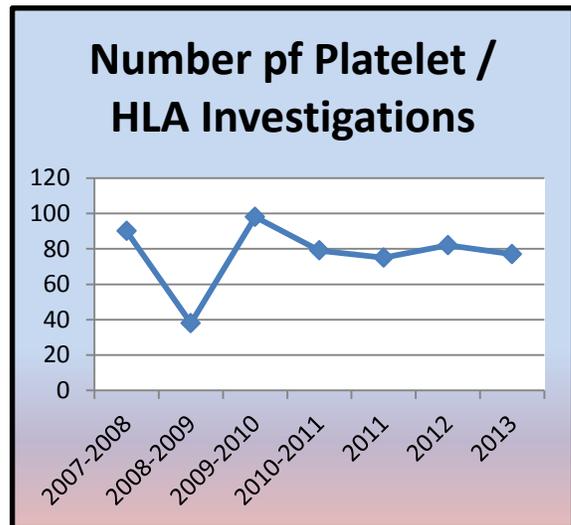
Once a hospital request for HLA matched platelets is approved and the recipient typing / screen results are available, the request for HLA matched platelets is forwarded to CBS Winnipeg Centre (by CBS BC&Yukon). Winnipeg CBS searches their national Platelet Database System (PDS) based on the recipient's ABO/Rh and HLA typing. A list of potential HLA-matched apheresis donors is then forwarded by CBS Winnipeg to CBS BC &Yukon.

BC & Yukon Centre will contact and schedule local apheresis donors and, if required, donors from other Centres, to meet the transfusion requirements of the recipient.

**Table 8:
Platelet / HLA Investigations 2012**

Platelet / HLA Investigations 2013	
Antibodies Identified	
Anti-HLA	27
Anti-HPA-1a	3
Anti-HPA-1b	2
Anti-HPA-5a	0
Anti-HPA-5b	3
None Detected / Indeterminate	42
TOTAL	77

**Figure 8:
Number of Platelet / HLA
Investigations**



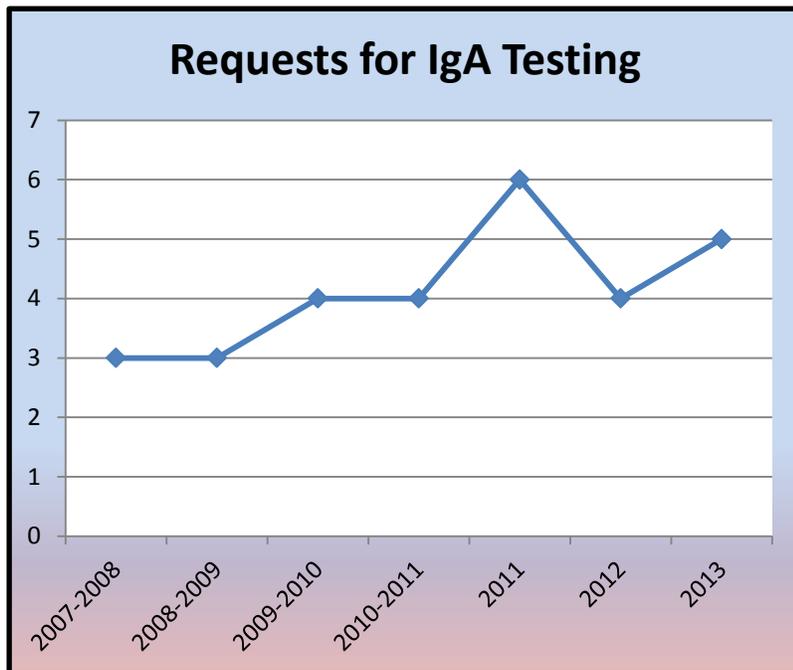
F. PATIENT IgA TESTING

- Patient IgA testing is available through CBS for patient transfusion-related needs. Specimens received at the Centre are forwarded to an external facility for IgA levels and detection of anti-IgA. Refer to Table 9 and Figure 12.

Table 9: Requests for IgA Testing

Requests for Patient IgA Testing 2013	
Number of samples tested	5

Figure 9: Number of Requests for IgA Testing



G. DIAGNOSTIC SERVICES ACCOMPLISHMENT AND GOALS

1. On-going accomplishments

- BC & Yukon Centre was selected as a recognized training facility for residents (physicians) studying Laboratory Medicine and Hematology-related specialities. This CBS designed program, along with other hospital training is required for proficiency in the practice of Transfusion Medicine and is in preparation of writing the Royal College exams.

The CBS program requirements were outlined by the CBS BC & Yukon Medical Director. The CBS program not only focused on the activities of CBS and its relationship to the rest of the healthcare system, but allowed trainees hands-on laboratory experience in the Diagnostic Services Laboratory.

A laboratory experience is also in place for Transfusion Residents enrolled in the CBS / Royal College training program.

- The Diagnostic Services Laboratory continues to participate in Serum Cells and Rare Fluids (SCARF), an international exchange program.
- BC & Yukon Centre, Diagnostic Services Laboratory Coordinator is a member of ICII (Invitational Conference of Investigative Immunohematologists). This an 'elite' international group of experienced reference researchers, physicians and technologists present unusual cases and discuss best practices.
- The Diagnostic Services Laboratory support continuing education by providing presentations at Provincial symposiums and conferences.
- Business Continuity Planning
Canadian Blood Services is in the process of developing business continuity plans for all sites. The plan for the Edmonton facility will be created in 2013 and decisions around who will perform back-up testing for the Diagnostic Services will be made then.
- Perinatal Advisory Committee
The Diagnostic Services Director, Medical Directors, Managers and Supervisors from all of the Canadian Blood Services Diagnostic Laboratory sites (in Vancouver, Edmonton, Regina, Winnipeg and Toronto) meet once annually to discuss operational issues and 'best practice' approaches for serological and perinatal laboratory testing. In discussions where expert advice is required, guest speakers are invited to provide input and direction. Working groups are set up as required to investigate specific issues and bring recommendations forward. Input is obtained from relevant stakeholders on planned policy changes.

Anecdotally, there had been some concern about anti-c causing HDFN even at low titres. As such, we had begun to recommend referral to the Maternal-Fetal Medicine clinic for all anti-c. Based on a retrospective study of clinical outcomes for antibodies other than anti-D which was done in the Edmonton area, the critical titre value of 16 for the other common antibodies appears to be valid. We have stopped referring patients with anti-c to the Maternal-Fetal Medicine clinic unless a critical titre of ≥ 16 is reached.

A review of literature regarding anti-M revealed that, although this antibody is rarely implicated in HDFN, it may cause suppression of fetal erythropoiesis and late onset

anemia (Trans Med Rev 2014: 28:1-6). The Perinatal Advisory Committee recommended that a comment be added to reports of anti-M advising that the baby be monitored for symptoms of late onset anemia for up to 2 months of age.

Monitoring the international developments in assessment of fetal RHD status based on analysis of cell-free fetal DNA (cff DNA) in mother's plasma as a basis for determining RhIG eligibility (targeted RhIG prophylaxis). This approach is becoming the standard in many European countries.

Red Cell Antigen Genotyping

Immucor's BioArray™ BeadChip™ testing system was installed in CBS Edmonton Centre in 2013 for a pilot project on red cell antigen genotyping. Use of genotyping can help to resolve complex red blood cell cases by using the patient's DNA. It will be used for some patients who require blood transfusions and for pregnant mothers with unclear RhD status to determine Rh Immune Globulin eligibility. Currently, samples for red cell antigen genotyping are sent to Canadian Blood Services National Immunohematology Reference Laboratory. Some samples can be genotyped in the laboratory in Ottawa, while others are referred to an American reference laboratory for RHD genotyping.

Goals

1. To Initiate the process of downloading patient test results directly into BC Provincial Laboratory Information Solution (PLIS)
2. Automated Antibody Screen Investigation Algorithm
All Diagnostic Services sites (Vancouver, Edmonton, Regina and Winnipeg) collaborated to develop a common algorithm for the investigation of positive antibody screens obtained on the Galileo Neo. The intention is to standardize the investigation process to facilitate data collection and comparability of results. All sites are expected to implement the new algorithm by the end of October 2014.
3. To monitor the international developments in providing screening for Neonatal Alloimmune Thrombocytopenia (NAIT)