Canadian Blood Services
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CANADIAN BLOOD SERVICES

SASKATCHEWAN DIAGNOSTIC SERVICES

YEAR IN REVIEW
January-December 2013

CANADIAN BLOOD SERVICES SASKATCHEWAN
DIAGNOSTIC SERVICES LABORATORY

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Perinatal Program Description

Canadian Blood Services provides screening of pregnant women for blood type and red blood cell antibodies under a program funded by the Saskatchewan 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. Testing is provided for all the facilities in Saskatchewan Health Regions.

Testing Performed

Canadian Blood Services (Diagnostic Services Laboratory) routinely performs the following tests:

- ABO/Rh blood type
- Screen for red blood cell antibodies
- Antibody identification, if antibodies are detected
- Antibody titre, if a clinically significant antibody is identified.

The routine method for blood group determination and antibody screen is by automated solid phase testing.

Specimen Type/Frequency

Mothers – Initial Testing – all women should be tested upon their first prenatal visit.

Mothers – 28 Weeks Gestation – all Rh negative women should be retested at approximately 28 weeks gestation (24-28 weeks acceptable). Rh positive women should also be retested at 28 weeks gestation when there is only one blood group result on file (usually first pregnancy) or if patient is at increased risk of allo-immunization (eg. previous transfusion, fetal trauma or procedure, IV drug use).

Mothers – Antibody Present – if the antibody is clinically significant and known to cause hemolytic disease of the fetus/newborn (HDFN), it is recommended that specimens be submitted again at 18-20 weeks, then every four weeks until 32 weeks gestation. Samples should then be submitted every two weeks until delivery.

Newborns (Cords) – cord blood or neonatal samples may be submitted for testing. ABO/Rh and direct antiglobulin testing is performed on cord or neonatal samples.

Fathers – when a woman has an antibody capable of causing HDFN, specimens from the father will be requested for antigen typing. This will assist in assessing the probability of the baby being affected by the antibody. Father samples may also be tested to assess RhIg eligibility of Rh negative mothers.

Samples Tested

The total number of specimens tested has shown a slight increase over the past three years as seen in ***Table 1*** below. ***Tables 2*** and ***3*** show the antibodies/combinations identified.

Table 1: Perinatal Sample Testing Totals

Sample Source	Test Type	2009/2010	2010/2011	2011	2012	2013
Blood - Mothers	ABO/Rh, Antibody Screen	16,066	16,750	16,904	17,765	20,074
Blood - Fathers	ABO/Rh	198	137	140	124	233
Blood - Cords	ABO/Rh, DAT	79	65	57	23	22

Table 2: Perinatal Antibodies Identified

Antibody	*# in 09-10*	*# in 10-11*	*# in 2011*	*# in 2012*	*# in 2013*
Anti-D	7	6	11	12	9
Anti-C	1	4	5	8	
Anti-E	17	15	25	32	33
Anti-c	4	6	10	11	3
Anti-e	1	2	2	4	2
Anti-M	5	10	12	14	12
Anti-N	1				2
Anti-S	3	1	5	3	4
Anti-s					
Anti-P1					
Anti-Le^{a}		4	9	7	10
Anti-Le^{b}			1	1	1
Anti-K	3	23	24	20	17
Anti-Fy^{a}	2	3	5	3	2
Anti-Fyb			1	1	1
Anti-Jk^{a}	5	7	6	6	10
Anti-Jk^{b}	1		3	1	1
Anti-C^{w}					
Anti-Lu^{a}					
Anti-Lu^{b}		1	1		
Anti-k					
Anti-Sd^{a}					
Anti-G			1	1	
Total	***50***	***82***	***121***	***170***	***107***

Table 3: Combination of Antibodies

Antibodies	*# in 2013*
Anti-D, -C	5
Anti-D, -E	1
Anti-D, -Jkb	1
Anti-C, -e	1
Anti-C, -S	1
Anti-E, -c	5
Anti-E, -K	1
Anti-E, -Lea	1
Anti-E, -S	2
Anti-K, -Kpa	1
Anti-Jkb, -S	1
Anti-S, -Fya	1
Anti-Lea, -Leb	1
Anti-D, -C, -Jka	1
Anti-C, -E, -G	1
Anti-C, -e, -K	1
Anti-E, -c, -Jka	1
Anti-E, -K, -Jka	1
Anti-E, -M, -Fya	1
Anti-M, -Lea, -Leb	1
Anti-c, -Fya, -s, -K, -E	1
Total	**30**

Crossmatch/Reference Program Description

The Crossmatch/Reference Laboratory within Diagnostic Services at Canadian Blood Services provides transfusion medicine services (Crossmatch) for numerous hospitals in rural Saskatchewan that currently do not routinely perform these tests. Antibody investigation (Reference) services are provided for hospitals in Saskatchewan. Specimens from these sites are submitted for antibody identification, blood group discrepancy resolution, direct antiglobulin testing, and other serological testing.

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
- Crossmatches
- Phenotyping (Patient and Donor Units)
- Direct Antiglobulin Tests
- Other serological testing as required, as part of serological investigations

The routine method for antibody screening and identification is by tube testing methods using PEG for enhancement.

Crossmatched blood components are distributed through the Diagnostic Services Laboratory to those hospitals which receive all of their transfusion medicine services from Canadian Blood Services. Hospitals which provide transfusion medicine services directly receive all of their blood components through the Product and Hospital Services area at Canadian Blood Services.

Samples Tested

The total number of crossmatch specimens tested has shown a slight decrease over the past five years as shown in ***Table 4.*** Number of antibody identifications has been added to the data.

Table 4: Crossmatch Sample Testing Totals

Test Type	2009/2010	2010/2011	2011	2012	2013
Crossmatch ABO/Rh, Antibody Screens	798	729	715	645	590
Antibody Identification			225	267	257
Blood Components Distributed	1693	1556	1520	1420	1321

Quality Program

Processes are in place to control the quality of the products and services provided by the Diagnostic Services laboratory. The laboratory participates in internal and external audits/ inspections, performs proficiency testing and monitors quality indicators for areas affecting pre-analytical, analytical and post-analytical processes. This data is collated and then analyzed internally and against other Diagnostic Services laboratories within CBS.

Turn-Around-Times

In keeping with the College of Physicians and Surgeons of Saskatchewan laboratory accreditation requirements and to ensure timely reporting of patient results, Canadian Blood Services monitors turn-around times (TAT) for perinatal and crossmatch samples from the day the specimen is received at Canadian Blood Services in Regina to the day the report is issued as seen in ***Tables 5*** and ***6***.

The TAT for Perinatal samples was changed from 85% to 75% in 72 hours in Q2 of 2013.

Table 5: Turn-Around Times for Perinatal Specimens in 2013

Quarter	Expected % TAT in 72 hrs	% TAT in 72 hrs
Q1	85%	88%
Q2	75%	87%
Q3	75%	86%
Q4	75%	89%

Table 6: Turn-Around Times for Crossmatch Specimens in 2013

Quarter	Expected % TAT in 24 hrs	% TAT in 24 hrs
Q1	85%	92%
Q2	85%	93%
Q3	85%	93%
Q4	85%	90%

Rejected Specimens

Each time a specimen is rejected, a reason for rejection is entered into the Laboratory Information System and a report is faxed to the physician's office indicating the rejection reason. The data is retrieved from the LIS and analysed on a quarterly basis. There has been a shift in the main reason for rejection of the perinatal samples. Previously, it was that samples fell outside of the testing requirements. With client education, this has drastically decreased. The majority of rejections in 2012 were due to incomplete information on the requisition and sample mislabelling. Staff have been working with sites to improve on these rates. Crossmatch samples main rejection reason remains test cancellation. Refer to ***Figures 1*** and ***2***.

Figure 1: Quarterly Rejection Rates for 2013

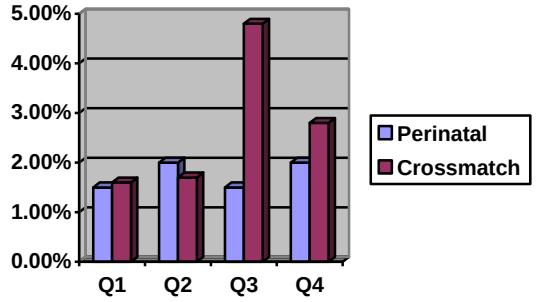
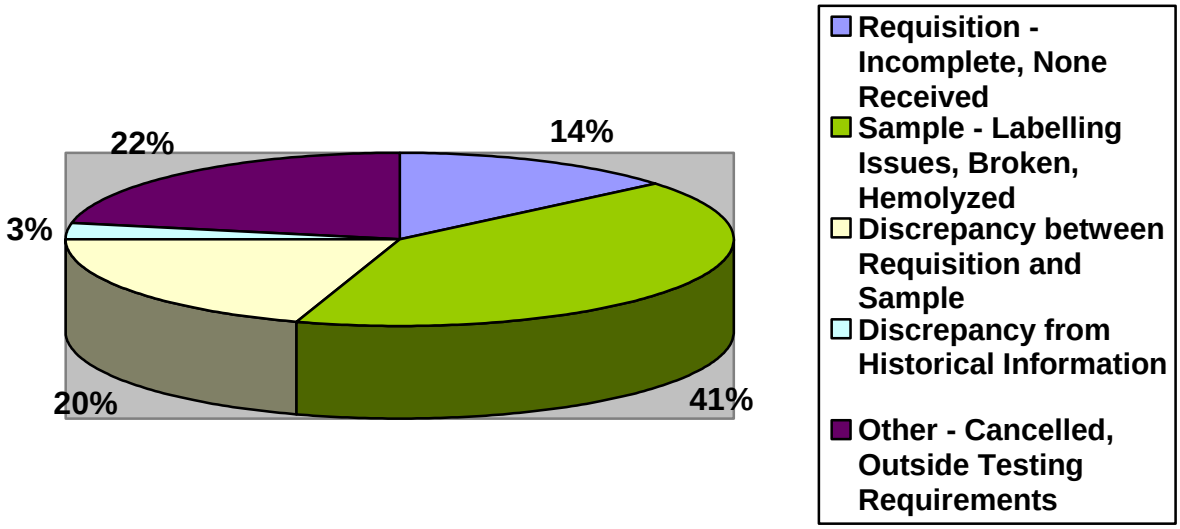


Figure 2: Rejection Reasons for 2013



Accomplishments for 2013

Automated Testing Instrumentation Update

Three of the Diagnostic Services sites (Vancouver, Edmonton and Winnipeg) worked on validating the Galileo NEO in 2012. This updated version of the Galileo instrument is used for Perinatal ABO/Rh typing and antibody screening. Regina's instrument was implemented in May of 2013.

Perinatal Advisory Committee

The Diagnostic Services Director, Medical Officers, Managers and Supervisors from all of the Canadian Blood Services Diagnostic Services Laboratory sites (in Vancouver, Edmonton, Regina, Winnipeg and Toronto) meet once or twice 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, recommends for referral to the Maternal-Fetal Medicine clinic for all anti-c have begun. 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. A decision regarding referrals stopping for patients with anti-c to the Maternal-Fetal Medicine clinic unless a critical titre of $\geq$16 is reached will be discussed.

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 (Tran 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. This comment will be implemented in 2014.

Other Accomplishments

- Compared CAP proficiencies across the Diagnostic Services laboratories – titre results consistent due to standardized method
- Establish and monitor performance indicators for Galileo NEO
- 5 year supply agreement reached with Dominion Biologicals

Program Goals for 2014

In keeping with the CBS commitment to excellence in patient testing, the following objectives are being pursued in the Diagnostic Services laboratory in 2014:

1. Continue to participate in the CBS Perinatal Advisory Committee in order to identify and implement 'best practices' in perinatal laboratory testing.

2. Monitoring the international developments in providing screening for Neonatal Alloimmune Thrombocytopenia (NAIT).

3. 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.

4. Continue the Talent Management review in order to perform succession planning.

5. Initiate process to download test results directly into the Saskatchewan Laboratory Result Repository (SLRR).

6. Business Continuity Planning – Canadian Blood Services is in the process of developing business continuity plans for all sites. Decisions around who will perform back-up testing for the Diagnostic Services laboratories will be made.

7. The Diagnostic Services Laboratory support continuing education by providing presentations at Provincial symposiums and conferences.

8. All Diagnostic Services sites 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.