Canadian Blood Services
Société canadienne du sang

DIAGNOSTIC SERVICES

ONTARIO

YEAR IN REVIEW

JANUARY – DECEMBER 2016

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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RED CELL SEROLOGY REFERENCE LABORATORY

The Red Cell Serology Reference Laboratory within Diagnostic Services provides testing for hospitals in the Central Ontario Region and Hamilton Region, and for private laboratories.

Testing Performed

The Reference Laboratory routinely performs the following tests:

- ABO/Rh blood type
- Screen for red blood cell antibodies
- Antibody Identification, if antibodies are detected
- Phenotyping (patient)
- Direct Antiglobulin Test
- Elution and Absorption

Antibody Screening and identification is routinely performed using a Gel Card testing methodology. A combination of Gel Card testing methodology and indirect antiglobulin tube testing using saline, enzymes or PEG enhancement are the most common antibody identification methods.

The laboratory also coordinates Red Cell Genotyping referral through the Canadian Blood Services National Immunohematology Reference Laboratory (NIRL). The Toronto laboratory is also responsible for maintaining the Central Ontario Sickle Cell Registry.

A. **Specimens Tested**

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

Table 1: Specimens Tested

Specimen Type	Test Type	2013	2014	2015	2016
Red Cell Serology Reference	ABO resolutions	0	3	0	0
	Antibody investigations-pretransfusion	557	585	610	579
	Antibody investigations- prenatal	217	226	188	163
	Phenotyping (number of antigens)	2,376	2,248	2,074	1,952
Test Totals		**3,924**	**3,873**	**3,651**	**2,694**
Number of Patients Tested		**701**	**728**	**716**	**670**

In 2016, a total of 883 antibodies were reported (see Table *1*). This is slightly lower than 2015. Antibodies identified were considered to be clinically significant if they have been reported to cause HDFN. The most common clinically significant antibodies identified were: anti-D, anti-E, anti-K, anti-C, anti-c and, anti-Fy^{a} anti-S, anti-Jk^{a}, and anti-Jk^{b} which together represented 61% of the total antibodies identified. Table 2, is

a lists the antibodies to low prevalence antigens detected while Table 3 is a list of antibodies to high prevalence antigens.

Table 2: Most Common Clinically Significant Antibodies (CSA) Detected

Antibody	Number Detected
Autoantibody	204
Anti-D	121
Anti-E	108
Anti-K	68
Anti-HLA/Bg	61
Anti-C	44
Cold Agglutinin	41
Anti-c	39
Anti-Fy^a	30
Anti-S	30
Anti-Jk^a	23
Anti-Jk^b	14
Unidentified	20
Total	803

Table 3: Antibodies to low prevalence antigens

Antibody	Number Identified
Anti-Lua	4
Anti-Wra	12
Anti-Cw	8
Anti-Cob	3
Anti-Kpa	3
Anti-Dia	1
Anti-Jsa	3
Anti-SC2	1
Anti-Dantu	2
Anti-V	2
Anti-PP1Pk	1

Table 4 - Antibodies to high prevalence antigens

Antibody	Number Identified
Anti-Ch	4
Anti-Yka	12
Anti-U	8
Anti-Lub	3
Anti-H	3
Anti-Rg	1
Anti-JMH	3
Anti-Jra	1
Anti-Ge2	2
Anti-Vel	2
Anti-k	1

Specimen Complexity

The investigations that are referred to the Diagnostic Services Immunohematology laboratory are classified into two categories. Depending on the investigation's 'complexity' they are tracked as follows:

> **Complexity 1:** Antibody investigation uncomplicated: Antibody identifications completed using a single cell panel of 12 cells or fewer, by up to three techniques (e.g. single antibody / no antibody).
>
> **Complexity 2:** Antibody investigation complex: Antibody identifications completed using more than a single cell panel of 12 cells or fewer, or by more than three techniques (e.g. multiple antibodies, autoantibodies).

A breakdown of complexity 1 and 2 cases for 2016 calendar year follows.

Table 5: Antibody Complexity 2016

Complexity 1	Complexity 1 Percent of Total	Complexity 2	Complexity 2 Percent of Total	# of Samples
172	25%	572	75%	670

Table 6: Antibody Complex Procedures Performed

Procedures	Number
Alloadsorption	44
Autoadsorption	78
Auto and Alloadsorption	32
Elution	193
Titre	25

REFERAL SAMPLES

A. Specimens Tested

The Canadian Blood Services Platelet Immunology Laboratory in Winnipeg 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 be affected by platelet function disorders (PTP). The figure below indicates the number of procedures referred by Canadian Blood Services, Toronto referred for testing in 2015:

Table 7: Procedures performed by the CBS Platelet Immunology Laboratory in Winnipeg

Procedures	Number
HPA Antigen Typing	114
HPA Antibody Screen/ID	81

HLA Testing

Until December 2016, Canadian Blood Services' diagnostic services acted as intermediary between Ontario health-care facilities and the University Health Network Regional Histocompatibility Laboratory (UHN lab) for the provision of HLA testing for platelet refractory patients. In January 2017, samples from hospitals in the GTA (i.e. Princess Margaret Cancer Centre, Mount Sinai Hospital, Sunnybrook Hospital, etc.) will be sent directly to the UHN lab at 67 College where the samples are tested and results reporting directly to the sending facility.

Table 8: HLA procedures performed by UHN

Number of HLA Procedures 2016	
Procedures	Number
HLA Antigen Typing	81
HLA Antibody Screen	185
HLA Antibody Identification Single Antigen Testing	170

Red Cell Genotyping

The BioArray Beadchip™ test system has been installed and validated in the Diagnostic Services Laboratory in Edmonton for RhD genotype testing used for the identification of Rh D variants. The Edmonton CBS laboratory is accredited by the College of Physicians and Surgeons of Alberta (CPSA). Any patient samples requiring extended red cell genotype testing other than for D variant are referred to the National Immunohematology Reference Laboratory (NIRL) in Ottawa. NIRL performs extended genotype testing using the Progenika ID Core XT™ assay. If genotype test results are required urgently, testing results can be provided within 24 hours of the sample receipt.

Table 9: Genotype procedures referred by Canadian Blood Services Toronto:

Number of Genotype Procedures 2016	
Procedures	Number
RhD Genotype Procedures	2
Non-RHD Genotype Procedures	177

Red Cell Serological Reference Testing

The National Immunohematology Reference Laboratory (NIRL) in Ottawa is a highly specialized laboratory that focuses its attention on the identification and resolution of exceedingly complex red cell transfusion-related problems. The laboratory is accredited by the Institute of Quality Management in Healthcare (IQMH).

Table 10: Red cell serological investigations referred to NIRL by Canadian Blood Services Toronto

Number of RSCI Procedures referred to NIRL 2016	
Procedures	Number
Antibody Investigations	17
Direct Antiglobulin Differential Testing	30

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 Toronto 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 of 75% of samples to be tested and reported within 72 hours of receipt. In 2016, 83% of the samples received were tested and reported within 72 hours of receipt. Samples whose testing exceeds the expected TAT are usually those where complex clinically significant antibodies are detected or where a referral to the National Immunohematology Reference Laboratory is required.

B. Rejected Specimens

The laboratory reserves the right to refuse improperly labelled specimens. Consistent practices for specimen rejection are employed across CBS. The laboratory takes measures to maintain specimen integrity during the process of following up on the receipt of an improperly identified specimen. The high number of specimens received by the laboratory makes it impossible to positively identify specimens that are not clearly labelled in accordance with standard specimen identification criteria. The specimen rejection rate in 2016 was 0.20%

C. Proficiency Testing

College of American Pathologists Survey Participation

This summary is based on all the College of American Pathologists (CAP) survey reports from the Toronto Diagnostic Services site. This summary includes all the blood group serology processes.

Changes to the Proficiency Testing Program 2016

SOP 08 256, *Proficiency Testing Program* and 08 257, *Proficiency Testing Program – National Review,* were revised to align all groups completing proficiency testing under one SOP. Work instructions were also revised to align with corporate restructuring. These revisions were implemented in February 2016.

The main change in SOP 08 256, *Proficiency Testing Program,* was the addition of work instructions and attachment for entry of CAP proficiency samples into Trace Line. Guidance for CAP proficiency requirements and CAP accreditation terms of compliance were also added.

Table 11: CAP Proficiency Testing Results

2016 College of American Pathologist Proficiency Survey Summary								
Diagnostic Site (Red Cell)	ABO/Rh Type	Antibody ID	Antibody ID Eluate	Compatibility Testing	Unexpected Antibody Detection	DAT	Titre	IQMH
Toronto	100%	100%	100%	100%	100%	100%	100%	100%

ACCOMPLISHMENTS IN 2016

A. Standard operating procedures and processes were implemented to enhance a standardized approach for antibody investigation with NIRL and Donor Testing.

B. Implemented Trace Line laboratory information system for specimen tracking and reporting at both NIRL and Toronto Diagnostic Services.

C. Finalized the preparation to transfer the testing operations from 67 College to the new Brampton Laboratory facility.

D. Perinatal Advisory Committee

The Perinatal Advisory Committee for 2016 was held on June 13th and 14th. This year, the PNAC meeting was hosted in Winnipeg and was held in conjunction with a Grifol's Transfusion Science Education Course, which followed the PNAC meeting on June 15th and 16th.

The PNAC meeting covered a range of topics relevant to the CBS diagnostic and perinatal laboratories. Our agenda included a review of laboratory internal audits which allowed us to compare practice across laboratories and identify areas for improvement and standardization. Specific standardization initiatives related to the antibody investigation algorithm for prenatal patients, the strategy and algorithm used for assessment of serological weak D patients through genotyping, and recommendations related to standard timing for prenatal sample testing were discussed. We developed a strategy for investigation of anti G in prenatal patients and discussed the feasibility of enhanced automated testing.

Results of projects from the prior year were also reviewed. These included the results of an audit amongst hospital transfusion services regarding the feasibility of using Kell negative phenotyped red cell units for transfusion to female patients of child bearing potential, as well as the results of a study into the utility of a new monoclonal anti Mia antibody.

In follow up to the 2016 meeting several projects have been selected for additional work. These include continued work on alignment of the algorithm for assessment for weak and partial D antigens by RHD genotyping. The second involves additional work on development and standardization of automated testing for passive anti D evaluation and the third major initiative chosen for additional work was the agreement on timing of sample testing for perinatal patients.

The PNAC meeting was followed by a one and one half day Grifol's Transfusion Science Education course. The course included a distinguished panel of speakers who covered diverse topics related to both blood group serology and the utility afforded by blood group genotyping. The education day was well attended by both local transfusion medicine staff and transfusion professionals from across Canada.

GOALS FOR 2017

1. Complete the move from 67 College to the Brampton location in May 2017.

2. Institute for Quality Management in Healthcare Accreditation

An on-site inspection of the laboratory is anticipated to occur in November of 2017.

3. Diagnostic Services Web Page Redesign

All Diagnostic Services sites (Vancouver, Edmonton, Regina, Winnipeg, and Brampton) and the National Immunohematology Reference Laboratory will collaborate in a project to redesign and refresh the current Diagnostic Services webpages on www.blood.ca that will include new features and information which will make the site more user friendly for hospital customers.