Canadian Blood Services
Société canadienne du sang

DIAGNOSTIC SERVICES

ONTARIO

YEAR IN REVIEW

JANUARY – DECEMBER 2015

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

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) and Platelet Immunology testing through Winnipeg Diagnostic Services and University Health Network. 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
Red Cell Serology Reference	ABO resolutions	0	3	0
	Antibody investigations-pretransfusion	557	585	610
	Antibody investigations- prenatal	217	226	188
	Phenotyping (number of antigens)	2,376	2,248	2,074
Test Totals (excluding components distributed)		**3,924**	**3,873**	**3,651**
Number of Patients Tested		**701**	**728**	**716**

Figure 1: Most Common Clinically Significant Antibodies (CSA) Detected

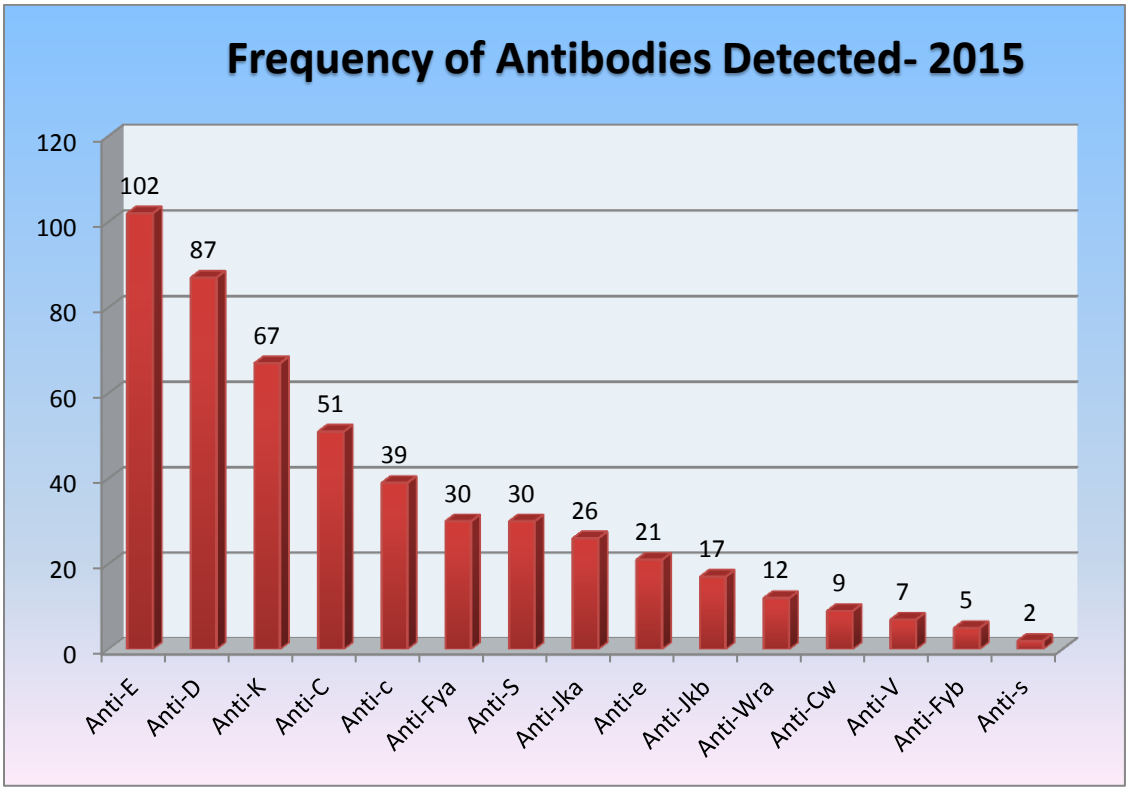


Table 2: Antibodies to low prevalence antigens

Antibodies to low incidence antigens	
Antibody	Number Identified
Anti-Lua	10
Anti-Cw	9
Anti-Cob	5
Anti-Vw	5
Unidentified	4
Anti-Dia	3
Anti-Jsa	3
Anti-Lu14	2
Anti-Vs	2

Table 3: Antibodies to high prevalence antigens

Antibodies to high incidence antigens	
Antibody	Number Identified
Anti-Yta	6
Unidentified	6
Anti-Ch	5
Anti-f	4
Anti-G	4
Anti-Yka	2
Anti-U	2
Anti-Lub	2
Anti-H	2
Anti-Ge2	2
Anti-Jra	2
Anti-Rg	1
Anti-JMH	1
Anti-Kpb	1

Table 4: Other antibodies

Other antibodies	
Antibody	Number Identified
Autoantibody	**201**
Anti-Bg/HLA	**58**
Cold Agglutinin	**31**
Antibody to Red Cell Preservative	**19**
Anti-M	**18**
Unidentified	**11**
Anti-Lea	**10**
Anti-Leb	**4**
Anti-P1	**3**
Anti-HI	**2**
Anti-N	**2**
Anti-Fy3	**2**
Anti-Jsa	**2**
Anti-Jra	**1**
Anti-Jk3	**1**
Anti-Tm	**1**
Anti-He	**1**
Anti-I	**1**
HTLA	**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 2015 calendar year follows.

Table 5: Antibody Complexity 2015

Complexity 1	Complexity 1 Percent of Total	Complexity 2	Complexity 2 Percent of Total	# of Samples
209	28%	589	72%	798

Table 6: Antibody Complex Procedures Performed

Number of complex investigation procedures 2015	
Procedures	Number
Alloadsorption	27
Autoadsorption	127
Auto and Alloadsorption	47
Elution	196
Titre	20

REFERRAL SAMPLES

Platelet Immunology

At the end of December 2014, human and platelet specific (HPA) antigen typing and antibody investigation testing was discontinued. Any request for platelet investigation testing is referred to the CBS Winnipeg Platelet Immunology laboratory. The Winnipeg laboratory is accredited by the College of American Pathologists (CAP). Since the transfer, turnaround time for hospitals receiving test results has significantly improved.

A. Specimens Tested

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 be affected by platelet function disorders (PTP). The figure below indicates the number of procedures performed in 2015:

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

Number of HPA Procedures 2015	
Procedures	Number
HPA Antigen Typing	114
HPA Antibody Screen/ID	69

HLA Testing

Currently, Canadian Blood Services' diagnostic services acts 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. Samples from hospitals in the GTA (i.e. Princess Margaret Cancer Centre, Mount Sinai Hospital, Sunnybrook Hospital, etc.) are sent to 67 College where the samples are logged into Canadian Blood Services' system then repackaged and delivered to the UHN lab at 67 College St.

Table 8: HLA procedures performed by UHN

Number of HLA Procedures 2015	
Procedures	Number
HLA Antigen Typing	52
HLA Antibody Screen	106
HLA Antibody Identification Single Antigen Testing	92

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. It is an 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 performed

Number of Genotype Procedures 2015	
Procedures	Number
RhD Genotype Procedures	42
Non-RHD Genotype Procedures	169

Red Cell Serological Reference Testing

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

Table 10: Red cell serological investigations referred to NIRL

Number of RSCI Procedures referred to NIRL 2015	
Procedures	Number
Antibody Investigations	44
Direct Antiglobulin Differential Testing	12

QUALITY INDICATORS

The laboratories monitor many quality indicators and the one which is most relevant to this document is turnaround times and rejected specimens which are presented below.

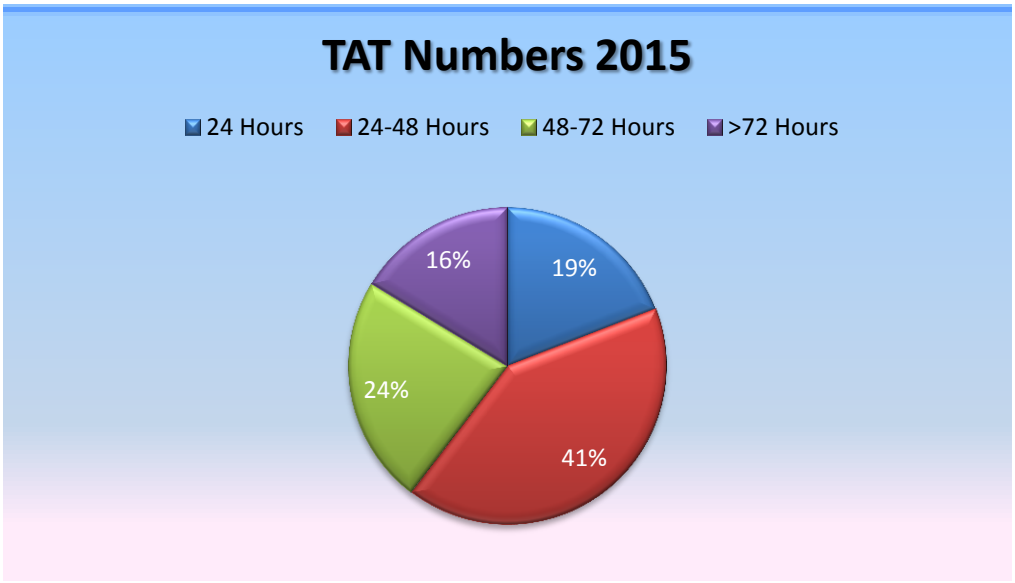
A. Turnaround Times

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. 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 2015 was 0.20%

Figure 2: Red Cell Serology Reference Testing Turnaround Time



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 since 2014

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

Survey Name	Survey Challenge	Results
CAP ABT (Antibody Titer) 2 surveys per year	A	Good
	B	Good
CAP DAT (DAT) 2 surveys per year	A	Good
	B	Good
CAP J (Transfusion Medicine - Comprehensive/ Limited) 3 surveys per year	A	Good
	B	Good
	C	Good
CAP ELU (Eluate) 2 surveys per year	A	Good
	B	Good

ACCOMPLISHMENTS IN 2015

A. Genotyping – Red Cell

Canadian Blood Services is able to provide red cell antigen genotyping services through our National Immunohematology Reference Laboratory (NIRL) and RhD genotyping at our Edmonton site. 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, in particular for sickle cell patients and patients with frequent transfusion requirements.

B. Resident Training Program in Transfusion Medicine

Canadian Blood Services participates in Transfusion Medicine Residency Programs with Royal College of Physicians and Surgeons-accredited Canadian Universities to train specialists in Transfusion Medicine. These residents are medical doctors who already have attained specialty status in one or more of the following specialties: Pediatrics/hematology, General Pathology, Hematological Pathology, Internal Medicine/hematology or Anesthesia. The Transfusion Medicine specialty covers the domain of laboratory and clinical medicine concerned with the study and the supervision of the collection, testing, preparation, storage, transportation, pre-transfusion testing, infusion and safety of human blood products, non-human alternatives and alternative products manufactured by recombinant DNA technology. In 2015 five residents completing a two week training program at the CBS Toronto site.

C. Perinatal Advisory Committee

The annual perinatal advisory committee meeting for 2016 is planned for June 13 and 14 2016 in Winnipeg MB. The PNAC meeting will be followed by an Educational Event sponsored by Grifols. Attendees will include laboratory Directors, Associate Directors and Managers as well as perinatal supervisory staff and laboratory physicians who oversee perinatal testing. We will also welcome some hospital colleagues, both technologists and physicians, who are involved with perinatal testing laboratories. Ongoing work on standardization among our laboratories is a theme for this year. Our meeting plan and ongoing work plan for the remainder of 2016 will include:

- Discussion and consensus on appropriate follow up for perinatal patients with inconclusive antibodies.
- Planning for investigation of patients with possible antibodies to low prevalence antigens in the perinatal setting. We will discuss the development of a standard “low prevalence” panel of cells that will allow for investigation of antibodies to low prevalence antigens which may be clinically significant in pregnancy.
- Discussion and consensus on the timing of repeat samples for patients with clinically significant or potentially significant antibodies in the perinatal setting.
- We will discuss the functionality of our standardized antibody investigation algorithm, including any necessary changes following one year of use.
- We will optimize and standardize the use of our algorithm used for RHD genotyping in perinatal patients with weak or variable Rh D serological typing.
- We will discuss the optimal serological evaluation for anti G, especially in the presence of passive anti D.
- We will discuss the results of an audit of Kell negative donor unit availability in transfusion of Kell negative (or Kell unknown) females of child bearing potential.

- We will have some updates and final discussions on completed projects including a study of anti Mia antisera in the BC perinatal testing lab as well as an update of testing and labeling strategies for platelet products in fetal/neonatal alloimmune thrombocytopenia.

D. Relocation to Brampton

The construction is well underway for the new laboratory facility in Brampton. Validation, relocation and human resources strategies have been developed to ensure there are no service interruptions during the transition. The plan is to move to the new facility in the spring of 2017.

GOALS FOR 2016

A. Continue revising operating procedures and processes to enhance a standardized approach for antibody investigation with NIRL and Donor Testing.

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

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