



**Canadian
Blood
Services**
BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
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Canada

2019-02-28
CBS Control #: CBS6278
HPFB File #: C1892-100390
REF: H-1819-TOR

Ms. Anita Mahadeo
Compliance Specialist
Regulatory Operations and Regions Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Ms. Mahadeo:

**Re: Responses to Health Canada Inspection of Licensed Activities at Toronto – 67 College
2019-01-21 to 2019-01-23**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-02-06.

Section 95 – Operating Procedures

1. **Some operating procedures were not always followed. For example:**
 - a) **Step 1.4 in Procedure 01 131, Collect Product – Multi Plasma, Revision 3 was not followed for a multi-plasma donation observed during an apheresis clinic held on Monday, January 21, 2019 at clinic T0001. The procedure indicated to enter a default value of 49 for Hct, when programming the collection device. However, during clinic it was observed that a value of 41 was entered for Hct which was based on the donor's previous donation.**

QER 56-19-130035 was initiated on 2019-01-24.

The staff member involved was made aware of the error and reminded of the requirements for multi-plasma collections. In addition, all staff involved in apheresis collections will complete refresher training on SOP 01 131 v 3, "Collect Product - Multi Plasma" step 1.4.3 by 2019-03-31.

- b) **Job Aide J800071 (2017-06-19) "PDA Entry – Whole Blood Phlebotomy" was not followed for an apheresis donation C05561922306700G regarding the entry of specimen information. There were no DNL labels scanned into ePROGESA in the phlebotomy questionnaire section for specimens "2" and "4". However "No" was entered as the response to "APLT - Is there any Specimen Information?" As a result, "Incomplete Set" and which specimens were missing were not entered in ePROGESA. This is contrary to the Job Aide.**

QER 56-19-130036 was initiated on 2019-01-24.

The staff member involved was made aware of the omission. All apheresis staff will review step

1.9.1 in SOP 01 143 v 9, Collect Product Plateletpheresis and step 1 in Job Aid J800073 (not J800071 as referenced above), PDA Entry Plateletpheresis Phlebotomy" by 2019-03-31.

c) Procedure 13 006, Temporary Building Access Control, Revision 8 was not followed on January 21, 2019 and January 22, 2019 for visitors (i.e., Health Canada inspectors) to 67 College Street site. The procedure indicated to issue a Visitor ID label (i.e., no cards). However, inspectors were issued the following:

- On January 21, 2019, two inspectors were issued "V" (volunteer) cards and no Visitor ID label.
 - On January 22, 2019, two inspectors were issued "E" (employee) cards, one of whom did not receive the Visitor ID label.
 - On January 22, 2019, a third inspector was issued a "V" card and no Visitor ID label
- It is acknowledged that the cards issued only provided access to general areas (e.g., washrooms, elevators).

QER # 56-19-137559 initiated on 2019-02-13.

The Facilities Manager spoke with security personnel involved on 2019-01-23. Security personnel working at Toronto - 67 College will complete refresher training on SOP 13 006, version 8, Temporary Building Access Control by 2019-03-31

d) Procedure 13 022, "Premises Cleaning", Revision 3 was not followed.

- The procedure indicated to conduct a monthly inspection. However the monthly inspection for August 2018 for the 67 College Street site was conducted on September 21, 2018 which was the same date as the September monthly inspection.
- The procedure indicated to monthly inspect disinfectants and equipment using the Sanitation Program Document as a reference and to confirm inspection completion on the Premises Monthly Inspection form. However, for the monthly inspection conducted on December 28, 2018, the review of Sanitation Program was not indicated as completed on the form.

QER # 56-19-137558 was initiated on 2019-02-13.

Facilities staff who initiate and review the documentation will complete refresher training on SOP 08 851, v6, Manual of Good Documentation Practices and SOP 13 022, v3, Premises Cleaning by 2019-03-31.

Section 117 – Records

2. Records were not always accurate, complete, legible, indelible and/or readily retrievable. For example:

a) For a multi-plasma donation C05561922307000Q, the medical questionnaire in ePROGESA indicated that the medications the donor was taking contained ASA. However, according to the 01 200 Donor Selection Criteria Manual, Part 2: Special Criteria, Section A: Apheresis Criteria, Version 8, Amendment 12, the medications listed on the questionnaire did not contain ASA.

QER 56-19-130037 was initiated on 2019-01-24.

The staff member involved was made aware of the inaccurate information in the donor record. The staff member will complete refresher training on step 1.8 of SOP 01 144 v11, Screen Donor, SOP 08 851 V6, Manual of Good Documentation Practices and 01 200 Donor Selection Criteria Manual, Part 2: Special Criteria, Section A: Apheresis Criteria, Version 8, Amendment 12 by 2019-03-31.

b) The Interim Storage Record for the incubator storing platelets that were collected on 2018-09-27 at clinic T0001 was not accurate. The clinic date recorded was 2018-10-27.

The incorrect date of 2018-10-27 on the Interim Storage Record was corrected to 2018-09-27 as per Good Documentation Practices. Staff members who documented and reviewed the Interim Storage Record were made aware of the error and will complete refresher training on SOP 08 851 v. 6 " Manual of Good Documentation Practice by 2019-03-31.

c) The Interim Storage Record for the incubator storing platelets that were collected on 2018-10-06 at clinic T0001 was not complete. The number of units was not documented on the record at time 10:45.

QER 56-19-130042 was initiated on 2019-02-01.

Staff members who documented and reviewed the Interim Storage Record were made aware of the omission. Both staff members will complete refresher training on step 1.1.2 of SOP 01 137 v 11 "Interim Storage at Clinic Site", and on SOP 08 851 v6, Manual of Good Documentation Practices by 2019-03-31.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please reference the above CBS control number in any correspondence.**

Sincerely,



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Vice-President
Quality & Regulatory Affairs
Fax Number: 613-739-2505

cc: Hugo Tremblay
Supervisor – Blood, Tissues, Organs and Xenografts
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