

2017-06-26
CBS Control #: CBS6062
HPFB File #: C1892-100390
REF: H-1718-BAR

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

Dear Ms. Rave:

**Re: Responses to Health Canada Inspection of Licensed Activities at Barrie Fixed Site
2017-05-11 and 2017-05-12**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-06-05.

Section 42 - Donor Suitability Assessment

1. **During the review of donor questionnaires for clinic T0005 (Barrie Fixed Site) held May 11, 2017, donation C05561722551000C indicated that a deferral was to be applied to the donor for consulting a doctor for a health problem related to an "episode of severe short of breath 2 weeks ago, waiting for cardiac workup to be done", however there was no deferral code applied in Progesa. A blood unit from this donor was not collected at clinic. During the inspection, an NCR was initiated.**

Nonconformance Report (NCR) #56-17-321191 was initiated on 2017-05-12.

Deferral code L0001 was applied on 2017-05-15 for 56 days and remarks entered in Donation Association Remarks in eProgesa. The staff member involved will complete refresher training to SOP 01 373, Manage Deferrals, Version 3 and J800093, PROGESA Entry Manage Deferrals Version 2016-08-05 by 2017-06-21.

Section 94 - Quality Management System

2. **The establishment did not carry out corrective and preventive actions when required. For a Refrigerator Temperature Log for clinic T0005, 2017-02 that was supervisory reviewed on 2017-02-28, it was not clear if equipment cleaning was performed. For example, there was a checkmark indicating that cleaning had been performed, however they were no corresponding initials or date. This was contrary to procedure 01-56-003, Refrigerator/Freezer/Incubator Monitoring and Maintenance - Permanent Site, effective date 2017-03-06.**

According to our equipment maintenance records for the refrigerator in question, it was cleaned

in January 2017. As per step 1.5.1 in procedure 01-56-003, Refrigerator/Freezer/Incubator Monitoring and Maintenance - Permanent Site, the next cleaning is scheduled for July 2017. The Refrigerator Temperature Log for clinic T0005 for 2017-02 was checked off in error and corrected by the Charge Nurse and reviewed by the Clinic Supervisor on 2017-05-16.

The Supervisor and Charge Nurse completed refresher training to the work instruction in procedure 01-56-003, Refrigerator/Freezer/Incubator Monitoring and Maintenance - Permanent Site completion on 2017-06-21. They will also complete refresher training to SOP 08 851, Manual of Good Documentation Practices by 2017-06-30.

Section 95- Operating Procedures

- 3. During the review of donor questionnaires for clinic T0005 (Barrie Fixed Site) held May 11, 2017, donation C055617225507002 indicated that the donor was deferred due to travel to Thailand and 'all risk' was identified as the malaria risk type. This was contrary to the Donor Selection Criteria Manual (01 200), Version 8, which indicated that Thailand is a partial risk malaria area. A blood unit from this donor was not collected at clinic and a malaria deferral of one year was applied. During the inspection, an NCR was initiated.**

Nonconformance Report (NCR) #56-17-321189 was initiated on 2017-05-16.

Staff member involved completed refresher training to Donor Selection Criteria Manual Part 1 and Part 2 (01 200) Version 8 on 2017-06-07.

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,

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affairs
Fax Number: 613-739-2505

cc: Hugo Tremblay
Supervisor – Blood Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch