Canadian Blood Services
Société canadienne du sang

1800 Alta Vista
Ottawa, ON K1G 4J5
T 613.739.2300 F 613.731.1411
www.blood.ca www.sang.ca

2017-11-01
CBS Control #: CBS6103
HPFB File #: C1892-100390
REF: H-1718-CAL

Ms. Sandra Jarvis
Compliance Specialist
Regulatory Operations and Regions Branch
Biological Products Compliance Program
730, 9700 Jasper Ave. NW
Edmonton, Alberta
T5J 4C3

Dear Ms. Jarvis:

Re: Responses to Health Canada Inspection of Licensed Activities at Calgary 2017-09-11 to 2017-09-22

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-10-11.

Section 95 - Operating Procedures

1. **Some operating procedures were not always followed.**
Contrary to Section 1.3.2 of SOP 08 772, V.14, the incorrect donation was associated with the Lookback Event created in eProgesa for the retrieval of an RBC component. Specifically, to address an incorrect Zika risk assessment for Donor 5588583 (NCR#2016205998), the Lookback Event was assigned to donation C05201656102600L, but should have been assigned to donation C05201658429600D. It was noted that the error had been corrected on the Component Retrieval Record and the correct component had been retrieved.

Quality Event Report # 20-17-119368 was initiated on 2017-09-11.

The implementation of enhancements to the non-conformance process (now called Quality Event Management process) on 2017-06-26 requires immediate verification of containment for fresh blood products which should prevent similar events from occurring. In addition, Quality Assurance staff were reminded to ensure that corrections are adequately assessed and confirmed.

Section 117 - Records

2. **Records were not always accurate, complete, legible, indelible and/or readily retrievable. For example:**
a) The average collection volume recorded on the Daily Buffy Coat Volume Log and the Daily Buffy Coat Volume Monitoring Chart were sometimes inaccurate and/or illegible. Specifically, for Compomat G4 ID B/R4865 on 2017-08-16, the average volume collected recorded on the log read as 58 ml but when calculated should have been 50. It was recorded on the monitoring chart as 49 ml. In addition, for Compomat G4 ID E/R4868 on 2017-08-18, the average volume collected recorded on the log read as 57, but when calculated should have been 53. It was recorded on the monitoring chart as 51.

b) The "Reviewed" stamp used to document the review of the Component Pooling Report for 09/06/2017 was missing the reviewer's initials and the date.

Combined response for 2a and 2b:

A reminder to staff to ensure proper calculation, accurate documentation and initialing and dating the stamp will be provided to staff in the form of a read and sign memo to be completed by 2017-11-30.

c) The next date due for the Contact Freezer (R16183) was identified on the PM sticker on the freezer as 2018-02-28. The correct due date, as identified in RAM and supported by documentation, was 2018-02-10. (Resolved during the inspection)

This was resolved at the time of the inspection. The corrected preventive maintenance (PM) label was placed on the contact freezer, R16183, per SOP 09 350 v4, Management of Equipment by Owners. Staff from facilities reviewed the equipment work detail within RAM with staff from Equipment Services and confirmed the PM labels located on equipment are accurate. In addition, staff from Facilities reviewed SOP 09 350, the RAM equipment work detail and document 1000104387 Preventive Maintenance (sample PM label) with the Building Technician on 2017-09-25 to ensure that information placed on the PM label corresponds with the RAM system information.

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