Canadian Blood Services
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2017-11-17
CBS Control #: CBS6114
HPFB File #: C1892-100390
REF: H-1718-EDM

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 Edmonton 2017-10-16 to 2017-10-20

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-10-30.

Section 117 - Records

1. **Records were not always accurate, complete, legible, indelible and/or readily retrievable.**
   a) **The Donor ID was missing on a Reaction Incident Report Form for a donor reaction that occurred at an August 22, 2017 clinic (E0001).**

This observation will be discussed with Clinic Services staff. This will include a presentation stressing the importance of good documentation practices with reference to SOP 08 851, Good Documentation Practices. All staff will be required to review the presentation and to sign a memo to that effect.

b) In Section 2 of a Reaction Incident Report dated 2017-08-07 for Progesa Donor #6108911 the clinic RN indicated that a follow-up phone call to the donor was required. However, there was no record of a follow-up phone call. The check box "see notes on page 3" in Section 3 of the form is checked but there was no page 3 attached.

The reaction Incident Report was corrected on 2017-11-02.

A follow up was done as indicated in Section 3 that a message was left for the donor. The check box "see notes on page 3" was, however, filled in by error. Feedback will be provided to the medical staff by 2017-11-30 highlighting the importance of complete and accurate records.

c) The hematocrit obtained from the PocH-100i Hematology Analyzer for platelet donation C052117110036 was incorrectly entered in Progesa as 4.41 % instead of 44.1 %.

Individual feedback was provided at the time of the observation and the process was reviewed.

Additionally, feedback will be provided to staff through a Read and Sign Memo to be completed by 2017-12-15 and will stress the importance of complete and accurate records in accordance with SOP 08 851, Good Documentation Practice.

d) The End Labelling Record for clinics E0001/E0067 on 2017-08-23 was missing the date of review.

The end labelling record was corrected on 2017-11-09.

A Read and Sign Memo was provided to all staff performing reviews, reminding staff of the importance of complete and accurate records. This was completed on 2017-11-11.

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