



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

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2020-11-23
CBS Control #: CBS6457
HPFB File #: C1892-100390
REF: H-2021-SAS

Ms. Shelley Smyth
Regional Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
300-391 York Avenue
Winnipeg, Manitoba
R3C 4W1

Dear Ms. Smyth:

**Re: Responses to Health Canada Inspection of Licensed Activities at Regina Operations
2020-10-26 to 2020-10-29**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2020-11-10.

Section 95 - Operating Procedures

- 1. Some operating procedures were not always followed. For example:
During the review of donor records in ePROGESA for the Regina clinic that took place on 2020-10-08 it was noted that for donation # C05302072950400J the phlebotomy was unsuccessful, no product was collected and there was blood in the sample diversion pouch, but the data entry was incorrect. As a result of this incorrect data entry an automatic deferral (C084) was not applied. The question "any special unit information?" was answered no, when it should have been answered yes. This was contrary to SOP 01 141 V6 Collect Product-Whole Blood, Attachment 5. A deviation was created on 2020-10-26 by clinic operations, DEV-20-008087.**

The Clinic Supervisor reviewed SOP 01 141 Collect Product – Whole Blood V6 Attachment 5 with the phlebotomist on 2020-10-29.

All audit observations will be reviewed with all clinic staff at the next staff meeting on 2020-11-27.

Section 117 – Records

- 2. Records were not always accurate, complete, legible, indelible and/or readily retrievable. For example:
During the review of the Pochi Maintenance and QC Log it was noted for the daily QC on 2020-09-05 that the date entered for the QC Control High, Open Expiry Date was 2020-09-18 instead of 2020-09-13 which was the correct date.**

Minor Quality Event MQE-20-003857 was initiated on 2020-11-13.

Clinic Supervisor addressed the transcription error with the staff member involved on 2020-10-28 and emphasized the importance of good documentation practices.

All audit observations will be reviewed with all clinic staff members on next staff meeting scheduled for 2020-11-27.

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: Naima Bendahmane
Supervisor – Biological Product Compliance
Regulatory Operations and Regions Branch