Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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2023-12-11
CBS Control #: CBS6783
HPFB File #: C1892-100390
REF: H-2324-BRMPDC

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

Dear Supriya:

Re: Responses to Health Canada Inspection of Licensed Activities at Brampton Plasma Donor Centre 2023-10-23 to 2023-10-27

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2023-11-16.

Section 39 - Donor Suitability Assessment

1. **For donation C070923302376006, clinic date May 23, 2023 (clinic PT001), the following were observed:**
   a) The Technical Questionnaire – Phlebotomy stated '<=25 mL – No deferral' for question 7B ('RBC Loss'). However, as per WI 01275, Collect Product – Plasma Program (Revision 4), because this donation was a routine non-saline procedure and a red blood cell loss of 26-50 mL, a 2 week deferral (P014) was required. This donor was not deferred for 2 weeks.

   It is acknowledged that up to the time of inspection, this donor had only made one donation.

   It was confirmed following the inspection that the unit in question was part of Dev-23-007954 that was initiated on 2023-09-20 for missed deferrals identified prior to the inspection at Brampton Plasma Donor Centre. The corrective action included the review of WI-01275 Collect Product – Plasma Program with staff prior to the closure of the deviation on 2023-10-04.

   Following the inspection, a huddle note outlining the steps to be followed in WI-01275 Collect Product - Plasma Program regarding calculating red blood cell loss was read and signed by all staff. This was completed by 2023-11-20.

b) On the PDC Source Plasma Anticoagulant and Saline Documentation form – Plasma Program, initials were recorded under the column 'Solutions, Connections Verified & Collection Started By: (initials)' for saline. However, a 'NA' should have been recorded because saline was not administered during this donation.

MQE-23-003690 was initiated on 2023-10-25.

All staff read and signed the huddle note on the correct documentation required as per F801408 PDC Source Plasma Anticoagulant and Saline Documentation Form – Plasma Program when performing solution checks. This was completed by 2023-11-20.

Section 95 – Operating Procedures

2. **On the Quality Inspection of Critical Supplies record for a Collect Separation Bowl 625B, Lot # 2303003C shipment received on 2023/05/02 and accepted on 2023/05/04, the comments section in section 2 did not have the proper documentation for the inspection of the outer packaging. This is contrary to WI 00773, Inspection of Critical Supplies (Revision 1), Section 4, Step 4.**

   DEV-23-009865 was initiated on 2023-11-20.

   Team Leads, Managers and Plasma Associates – Process Leads completed a read and sign huddle note regarding following the instructions in step 4 of WI-00773 Inspection of Critical Supplies (Revision 2) for the documentation requirements of the Outer Shipment Conditions in Section 2 of the Critical Supplies form.

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,

Christian Choquet

Dr. Christian Choquet
Vice-President