

2023-10-16

CBS Control #: CBS6774

HPFB File #: C1892-100390

REF: H-2324-EAU

Danny Phan
A/Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
400-4595 Canada Way
Burnaby, British Columbia
V5G 1J9

Dear Danny:

**Re: Responses to the Health Canada Inspection of Calgary – Eau Claire Market
2023-09-12 to 2023-09-13**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2023-10-04.

Section 95 – Operating Procedures

- 1. Some operating procedures were not always followed. Contrary to WI-00278 Screen Donor for Plasmapheresis (Revision 1, Effective 2023-06-26), Step 3 (16%, 825 mL) of the required four-step large volume plasma collection progression was omitted for Donor #3507135 and resulted in overcollection of plasma at Step 4 (18%, 880 mL) during their third donation.**

MQE-23-003417 was initiated on 2023-10-04.

At the time of this donation in December 2018, the work instructions in place were 01 807 v1 Collect Product - Large Volume Source Plasma and 01 144 v10 Screen Donor. These work instructions directed staff to select the next appropriate progression step based on the documentation in eProgesa Medical Notes that was made at the previous donation.

Process revisions implemented 2022-02-07 removed the requirement for manual documentation of the percentage of total estimated blood volume (%TEBV) in eProgesa Medical Notes for successful donations. The donor's total blood volume and maximum acceptable donation volume is now calculated automatically by eProgesa based on the donor's gender, height and weight. The %TEBV is selected based on the Previous



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Response field displayed by eProgesa during screening. These changes are reflected in the current versions of WI-00272 Rev 4 Collect Product - Large Volume Source Plasma; WI-00278 Rev 1 Screen Donor For Plasmapheresis, and CO-00372 Rev 0 eProgesa Screening Guide. These revisions mitigate against an incorrect progression step being taken.

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

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