Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
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2021-02-24
CBS Control #: CBS6488
HPFB File #: C1892-10039
0 REF: H-2021-HAL-L

Ms. Victoria Hurlbut
Regional Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
Suite 1625, 16th Floor
1505 Barrington Street
Halifax, Nova Scotia
B3J 3Y6

Dear Ms. Hurlbut:

Re: Responses to Health Canada Inspection of Licensed Activities at Halifax 2021-02-02 to 2021-02-04

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-02-10.

Section 95 - Operating Procedures

1. **Some operating procedures were not always followed, Contrary to:**
   a) Procedure 01 144 Version 25 (effective 2020-11-02) Screen Donor, the following first-time donors did not have their height and weight documented.
   i. Donation C057119629091005 donated April 13, 2019
   ii. Donation C057120660520005 donated Oct 10, 2020.

   MQE-21-000483 and MQE-21-000488 were initiated on 2021-02-11.

   The collection staff was reminded to document the height and weight of new donors between the ages of 17 and 23 as per SOP 01 144 V25 Screen Donor Step 6.

   In addition, on 2021-02-15, eProgesa was updated to make the entries of height and weight of new donors between the ages of 17 and 23 mandatory.

   b) Procedure 01 141.001 Version 5 (effective 2020-11-06) Collect Product-Whole Blood Attachment 2-Venepuncture not attempted whole blood, the phlebotomist did not answer the question "Is there any phlebotomy related information" yes and then select the appropriate related information "Vein related" when C05711961702600* was not collected due to venepuncture issue.

   c) Procedure 25 349 Rev 10.1 (effective 2019-08-12) Apheresis Hematology Analyzer-Maintenance, the following maintenance logs were not complete.
   a. For PocH-I unit R000000382:

i. PocH-I Maintenance and QC Log 2019/06/28 did not have documentation for "shutdown procedure" or "cleaning"
ii. PocH-I Maintenance and QC Log (Aug 31 to Sep 6, 2019) did not have documentation for Maintenance "Clean Transducer" and "Clean Waste Chamber". In addition, the log had not been supervisory reviewed and dated.
iii. PocH-I Maintenance and QC Log (Sep 28 to Oct 4, 2019) did not have documentation for Maintenance "Clean Transducer" and "Clean Waste Chamber".

d) Procedure 26 024 Rev 13 (effective 2020-11-16) TRIMA ACCEL, Yield Scaling Factor and Target Yield Determination, the TRIMA ACCEL Maintenance Log for August 2020 did not document the YSF/Target Yield Changes.

Combined Responses for b), c) and d)

Minor Quality Events were initiated on 2021-02-11.

Follow-up with the staff members involved will be done by 2021-02-28 to ensure documentation requirements are understood and followed. In addition, all staff will be reminded of the documentation requirements during the clinic huddle and will be required to read and sign a memo to that effect prior to 2021-03-31.

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
Quality & Regulatory Affairs
Fax Number: 613-739-2505

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