Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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2023-02-07
CBS Control #: CBS6690
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REF: H-2223-KELPDC

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 Kelowna Plasma Donor Centre 2022-12-13 to 2022-12-16

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2023-01-11.

Section 39 - Donor Suitability

1. **For donation C06802140110600H on clinic date 2021-07-21, there was a discrepancy in the answers to questions related to medications and shots that may have been taken by the donor, yet there was no follow-up indicated to resolve the discrepancy.**

   For example, the donor answered 'YES' to question 3 ('In the last 3 days have you taken any medication including Aspirin? Vitamins and birth control are excluded.') and 'No' to the subsequent three questions: #4 ('Have you taken ASA or Aspirin in the last 3 days?'), #5 ('Other medications?') and #6 ('Medication(s) contains ASA').

MQE-22-004146 initiated on 2022-12-13.

No retrieval was required as the donation was not completed, and a component was not collected.

Work instruction 17 005 Screen Donor – Plasma Program was discussed during the staff huddle on 2023-01-12 to reinforce that staff are to address all exceptional or unsure responses as per Donor Selection Criteria Manual.

Section 99 – Facilities

2. **The following were observed when reviewing records pertaining to deactivating building access for 3 employees that had left Canadian Blood Services (e.g., one employee resigned, one student's contract came to an end, and one was dismissed):**
   a) There was no evidence to indicate that the building access card had been deactivated. WI 13 025, Security Access Control (Revision Number 7.1) indicates a timeline of no later than 10 am the next day after the three employees left permanently to complete this task
   b) Security access forms were not completed for the three employees when their building access had changed upon termination. This is contrary to WI 13 025, Security Access Control (Revision Number 7.1).

Deviations DEV-23-000732 and DEV-23-000738 were initiated on 2023-01-23.

The building access cards for the three employees who departed Canadian Blood Services were deactivated on 2022-12-13 and 2022-12-14.

Facilities and PDC staff responsible for activating access/ removing access have been reminded of the importance in following procedures by 2023-02-10 and had a refresher training to WI 13 025 Security Access Control completed.

A review will be completed by 2023-02-28 to ensure building access cards have been deactivated and Security Access Forms (SAFs) are completed as per WI 13 025 Security Access Control for all applicable employees across all plasma donor centers.

Section 94 - Quality Management System

3. **Form F800968, Viewlinc Daily System Checks, was revised and implemented on June 10, 2022 yet was not used until June 13, 2022. Entries were made on the old version of the form on June 11 and 12, 2022**.

MQE-22-004177 was initiated on 2022-12-15.

An assessment of the revision to the form was performed, and it was confirmed that the change was an editorial update to the logo.

Entries on the Viewlinc Daily System Checks forms for 2022-06-10 and 2022-06-11 were updated with the reference to the MQE.

The issue was discussed with clinic staff on 2023-01-12 to ensure forms are implemented on the appropriate date per work instruction 09 115 Document Management – Area Document Distributor. Staff are to ensure documents are distributed to the assigned areas on the date of the implementation.

Section 95 - Quality Management System

4. **During the review of Viewlinc alarm reports the following was observed, contrary to WI 13 036, Viewlinc Operation (Revision 5):**

   a) There was a discrepancy in the number of alarms acknowledged between the Viewlinc Alarm report and the Viewlinc Daily Systems Checks for September 14, 2022 (e.g., 8 vs 9 alarms acknowledged, respectively) and September 15, 2022 (e.g., 10 vs 11) yet there was no follow up.

   b) The alarm acknowledgement was not reviewed the following business day. For example, the Viewlinc Alarm report for September 19, 2022 indicated that the alarm was activated (08:44:10) and deactivated (08:45:11) on September 13, 2022, yet it was not acknowledged until September 17, 2022

MQE was initiated on 2023-01-17.

The alarm data was reviewed and the temperature was within acceptable range for all dates.

The observation was reviewed with staff on 2023-01-12. In addition, staff were reminded to review alarms that have occurred since the start of the previous business day as per WI 13 065 Viewlinc

Operation on 2023-01-12.

Section 99 - Facilities

5. **Donor Centre Evaluation Checklist completed March 23, 2021 for an initial inspection indicated 12 beds in reference to the 'Adequate square footage for bed model', yet, there was a discrepancy with the floor plan which indicated a 16 bed capacity.**

The Donor Centre Evaluation Checklist and associated work instructions are no longer in use in plasma operations. The floorplan for the plasma donor centre was created and approved on 2020-06-29 to accommodate 16 beds.

Section 117 - Records

6. **The following were observed during record review:**

a) The date of vaccination was not always recorded in eProgesa for donors that had indicated that they had taken the COVID vaccination (e.g., donations C0680214010500J and C06802140109600Q on clinic date 2021-07-21).

a) MQE-22-004414 was initiated on 2023-01-12.

Work instruction 17 005 Screen Donor Plasma Program was reviewed with staff during the huddle on 2023-01-12.

b) The August 2022 Centrifuge Maintenance Log for R25704 was reviewed on August 29, 2022, however an additional weekly maintenance was conducted and documented on August 31, 2022 without submission for a re-review. MQE-22-004176 was initiated during the inspection

b) MQE-22-004176 was initiated on 2022-12-13.

An additional review of the Centrifuge Maintenance Log for August 2022 was completed on 2022-12-15. Work instruction 01 288 Centrifuge Maintenance Plasma Program was reviewed with staff during the huddle on 2023-01-12.

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.

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Quality & Regulatory Affairs
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c.c.: Naima Bendahmane
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