Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

2023-08-23
CBS Control #: CBS6755
HPFB File #: C1892-100390
REF: H-2223-HAM

Urbee Shome-Pal
Regulatory Compliance & Enforcement Specialist
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Regulatory Operations and Enforcement Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Urbee:

Re: Further to the Responses to the Health Canada Inspection of Hamilton 2023-06-08 to 2023-06-09

The following are the responses from Canadian Blood Services to the Health Canada email dated 2023-08-18, requesting clarification for an observation to the Exit Notice for Health Canada's Inspection of licensed activities at Hamilton.

2c) Form 1000106028 (2019-06-21): CompoLab TM Hemoglobinometer Verification Log does not track all relevant test equipment. Specifically, there is no place on the form to track the lot numbers and expiry dates of the DiaSpect Cuvettes, used during the verification of the relevant equipment. As a result, this information was not being documented on these forms.

Canadian Blood Services Response:
DiaSpect cuvette lot numbers and expiry dates are entered in ePROGESA upon receipt as it is a critical supply, as per WI-00599 (12 111) Entering Supplies in PROGESA, Section 1 Step 2. At every donor event the DiaSpect cuvette lot number is again entered in ePROGESA during drive set-up are per WI-00260 (01 371.001) Drive Set-Up. ePROGESA verifies the entry matches a lot number previously entered and released for use. Diaspect Cuvette lot number and expiry date are not documented on F1000106028 (2019-06-21) CompoLab TM Hemoglobin Maintenance Log, as the lot number can be traced by date in ePROGESA.

Health Canada Follow-up email dated 2023-08-14:
During the inspection it was noted that the DiaSpect controls were tracked on the cited form, however the DiaSpect cuvettes were not. The response to the observation indicates that the DiaSpect cuvette lot numbers and expiry dates are entered into ePROGESA upon receipt as it is a critical supply and tracked in that manner. The following clarifications are requested to this response:

1. Are DiaSpect controls also considered a critical supply and tracked the same way?
2. If yes, then why is there a difference between tracking the controls and not the cuvettes on the form?

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3. If the controls are not considered as a critical supply, then please provide a rationale as to why they are not.
4. If there are multiple DiaSpect cuvette lot numbers being tracked in eProgesa at the same time, then how could it be confirmed as to which lot number of the cuvettes was used for a specific hemoglobinometer verification?

Canadian Blood Services Follow-up Response:

1. *Yes, the DiaSpect Controls are a critical supply and are not tracked in the same way.*
2. *There is a difference in tracking the lot number of controls and cuvettes since cuvettes are used and tracked daily at each donor event as part of the Drive Set Up. The DiaSpect controls are used as scheduled on a 6-month basis or when a new machine and/or vendor repair maintenance is performed. Therefore, they are not required to be tracked daily.*
3. *Controls are a critical supply and tracked on the CompoLab TM Hemoglobinometer forms as they are used as scheduled on a 6-month basis or when a new machine and/or vendor repair maintenance was performed.*
4. *There may be multiple DiaSpect cuvette lot numbers entered by Warehouse as an available critical supply as per WI-00599, Entering Supplies in PROGESA. If one or more lot numbers of cuvettes are in use at the donor event each lot number is entered into Drive Set Up as per WI -00260, Drive Set-up.*

Health Canada Follow-up email dated 2023-08-18:

If there are instances where multiple lot numbers of these cuvettes may be in use, then how do you confirm which lot# of the cuvettes was used to conduct a specific hemoglobinometer verification, if this information is not tracked on the form and only in eProgesa?

Canadian Blood Services Follow-up Response #2:

It would be assumed either lot number could have been used that day for the hemoglobinometer verification. If there was a recall of a lot number of a supply, we would assume the lot number could have impact on all the donations collected since the affected lot number was used. The quality event management process would be followed.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please refer to the above control number in all correspondence.**

Sincerely,

for

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Vice-President
Quality & Regulatory Affairs
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