



**Canadian  
Blood  
Services**

BLOOD  
PLASMA  
STEM CELLS  
ORGANS  
& TISSUES

1800 Alta Vista Drive  
Ottawa ON  
K1G 4J5  
Canada

2021-03-11

CBS Control #: CBS6494

HPFB File #: C1892-100390

REF: H-2021-BUR

Ms. 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 Ms. Rave:

**Re: Responses to Health Canada Inspection of Licensed Activities at Burlington  
2021-02-10 and 2021-02-11**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-02-18.

**Section 117 - Records**

1. **Records were not always accurate, complete, legible, indelible and/or readily retrievable. The following were observed during record review:**
  - a) **For donation number C055621211474004, the Medical Questionnaire in eProgesa indicated that the donor was new, even though this donor had donated whole blood once in the past.**

*MQE-21-000474 was initiated on 2021-02-10.*

*The staff member was reminded on 2021-02-24 of the importance of good documentation practices and the need for accurate documentation.*

- b) **The December 2020 Vital Signs Monitor Maintenance Log (Daily/Monthly) for Careescape R2546 was reviewed by the Department Manager/Designate on December 31, 2020. Comments were added to this record on January 20 and 21, 2021, after the review had been completed, however, this record had not been re-reviewed.**

*The supervisor re-reviewed the document with the two additional comments when identified during the inspection.*

*The staff member was reminded during the inspection of the requirement to send records for re-review and signature when additional entries are made to records.*

*All staff responsible for the completion and review of records will be reminded in a clinic huddle of the importance of good documentation practices when additional entries are made to records.*

*This will be completed by 2021-03-15.*

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,

A handwritten signature in blue ink that reads "Christian Choquet". The signature is written in a cursive style.

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