

1800 Alta Vista Ottawa, ON K1G 4J5 T 613.739.2300 F 613.731.1411 www.blood.ca www.sang.ca

2017-08-01

CBS Control #: CBS6086 HPFB File #: C1892-100390

REF: H-1718-PEI

Ms. Victoria Hurlbut
Biologic Products Specialist
Regulatory Operations and Regions 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 Charlottetown Collection Centre – PEI Sub-Centre on 2017-07-19 to 2017-07-20

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-07-24.

<u>Section 95 - Operating Procedures</u>

1. Some operating procedures were not always followed.

The height and weight of a first time donor under the age of 23 years was not documented for donation C05711651295000B as required by steps 1.54 and 1.55 of procedure 01 144 Screen Donor Version 3 effective 2016-07-02.

All Clinic Services Managers were made aware of this observation during the national management call on 2017-07-24. Further, this will also be discussed with all sites during the national Trainer/Supervisor call, on 2017-08-17 and they will be reminded to follow the approved process for assessments of first time donors under the age of 23.

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

cc: Hugo Tremblay
Supervisor – Blood Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch