

2019-02-28  
CBS Control #: CBS6278  
HPFB File #: C1892-100390  
REF: H-1819-TOR-R

Ms. Anita Mahadeo  
Compliance Specialist  
Regulatory Operations and Regions Branch  
Health Canada  
180 Queen Street West, 10th Floor  
Toronto, ON M5V 3L7

Dear Ms. Mahadeo:

**Re: Responses to Health Canada Inspection of Registered Activities at Toronto – 67 College  
2019-01-21 to 2019-01-23**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-02-06.

**Section 95 – Operating Procedures**

Some operating procedures were not always followed. For example:

1. Specifically, Job Aide J800071 (2017-06-19) "PDA Entry – Whole Blood Phlebotomy" was not followed for autologous donations C05561824837600B, C05561824809800N, and C055618265050002, regarding the entry of specimen information. No B19 specimens are not collected for autologous donations. According to the Job Aide, specimen information related to not collecting B19 specimens is to be entered in ePROGESA in the phlebotomy questionnaire section. However, this information was not entered for the donations mentioned.

*All staff will complete refresher training on J800071, "PDA Entry - Whole Blood Phlebotomy" regarding the work instructions for entering B19 specimen information for autologous donations by 2019-03-31.*

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,



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