



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2019-04-11
CBS Control #: CBS6287
HPFB File #: C1892-100390
REF: H-1819-ANC-R

Mr. Kevin Donato
Regulatory Compliance and Enforcement Specialist
Regulatory Operations and Regions Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Mr. Donato:

**Re: Responses to Health Canada Inspection of Registered Activities at Hamilton
2019-03-04 to 2019-03-06**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-03.

Section 95 – Operating Procedures

- 1. Job Aid J800071 (2017-06-19) "PDA Entry - Whole Blood Phlebotomy" was not followed for autologous donations including C05561841844600K and C05561722687000M, regarding the entry of specimen information. B19 specimens are not collected for autologous donations. According to the Job Aid, specimen information related to not collecting B19 specimens is to be entered into ePROGESA (refer to "select specimen information"). However, this information was not entered for the donations mentioned.**

Job Aid J800071 "PDA Entry – Whole Blood Phlebotomy" will be revised by 2019-07-30 to clarify sample entries for Autologous and Directed collections to align with 01 141, Collect Product-Whole Blood.

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: Anita Mahadeo
A/Supervisor – Blood, Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch