



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2019-07-19
CBS Control #: CBS6331
HPFB File #: C1892-100390
REF: H-1920-WSO-R

Farah-Michelle Manigat-McLaughlin
Regional Compliance & Enforcement Specialist
Regulatory Operations and Regions Branch
Health Canada

Dear Ms. Manigat-McLaughlin:

**Re: Responses to Health Canada Inspection of Registered Activities at Windsor
2019-06-05 to 2019-06-06**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-07-05.

Section 117 - Records

1. Records were not always accurate, complete, legible, indelible and/or readily retrievable.

1. The Autologous utilization report, form F020079, version code 2008-09-16, was not filled out by Canadian Blood Services for the following donors:

- a) 5933587
- b) 4302523
- c) 5406833

QER 56-18-140458 was initiated on 2019-07-16.

Data from eProgesa confirmed that the autologous units were issued as required. The records will be corrected by 2019-07-31 as per good documentation practices.

Distribution Lab Assistants will complete retraining to SOP 05 071, Packing Blood Components by 2019-07-30.

2. A check mark to indicate whether information was obtained from the "donor, a family member or other" was missing on the Autologous Program -Donor Health History, form F2923 v4, for autologous donor 4302523.

Staff was made aware of the error at the time of the inspection. The error was also reviewed with the record reviewer on 2019-07-11.

The autologous unit from donor 4302523 was collected on 2016-08-04 and since that time form F2923 has been replaced with 56F:080 Autologous Program – Donor Health History, effective 2017-09-06. The "information obtained from" is no longer a required field.

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