

2022-09-09

CBS Control #: CBS6661

HPFB File #: C1892-100390

REF: H-2223-NF

Kevin Donato, PhD
Compliance Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Kevin:

**Re: Responses to Health Canada Inspection of Licensed Activities at St. John's
Operations
2022-07-25 to 2022-07-29**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2022-08-16.

Section 39 – Donor Suitability Assessment

- 1. During the clinic date of 2022-01-20, for the two donors, Donor 5157739, C059022100883003 (platelets), and Donor 6557528, C059022100945007 (whole blood)
For question 06 "In the last 3 months have you had a vaccination?" the response was YES. The follow up, "Type of vaccination and/or vaccine brand name" was nondescriptly answered "booster". There are vaccinations as, defined in the DSCM, that present a reason for deferral. The two donors were accepted to donate.**

During the inspection DEV-22-005568 was initiated.

A read and sign memo was created for all screening staff at the site to remind them of the documentation requirements for vaccine boosters. This was completed by 2022-08-23.

In addition, a communication will be sent to all collection sites, including St. John's, to remind all screening staff of the requirement to consult the DSCM for all vaccine types and the proper vaccination criteria documentation. This will be completed by 2022-10-28.



**Canadian
Blood
Services** BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

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

c.c.: Naima Bendahmane
Supervisor – Biological Product Compliance
Regulatory Operations and Regions Branch