

2023-06-22

CBS Control #: CBS6750 HPFB File #: C1892-100390

REF: H-2324-TOR

Supriya Rave Regulatory Compliance & Enforcement Specialist Biological Product Compliance Program Regulatory Operations and Enforcement Branch, Health Canada

Dear Supriya:

Re: Responses to Health Canada Inspection of Toronto - College Street 2023-05-23 to 2023-05-24

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2023-06-06.

Section 39 - Donor Suitability

For donation C05562234599400B (clinic T0001 on July 13, 2022), the donor indicated having COVID-19 in the last 28 days (Question # 20 on Medical Questionnaire). The date of recovery (Question # 21 on the Medical Questionnaire) was recorded as 28/07/22 which is after the July 13, 2022 clinic date. The date of full recovery was inaccurate and a deferral period based on full recovery was not properly assessed. No deferral was applied (Question # 22 on the Medical Questionnaire). DEV#23 004309 was initiated during the inspection.

DEV-23-004309 was initiated on 2023-05-24.

The error was reviewed with the staff member who completed the questionnaire and the staff was retrained to CO-00314 (legacy 01 200) Donor Selection Criteria Manual: Part C on 2023-05-24.

In addition, a read and sign memo related to the documentation requirements for COVID-19 criteria will be sent to all Toronto-College clinic staff who perform screening and will be completed by 2023-06-30.

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

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

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