



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2021-09-01

CBS Control #: CBS6544

HPFB File #: C1892-100390

REF: H-2122-LON

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

Dear Mr. Donato:

Re: Responses to Health Canada Inspection of London

2021-07-13 to 2021-07-15

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-08-10.

Section 39 - Donor Suitability Assessment

1. **During the whole blood clinic of January 20, 2021, a donor answered YES to the question “In the last 14 days have you been exposed to someone with suspected or confirmed COVID-19?” and responded January 15, 2021 to the follow up question “Last date of exposure?” No deferral was applied.**

The DSCM, Part 1, Section C outlines the follow up questions to determine the nature of the exposure, with some aspects that require the deferral of the donor. There was no further documentation in the donation record to show whether or not the questions were addressed to determine if donor was suitable to donate.

During the inspection, an investigation was initiated to retrieve all in-date transfusable components collected during the retrieval timeframe for this donor (DEV#21-005305, no in-date components were found).

Deviation 21-005305 was initiated on 2021-07-13.

The staff member was reminded of the requirement of complete documentation during screening. In addition, a read and sign memo related to the documentation requirements for COVID-19 criteria was developed and sent to all staff who perform screening; to be completed by 2021-08-30.

Section 117 - Records

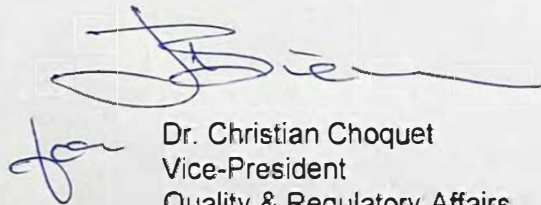
2. The Daily Temperature Monitoring Log for platelet incubator R000003509, the entry for March 1, 2021, was incomplete, despite the incubator being in use that day. During the inspection, MQE-21-002271 was initiated and implemented.

MQE-21-002271 was initiated on 2021-07-14

The staff member was reminded on 2021-07-16 of the requirement to complete the documentation correctly. As the staff member performed this correctly on days following the incident, this was considered an isolated incident and no further actions were required. This was resolved during inspection.

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