



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2019-05-22

CBS Control #: CBS6309

HPFB File #: C1892-100390

REF: H-1920-KIN-G-L

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 Licensed Activities at Kingston
2019-04-30 and 2019-05-01**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-05-03.

Section 95 – Operating Procedures

1. Some operating procedures were not always followed.

In PCM conditioning cycles – Transport to Clinic, the record of RAM Asset ID # R17775, the series 4 PCM plates were not conditioned for the required minimum of 22 hrs during phase 1, on 2018-07-02 (10:39) to 2018-07-03 (7:20). This is contrary to SOP 12 921 v. 4, effective 2018-03-05, Condition series 4 and series 0 phase change material plates – transport to clinic (section 1.3).

QER 55-19-115437 was initiated on 2019-05-10. An assessment was completed to determine that there was no impact to product.

The conditioning requirements in SOP 12 921, Condition Series 4 and Series 0 Phase Change Material Plates - Transport to Clinic will be reviewed with the staff involved.

Section 117 – Records

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

a) For the Clinic Temperature Monitoring Log – Buffy Coat, for the clinic date of 2019-04-18 the thermometer ID number was not recorded.

b) In the Vital Signs Monitor Maintenance Logs the monthly maintenance section for the following months was not completed: November 2018 (for units R000013012 and R000001559), December 2018 (for unit R000001578).

Combined response for 2a and 2b:

QER #55-19-129476 was initiated on 2019-05-09.

It was confirmed with the Dickson temperature monitoring system that the temperature of the clinic was within acceptable range for that day. The Clinic Temperature Monitoring Log – Buffy Coat was corrected.

The observation was reviewed with staff involved in completing the required documentation. Additionally, supervisors and other staff involved in the review of completed records will be reminded of the importance of reviewing for accuracy and completeness.

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
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cc: Anita Mahadeo
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