



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2021-07-23

CBS Control #: CBS6506

HPFB File #: C1892-100390

REF: H-2122-EDM-L

Jodie Leiman
Regional Regulatory Compliance and Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada / Government of Canada
391 York Avenue, Winnipeg, MB

Dear Jodie:

**Re: Responses to Health Canada Inspection of Licensed Activities at Edmonton Operations
2021-05-31 to 2021-06-11**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-07-08.

Section 100 - Equipment

- 1. During the verification performed on 2020-03-19 for the CompoLab Hemoglobinometer, R000012450, the unit read 134 g/L which was beyond the range of the Diaspect control 122-130 g/L. The log was marked YES as being within the acceptable range but the verification should have been re-done as instructed on the form, 1000106028, version 2019-06-21.**

DEV-21-004381 was initiated on 2021-06-07.

A review of the previous as well as subsequent 6th month verification were done and confirmed that all results were within specification.

The process as outlined in WI 27 036 Compolab TM Hemoglobinometer Verification will be reviewed with the staff member on 2021-08-02 upon return from extended leave. In addition, the supervisor was reminded on 2021-06-09 of the importance of recording complete and accurate information along with the importance of thorough and complete review of records.

Section 117 - Records

- 2. In EtQ, RFB-20-000252 associated with lookback 129617 incorrectly identified donation C05212030978900G as collected on 2020-02-29. It is noted in eProgesa the date of collection was 2020-01-29.**

MQE-21-002294 was initiated on 2021-07-15.

Additional information was added to RFB-20-000252 in ETQ to clarify the correct donation date for RBC C05212030978900G with reference to MQE-21-002294.

In addition, all staff involved will take a GDP refresher training by 2021-08-31.

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