Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

2022-01-14
CBS Control #: CBS6606
HPFB File #: C1892-100390
REF: H-2122-CALDT

Supriya Rave
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 Supriya:

Re: Responses to Health Canada Inspection of Licensed Activities at Calgary Donor Testing 2021-12-06 to 2021-12-10

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2022-01-05.

Section 117 - Records

1. **During the review of cobas 8000 Preventative Maintenance Checklists which had previously been supervisory reviewed, it was observed that the date on the preventative maintenance (PM) record and the date on the PM sticker on the equipment did not always match. For example, cobas 8000 with serial numbers 20K0-03, 20U4-08, 20U4-09, 20U4-10, 2009-08, 2009-09 and 2009-07 stated a date of 2021/07/21 on the PM record whereas the PM sticker stated a date of 2021/07/23. For serial number 20U5-01, the PM record stated 2021/07/21 whereas the PM sticker stated 2021/07/30. During the inspection, the service provider clarified that the PM start date was recorded on the PM record whereas the PM completion date was written on the PM sticker. The service provider amended the records to indicate the start and completion dates of the PM. The PM completion date was used to establish the next due date for the equipment.**

   MQE-22-000140 was initiated.

   The vendor amended the preventive maintenance (PM) checklist records during the inspection on 2021-12-08 to indicate the start and completion dates of the PM.

   Canadian Blood Services Donor Testing Laboratory staff in Calgary who perform the role of supervisory review of PM documentation completed by the vendor for the cobas 8000 Test System, will be retrained to work instruction 25 676 cobas 8000 - Maintenance

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Review, Preventative Maintenance/Vendor Service calls. The intent is to reinforce the assurance that the information documented on PM Checklist records by the vendor is reflective of the information documented on the PM stickers. Retraining will be completed by 2022-02-28.

In addition, documentation practices by the vendor will be discussed at the monthly Technical Issues calls held with Canadian Blood Services personnel and the vendor technical representatives. The item will be added to the technical list for the meeting to be held 2022-01-20. The discussion will be documented on the Technical Issues Action List.

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,

Christian Choquet

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