Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

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Melanie Mercier
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 Melanie:

Re: Further to the Responses to the Health Canada Inspection of Licensed Activities at Dartmouth Operations from 2023-09-12 to 2023-09-15

The following are the actions taken by Canadian Blood Services in response to the Health Canada Follow-up letter dated 2024-01-19, requesting additional information to the response provided in our Follow-up Letter dated 2023-12-18.

Section 100 – Equipment

3. The rationale for granting all BacT/ALERT users the "Administrator" access level to the system was inadequate, as this allowed all users to modify some of the parameters in the system. There was no process in place to evaluate and verify the impact of the user abilities under the Administrator level, such as deletion and modification of data that could potentially impact the results.

Canadian Blood Services will assess the access levels for Bac-T/Alert users at all sites and provide guidance as to who should have administrator level.

If required, the training material will be updated with the information that defines the differences between the access levels.

The completion date for the above is 2023-12-31.

Health Canada Follow-up letter dated 2023-11-27:

Has there been any evaluation as to the possible impacts of the different changes which could have been done by all employees given Administrator access? If Administrator level access are given to employees, there should be documentation of what actions could be taken and how results could be impacted.

Furthermore, will there be any measures put in place to verify that results have not been modified? What will those measures consist of?

Canadian Blood Services Follow-up Response:

To add clarification, changes to the bacterial testing results (i.e. initial positive or negative) cannot be altered regardless of staff having administrator access.

As part of the investigation regarding this observation, audit trail reports for Dartmouth Operations for the 6 months prior to the Health Canada inspection were reviewed and no changes had been identified.

As part of our monitoring program, bacterial testing results have been tracked and trended monthly since 2018. This includes the tracking and trending of initial positives, false positives and confirmed positives. As per WI-00500 Data Monitoring and Trending, threshold limits based on initial positives, have been established and in the event where they are exceeded, a CAPA is initiated to investigate and address the event. This monthly BACT site file report is reviewed as part of our Quality Management System Review meetings and any trends/issues are discussed. Based on our monitoring, there is no indication the bacterial screening process, which has been in place since 2018, is not performing as expected.

Health Canada Follow-up letter dated 2024-01-19:

Could you please confirm that the bacterial testing results after the required incubation period can not be changed in the computerized system? The information received during the inspection seem to indicate that they could, as I was shown a printed report with the result changed from negative to positive, so perhaps this information could be confirmed with the manufacturer.

If the results can be manually changed in the system, has there been any evaluation as to the possible impacts of the different changes which can be done by all employees given Administrator access? If Administrator level access are given to employees, there should be documentation what actions the staff can take and changes they can make in the system, in addition to how results can be impacted.

Furthermore, will there be any measures put in place in the future to regularly verify that results have not been manually modified? What will those measures consist of?

Canadian Blood Services Follow-up Response:

To clarify, during the inspection, the operator manual for the bacterial detection system was provided for review which detailed the activities that may be done with administrator access level, there was no report reviewed that included altered test results.

Staff are required to have administrative level access in order to add and remove users, enable and disable modules, drawers, racks and cells when troubleshooting is necessary. Upon further investigation of this issue, we did uncover that test results can be modified. If a test result is modified before unloading, there would be a visible icon beside the result on the printed unload report. Once a bottle is unloaded, the unload report cannot be altered. An unload report is printed with every bottle unload. In addition, there are no work instructions or training provided to staff to edit test results.

Work instructions will be updated by 2024-08-30 to include who should have administrator access, what activities they are able to perform, and a verification of the unload report,

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printed with every bottle unload, for anomalies such as the icon indicating a result has been changed.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please refer to the above control number in all correspondence.**

Sincerely,

Christian Choquet

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affairs
Fax Number: 613-739-2505