

2020-10-19
CBS Control #: CBS6445
HPFB File #: C1892-100390
REF: H-2021-EDMCBB

Ms. Sandra Jarvis
Compliance Specialist
Regulatory Operations and Regions Branch
Biological Products Compliance Program
730, 9700 Jasper Ave. NW
Edmonton, Alberta T5J 4C3

Dear Sandra:

**Re: Responses to Health Canada Inspection of Edmonton Cord Blood Bank
2020-09-08 to 2020-09-14**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2020-09-17.

Biological CTO - Quality Assurance System - Standard Operating Procedures - 76

1. **The establishment did not conduct an audit of all regulated activities every two years.**

The establishment did not audit laboratories performing regulated activities on their behalf every two years.

Any suppliers performing regulated activities for the Cord Blood Bank will now be placed on a 2-year cycle. SOP 08 089 Supplier Audits will be revised accordingly by Q1 of 2021-2022.

The audit of Donor Testing, which includes the audit of the HLA laboratory, has been scheduled for Q4 of this fiscal year (2020-2021).

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
Christian.Choquet@blood.ca