

2017-08-28
CBS Control #: CBS6100
HPFB File #: C1892-100390
REF: H-1718-EDMCBB

Ms. Sandra Jarvis
Regulatory Compliance and Enforcement Specialist
Regulatory Operations and Regions Branch
Health Canada
#730, 9700 Jasper Ave. NW
Edmonton, Alberta
T5J 4C3

Dear Ms. Jarvis:

**Re: Responses to Health Canada Inspection of Licensed Activities at
Edmonton Cord Blood Bank from 2017-07-31 to 2017-08-04**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-08-08.

Section 73 –Standard Operating Procedures

- 1. According to the Stem Cell Manufacturing Monitoring Record dated 2017-07-13 for Biosafety Cabinet R5376, both the left and right settle plates for the static state were exposed for 5 hours and 10 minutes. This is contrary to Section 1.5.3 of SOP 15 930 Stem Cell Environmental Monitoring, Rev. 2, which states the plates are to be exposed for 4 hours. According to the Site Manager, Stem Cell Manufacturing and Hospital Services, their practice is to expose the plates for a minimum of 4 hours and can exceed that time.**

Quality Event Report # 44-17-109778 was initiated on 2017-08-23.

Exposing the plates for a longer period of time would increase the possibility of capturing bacteria, unless the plates were to dry out which was not the case. Therefore, although exposing the plates longer than 4 hours had no impact on obtaining a valid result, effective immediately, staff will be reminded/instructed to follow current work instructions in SOP 15 930, Stem Cell Environmental Monitoring when completing stem cell environmental monitoring.

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: Hugo Tremblay, Supervisor – Blood, Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch