



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2021-09-13

CBS Control #: CBS6585

HPFB File #: C1892-100390

REF: H-2122-WIN-W

Ms. Erin Vandendyck
Regional Regulatory Compliance & Enforcement Officer, GMP Inspection West
Regulatory Operations and Enforcement Branch
Health Canada

Dear Ms. Vandendyck:

**Re: Responses to Health Canada Inspection of Wholesale Activities at Winnipeg Operations
from 2021-08-09 to 2021-08-13**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-08-19.

C.02.014 - Quality control department

1. **There were no written instructions in procedures for the physical marking and segregation of returns and quarantined products although electronic quarantine procedures were in place. Returns may be stored in a labelled bin, locked cage, or a cooler in the basement but this was not described in written procedures. The cooler was also not on the facility map controlling product storage location.**

A floor plan of the basement identifying the location of the quarantine cooler, room 042, is provided.

Associated procedures will be assessed and revised by 2022-06-27 to include requirements for identification of quarantine locations including physical markings as well as segregation requirements of returns or other unsuitable or potentially unsuitable products.

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: Betty Palma
Regional Regulatory Compliance & Enforcement Officer
Regulatory Operations and Enforcement Branch