



ACTION REQUIRED

Change to RiaSTAP® Storage Conditions
Customer Letter # 2019-08

2019-05-08

Dear Colleagues:

The attached customer letter from CSL Behring provides important information pertaining to the change to RiaSTAP® (1g) Fibrinogen Concentrate [Human] storage conditions. **The new storage temperature will be 2-8°C** (previously 2-25°C).

All existing RiaSTAP® inventory at your facility will need to be placed in the new storage temperature of 2-8°C upon receipt of this communication.

Starting May 8th, 2019, Canadian Blood Services will begin to receive relabeled cartons of RiaSTAP® from CSL Behring with a yellow beacon sticker affixed only to the outer packaging. Notably, the label on the vial of RiaSTAP® will not be relabeled. Packages with the yellow beacon sticker will continue to be received until the packaging components have been revised.

Customers can anticipate future deliveries of RiaSTAP® will have the revised storage temperature on

- the outer packaging of RiaSTAP® and
- the Canadian Blood Services packing slip associated with the order

There may be a brief period when both non-relabeled and relabeled packages may exist at the same time. Both relabeled and non-relabeled packages should be considered to have the new storage temperature requirements.

It is important to note that the expiry date is not impacted by the storage temperature change.

Updates to the Plasma Protein Products Customer Table of Information have been made and can be viewed at www.blood.ca in the "Products Section".

CBS recognizes that the requirement to refrigerate this product may pose a significant burden on hospital transfusion services. The issues below have been raised with CSL Behring. We are sharing the information we have received to inform transfusion services in your decision on how to manage this product.

The following questions were asked of CSL Behring and these are their responses.

Q1 Should RiaSTAP® be brought to room temperature prior to reconstitution?

R1 *RiaSTA®P and the diluent should be brought up to room temperature as the RiaSTAP® will more readily go into solution with the diluent at room temperature. How long it takes will depend on the ambient temperature as well as how cold the fridge was. A reasonable amount of time to allow the vial to acclimate to the ambient conditions should be allocated. CSL Behring does not have data to support the safe use of warming devices.*

Q2 How long can it be out of the fridge before it must be discarded?

R2 *Product can be taken out of the fridge in anticipation of being used but then must be returned as soon as possible. As a general rule, reuse of the product is acceptable as long as the product is returned to the fridge within 24 hours and has not exceeded 25°C¹. For situations or excursions that are longer in duration or exceed 25°C, please contact CSL Behring Customer Service at 1-866-773-7721 ext 2386.*

Q3 Can product stored at room temperature be used at all?

R3 *Yes, product that was previously stored at room temperature can be used up to expiry date. Due to the potential for flake formation for product that has been previously stored at room temperature, users should pay special attention to the patient leaflet and carefully visually inspect every vial before administration*

As per the product monograph, a visual inspection of the product should always be done prior to issue, regardless of storage temperature.

We understand that these measures implemented by CSL Behring may cause some inconveniences, and we ask for your understanding and support.

Please share a copy of this customer letter with healthcare professionals at your hospital who might be interested in this information.

This customer letter can also be viewed at www.blood.ca in the “Hospitals Services” section. If you have questions about this letter, or if you require it in an accessible format, please contact your local hospital liaison specialist.

Sincerely,



Mark Newburgh
Director, Integrated Supply Chain Planning