

27 January 2021

Dear Colleague,

**Re: Advance notice of our intention to transition to platelets with a 7-day shelf life**

Australian Red Cross Lifeblood is pleased to advise that we will soon extend the shelf life of pooled platelets, apheresis platelets and paediatric platelets to 7 days.

After receiving approval from the Therapeutic Goods Administration (TGA) in mid-2020 our project team has been working towards implementation. Currently, we are working towards a go-live date of 21 March, 2021. However, there are still some pending approvals, system changes and process verification steps that must occur, which will require us to re-confirm this go-live date with you as this work is completed.

**What is changing?**

- The shelf life of pooled platelets, apheresis platelets and paediatric platelets will change from 5 days to 7 days
- Lifeblood will implement large volume, delayed sampling (LVDS) bacterial contamination screening

**What is NOT changing?**

- The platelet packs or platelet product specifications
- Platelet component codes and barcodes
- Platelet storage conditions i.e. 20°C to 24°C, with gentle and continuous agitation on a single layer platelet agitator
- The process for ordering platelets on Bloodnet
- The process for actioning recalls for initial machine positives from bacterial contamination screening

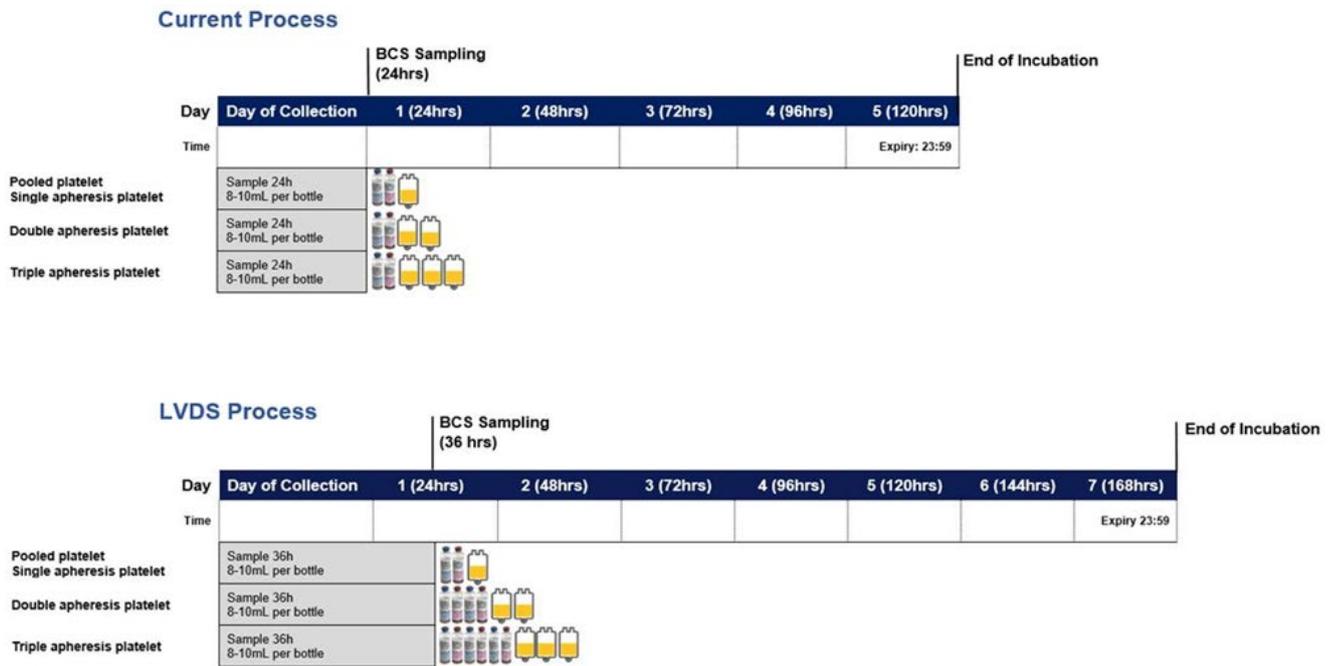
**What is large volume delayed, sampling (LVDS) bacterial contamination screening?**

With platelet storage at 20°C to 24°C, bacterial contamination remains the greatest risk to patient safety. To mitigate that risk, the TGA have approved large volume, delayed sampling bacterial contamination screening.

- Bacterial contamination screening (BCS) sampling will occur 36 hours after collection. This is an additional 12 hours compared to the current process of BCS sampling 24 hours after collection.
- Large volume sampling was implemented on 30 November, as the first stage towards the LVDS bacterial contamination screening strategy. With large volume sampling, platelet components are sampled based on the platelet dose, which means that a larger volume is sampled from double and triple apheresis platelets and inoculated in additional sets of aerobic and anaerobic culture bottles. An 8-10mL sample is inoculated into each culture bottle. (Fig.1)

- Samples are then screened on the bioMerieux BacT/ALERT Automated Microbial Detection System for 7 days from the time of inoculation. This is an extension from 5 days to 7 days.

**Figure 1 Comparison of current BCS sampling to the LVDS process**



Lifeblood has adjusted the target collection volume during the apheresis collection process to compensate for the increase in BCS sample volume for double and triple apheresis platelets. As such, we do not expect to see a significant variation to the typical unit content.

### How long will the platelet shelf life be extended by?

Implementation of LVDS will allow us to safely extend the shelf life of the platelets to 7 days. With the BCS sampling occurring 36 hours after collection, the platelets will therefore be released into Lifeblood's inventory 12 hours later than the current 5-day expiry platelets.

In effect, the additional shelf life of the platelets is around 1.5 days.

### What do you need to do?

- Prepare to make the necessary changes to your Laboratory Information System (LIS) to accept platelets with a 7-day shelf life.
- There will be a few days where there will be both 5-day and 7-day expiry platelets in your inventory. Please take the time to consider how your LIS and processes will manage these 2 different expiries for the same product.
- BCS testing will be performed over 7 days and any products associated with an initial machine positive will be recalled. Take the necessary action for any recall notices as per current processes.

Lifeblood will advise you once our final approvals and process verification processes are complete to confirm the go-live date for implementation.

In the meantime, if you have any questions regarding this change, please contact your local Transfusion Scientist.

Yours sincerely



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