

30 April 2018

Dear Colleague

RE: Red Cell Leucodepleted Washed in SAG-M – Notification of Change in Manufacturing Process

We are writing to advise of a modification to the manufacturing process for washed red cell components, which will commence from 14 May 2018.

Please note that there will be no changes to the component labelling, specifications, shelf-life, or storage requirements associated with this process modification. More specifically, the component name (**Red Cell Leucodepleted Washed in SAGM**), component code (**04880**) and barcode will remain unchanged.

What is going to happen?

Currently, washed red cell (wRBC) components are produced via a three-step wash process using 0.9% saline. This saline product is being withdrawn from the market from May 2018 and, as a consequence, a change in the wRBC manufacturing process has been required.

Following international review and the completion of evaluation and validation studies, the Blood Service will be adopting a manufacturing process which involves a two-step wash using Saline Adenine Glucose Mannitol solution (SAG-M). SAG-M is the red cell additive solution that is used routinely to resuspend all leucodepleted red cells manufactured by the Blood Service for the Australian community.

Our validation studies confirm that wRBC components prepared using SAG-M meet all prescribed quality specifications for washed components. Please refer to Table 1 overleaf for the component specifications and comparative typical unit content for wRBC manufactured using the current saline wash process and the new SAG-M wash process.

What do I need to do?

Note the modified manufacturing process for wRBC components will commence 14 May 2018 and advise relevant staff within your organisation of this change as appropriate. As wRBC components resuspended in SAG-M have a shelf-life of 28 days, there will be a four-week transition period during which you may receive wRBC components manufactured using the current or the new manufacturing process.

If you have any queries, please contact your local Transfusion Medicine Specialist.

Yours sincerely,



Greg Wilkie
Executive Director Manufacturing



Dr Janet Wong
Acting Chief Medical Officer