

30 April 2018

# Red Cells Leucodepleted Washed in SAG-M

## Information sheet – Modification to manufacturing process from 14 May 2018

Blood Service evaluation and validation studies confirm that washed red cell (wRBC) components manufactured using the new Saline Adenine Glucose Mannitol (SAG-M) wash process meet all quality specifications prescribed for washed components. The component specifications and comparative typical unit content for wRBC manufactured using the new wash process and the current 0.9% saline wash process is provided in the table below.

**Table 1: Comparative washed red cell (wRBC) component data**

Component	Volume (mL)	Haemoglobin (g/unit)	Haematocrit (L/L)	Haemolysis (%)	Leucocyte Count (x10 <sup>6</sup> /unit)	Last Wash Supernatant Total Protein (g/unit)	IgA (g/L)
<b>Specification</b>	<b>&gt;130</b>	<b>≥ 37</b>	<b>0.50 – 0.70</b>	<b>&lt;0.8</b>	<b>&lt;1.0</b>	<b>&lt;0.5</b>	<b>N/A</b>
<b>wRBC prepared using 0.9% saline wash process<sup>1</sup></b>	274 ± 21	46 ± 5	0.53 ± 0.03	0.20 ± 0.1	Initial unit equivalent to <1.0	0.1 ± 0.1	Not available
<b>wRBC prepared using SAG-M wash process</b>	266 ± 15	49 ± 5	0.62 ± 0.02	0.11 ± 0.05*	0.01 ± 0.03	0.11 ± 0.04	<0.001 **

<sup>1</sup> Refer [https://transfusion.com.au/blood\\_products/components/red\\_cells](https://transfusion.com.au/blood_products/components/red_cells) (Blood Service data 01 Jan – 31 Dec 2017)

\*14 days post washing / 28 days post collection (Blood service data on file)

\*\* Below assay limit of detection (Blood service data on file)