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Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 18 - 2015

Interruptions to agitation and testing of Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted and Platelets, Apheresis, Leucocyte Depleted

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom – 8th Edition 2013

The current guidance in relation to interruption of agitation has been changed to indicate that no single interruption may last for more than eight hours. The minimum percentage of components that must meet the specified value of 6.4-7.4 for pH at end of shelf-life has been increased to 95% and a requirement to temporarily split double or triple apheresis donations at the point of collection has been added to the specification for Platelets, Apheresis, Leucocyte Depleted.

Therefore the fourth bullet point under “Storage” and the table under testing need to be amended, for the following:

7.9 Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted

7.9.3 Storage

- Platelets should be gently agitated during storage. If agitation is interrupted, for example due to equipment failure or prolonged transportation, the components are suitable for use, retaining the same shelf life, provided the interruption is for no longer than a total of 24 hours *and no single interruption lasts for more than eight hours.*

7.9.4 Testing

Table 7.6 Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted – additional tests

An additional footnote has been added to pH at end of shelf-life to note that a minimum of 95% of components tested shall meet the specified values. (See page 2)

The changes listed above are also required to be made to **7.11 Platelets in Additive Solution and Plasma, Leucocyte Depleted**. These are contained in a separate change notification relating to this component (*Change Notification No 19 2015*).

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7.10 Platelets, Apheresis, Leucocyte Depleted

A single-donor platelet component containing less than 1×10^6 leucocytes.

7.10.1 Technical information

An additional bullet point is required

- If a double or triple dose is collected the platelet concentrate must be temporarily split, as a continuous part of the collection process, into the storage packs integral to the collection set so that the capacity of an individual pack is not exceeded

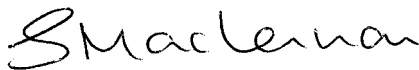
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7.10.4 Testing

Table 7.7 Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted – additional tests

An additional footnote has been added to pH at end of shelf-life to note that a minimum of 95% of components tested shall meet the specified values. (See below)



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Changes to Tables 7.6 and 7.7

Parameter	Frequency of test	Specification
Volume	1% or as determined by statistical process control (if ≤ 10 components produced per month then test every available component)	Within locally defined nominal volume range
Platelet count		$\geq 240 \times 10^9/\text{pool}^{**}$
pH at end of shelf life ^{***}		6.4–7.4
Leucocyte count*	As per sections 6.3 and 7.1	$< 1 \times 10^6/\text{pool}$
* Methods validated for counting low numbers of leucocytes must be used		
^{**} Units tested and found to have $< 160 \times 10^9/\text{pool}$ should not be issued for transfusion		
^{***} <i>A minimum of 95% of components tested shall meet the specified values.</i>		