

Joint UKBTS Professional Advisory Committee (1)

UKBTS General Information 08

Deviations from the specified storage temperature for Fresh-Frozen Plasma (FFP) whilst in its frozen state

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This document will be reviewed whenever further information becomes available. Please continue to refer to the website for in-date versions.

Current UK guidelines specify that FFP should be stored at a core temperature of -25°C or below for a maximum of 36 months, and transfused as soon as possible after thawing although if delay is unavoidable, the component may be stored and should be used within 4 hours if maintained at $22^{\circ}\text{C}\pm 2^{\circ}\text{C}$ or up to 120 hours if stored at $4^{\circ}\text{C}\pm 2^{\circ}\text{C}$, depending on the indication.¹

Occasionally blood services and hospitals experience problems with freezers that have temporarily failed to maintain specified temperatures for a brief period of time. Requests for advice on whether the product is still acceptable have been received not infrequently. As such products are prepared in a closed system provided the bag remains intact such excursions do not give rise to any safety concerns provided the product has not overtly thawed. Hence the requested advice really relates to any change in potency as a result of the excursion.

The NHSBT Components Development Laboratory completed a study to test several scenarios under which frozen plasma was subjected to a deviation in its normal storage temperature. This allows conclusions about temperature excursions that DO or DO NOT affect product potency to be made.² The study involved taking paired units of FFP (10 each of group A and group O), storing them at standard (-40°C for 2 weeks), then imposing various excursions before returning them to -40°C for at least 7 days before assay of coagulation factor VIII (fibrinogen, PT and APTT). The Table summarises the impact of excursions on FVIII (the most sensitive of the 4 markers assessed):

Impact	Temperature Deviation whilst Frozen (ambient not core temp)	Period	Mean (95% confidence interval) FVIII IU/ml (specification for FFP is mean > 0.7 IU/ml)	% units remaining above 0.5 FVIII IU/ml (specification for FFP is >90%)
Acceptable	-18°C	1 week	0.84 (0.75-0.92)	100%
		1 month	0.82 (0.73-0.91)	95%
		2 months	0.82 (0.74-0.90)	95%
Not acceptable	-10°C	1 week	0.76 (0.68-0.84)	90%
		4 hours	0.79 (0.71-0.87)	100%
		1 month	0.68 (0.60-0.76)	85%
Not acceptable	$+4^{\circ}\text{C}$	2 months	0.62 (0.55-0.69)	80%
		24 hours	0.57 (0.49-0.64)	65%
		72 hours	0.47 (0.41-0.53)	40%

The acceptability of transfusing plasma that has been subjected to excursions in temperature out with the normal recommended storage temperature of FFP, should be informed by local risk assessment. Blood services and hospitals may find this data useful as part of that process. This information is not applicable to plasma for fractionation.

(1) Joint United Kingdom Blood Transfusion Services Professional Advisory Committee

¹ Guidelines for the Blood Transfusion Services in the United Kingdom. 8th edition. The Stationary Office, London, 2013.

² Cardigan R, Themessl A, Garwood Margaret. Short-term Deviations in Temperature During Storage of Plasma at -40°C Do Not Affect Its Quality. Transfusion 2011: 511541-1545.