Change Notification for the UK Blood Transfusion Services

Date of Issue: 02 November 2023 **Implementation:** to be determined by each Service

No. 39 – 2023

Amendments to Red Book Annexe 7

This notification includes the following changes:

	BM-DSG Bone Marrow & Peripheral Blood Stem Cell	CB-DSG Cord Blood	GDRI Geographical Disease Risk Index	TD-DSG Tissue - Deceased Donors	TL-DSG Tissue - Live Donors	WB-DSG Whole Blood & Components	Red Book Guidelines for the BTS in the UK
1 Red Book Annexe 7	○	○	○	○	○	○	●

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Chair of Standing Advisory Committee on Tissues & Cellular Therapy Products (SACTCTP)

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Professional Director of JPAC

Changes are indicated using the key below. This formatting will not appear in the final entry.

original text	«inserted text»	~~deleted text~~

1 Changes apply to the **Guidelines for the Blood Transfusion Services**

Annexe 7: Requirements for the timing of testing for Hematopoietic Progenitor Cells (HPCs): Minimum standards and good practice

Terminology

HPC-A	Peripheral blood (stem cells, collected by apheresis)
HPC-M	Bone marrow (stem cells, collected from bone marrow)
MNC-A	Mononuclear cells (collected by apheresis, including starting material for advanced therapy medicinal product (ATMP) manufacture and donor lymphocyte infusions (DLIs))
HPC-CB	Umbilical cord blood
Mandatory	The test is either a regulatory requirement or deemed necessary to ensure regulatory requirements relating to the assessment of donor suitability are met «to ensure donor and recipient protection»
Discretionary	The test must be performed on certain donors/donations if indicated by medical, social or travel history
Recommended	This test is recommended by an advisory committee or a professional body, but is not a regulatory requirement
Optional	The test may be done at timepoints outside of the mandatory testing timeline

Table 1 - Allogeneic HPC-A, HPC-M **(only amended row shown)**

Test	Performed on donor, product or both?	Test mandatory, discretionary, recommended or optional?	Timing of test	Notes
Discretionary Additional infectious markers (e.g. Malaria, WNV, *T.cruzi*)	Donor	Discretionary	Prior to donation, depending on travel history «or residential risk»	Align with JPAC Donor Selection Guidelines

Table 2 - Autologous HPC-A, HPC-M **(only amended row shown)**

Test	Performed on donor, product or both?	Test mandatory, discretionary, recommended or optional?	Timing of test	Notes
Discretionary Additional infectious markers (e.g. Malaria, WNV, *T.cruzi*)	Donor	Discretionary	Prior to donation, depending on travel history «or residential risk»	In selected circumstances based on individual risk assessment, testing may be requested/required. Align with JPAC donor selection guidelines.

Table 3 - Autologous & Allogeneic MNC-A (complete table shown)

Test	Performed on donor, product or both?	Test mandatory, discretionary, recommended or optional?	Timing of test	Notes
ABO + RhD	Donor «(allogeneic)»	Mandatory	Prior to donation	Using two independently collected samples; different needlesticks
	«Donor (autologous)»	«Optional»	«Prior to donation»	«Due to autologous nature of product, not essential»
Mandatory infectious markers	Donor	Mandatory	At the time of donation or within seven days post donation«(1)»	See Table 9.2
Discretionary Additional infectious markers (e.g. Malaria, WNV, *T.cruzi*)	Donor	Discretionary	Prior to donation, depending on travel history «or residential risk»	Align with JPAC donor selection guidelines. «For autologous donors in selected circumstances based on individual risk assessment, testing may be requested/required.»
CMV	Donor	Recommended	At donor selection and within 30 days prior to the donation episode	
Toxoplasma, Epstein Barr Virus	Donor	Recommended	Within 30 days prior to the donation episode	
Pregnancy test	Donor	Discretionary	7 days prior to starting donor mobilisation regime, and, as applicable, within 7 days prior to the initiation of the recipient's preparative regime	Applies to all donors of childbearing potential
Haemoglobinopathies	Donor	Discretionary	At the time of donor assessment	Applies to those donors thought to be at risk of sickle cell disease and compound haemoglobinopathies
Bacteriology testing	Product (processed)	Optional	Pre-processing	
		Mandatory	Post-processing	
	Product (fresh)	Mandatory	Post collection	
FBC	Donor	Mandatory	Immediately before every collection	
«[1] If MNC are collected at the same time as HPC, the same time specified in Tables 1 and 2 apply»				

Table 4 - HPC-CB **(only amended row shown)**

Test	Performed on donor, product or both?	Test mandatory, discretionary, recommended or optional?	Timing of test	Notes
Discretionary Additional infectious markers (e.g. Malaria, WNV, *T.cruzi*)	Mother	Discretionary	0 to +7 days	Depending on travel history «or residential risk». Align with JPAC Donor Selection Guidelines.
	Product	Discretionary	Prior to release, where applicable	