

Guidelines for the Blood Transfusion Services

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

<http://www.transfusionsguidelines.org/red-book/annexe-7>

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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 is not mandatory and done at the discretion of individual organisations or establishments. This also applies to situations where a mandatory test is repeated at the discretion of individual organisations or establishments.

Table 1 - Allogeneic HPC-A, HPC-M

Test	Performed on donor, product or both?	Test mandatory, discretionary, recommended or optional?	Timing of test	Notes
ABO + RhD	Donor	Mandatory	Prior to donation	Using two independently collected samples; different needlesticks

Mandatory infectious markers	Donor	Mandatory	Within 30 days prior to the donation episode	See Table 9.2
		Optional	At the time of donation or within seven days post donation	Testing the donor once within the specified timescale is mandatory, repeating the test is optional
Discretionary Additional infectious markers (e.g. Malaria, WNV, <i>T. cruzi</i>)	Donor	Discretionary	Prior to donation, depending on travel history or residential risk	Align with JPAC Donor Selection Guidelines
CMV	Donor	Recommended	At donor selection, and Within 30 days prior to the donation episode	
Toxoplasma	Donor	Recommended	Within 30 days prior to the donation episode	
EBV	Donor	Recommended	Within 30 days prior to the donation episode	
Pregnancy test	Donor	Discretionary	Seven days prior to starting donor mobilisation regime (G-CSF), and (as applicable) within seven 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 for HPC-A; prior to first donation for HPC-M	

Table 2 - Autologous HPC-A, HPC-M

Test	Performed on donor, product or both?	Test mandatory, discretionary or optional?	Timing of test	Notes
ABO + RhD	Donor	Optional	Prior to donation	Due to autologous nature of product, not essential
Mandatory infectious markers	Donor	Mandatory	Within 30 days prior to the donation episode	<p>April 2023: Sample timing currently under review by HTA.</p> <p>See Table 9.2</p> <p>Testing the donor once within the specified timescale is mandatory, repeating the test is optional</p>
		Optional	At the time of donation or within seven days post donation	
Discretionary Additional infectious markers (e.g. Malaria, WNV, <i>T. cruzi</i>)	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.
Pregnancy test	Donor	Discretionary	7 days prior to starting donor mobilisation regime (G-CSF), and, as applicable, within 7 days prior to the initiation of the recipient's preparative regime	Applies to all donors of childbearing potential
CMV	Donor	Optional	Within 30 days prior to the donation episode	In selected circumstances based on individual risk assessment, testing may be requested/required if indicated by donor history
Toxoplasma	Donor	Optional	Within 30 days prior to the donation episode	In selected circumstances based on individual risk assessment, testing may be requested/ required if indicated by donor history
EBV	Donor	Optional	Within 30 days prior to the donation episode	In selected circumstances based on individual risk assessment, testing may be requested/ required if indicated by donor history

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 for HPC-A; prior to first donation for HPC-M	

Table 3 - Autologous & Allogeneic MNC-A

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 (allogeneic and autologous)	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, <i>T. cruzi</i>)	Donor (allogeneic and autologous)	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 (allogeneic)	Recommended	At donor selection, and Within 30 days prior to the donation episode	
	Donor (autologous)	Optional	Within 30 days prior to the donation episode	In selected circumstances based on individual risk assessment, testing may be requested/required if indicated by donor history

Toxoplasma	Donor (allogeneic)	Recommended	Within 30 days prior to the donation episode	
	Donor (autologous)	Optional	Within 30 days prior to the donation episode	In selected circumstances based on individual risk assessment, testing may be requested/required if indicated by donor history
EBV	Donor (allogeneic)	Recommended	Within 30 days prior to the donation episode	
	Donor (autologous)	Optional	Within 30 days prior to the donation episode	In selected circumstances based on individual risk assessment, testing may be requested/required if indicated by donor history
Pregnancy test	Donor (allogeneic and autologous)	Discretionary	Within 7 days prior to collection	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

Test	Performed on mother, product or both?	Test mandatory, discretionary, recommended or optional?	Timing of test	Notes
ABO + RhD	Product	Mandatory	Prior to cryopreservation	
Mandatory infectious markers	Mother	Mandatory	At the time of donation or within seven days post donation	See Table 9.2
	Product	Recommended	Prior to release	Testing of the maternal sample at the time of donation, including NAT, may be used as a surrogate marker for the product. Testing of the product is recommended but not mandatory.
Discretionary Additional infectious markers (e.g. Malaria, WNV, <i>T. cruzi</i>)	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	
CMV	Mother	Recommended	0 to +7 days	
	Product	Recommended	Prior to release	
Toxoplasma	Mother	Recommended	0 to +7 days	
EBV	Mother	Recommended	0 to +7 days	
Haemoglobinopathies	Product	Discretionary	Prior to release	Sample from product or neonatal screen
Bacteriology testing	Product	Mandatory	Post processing, prior to cryopreservation	
FBC	Product	Mandatory	Between the end of collection and pre-processing	