

Change Notification for the UK Blood Transfusion Services

Date of Issue: 12 April 2023

Implementation: to be determined by each Service

No. 21 – 2023

Malaria

Revised entry

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

original text

«inserted text»

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The following changes apply to:

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

«Definition	<p>Resident – A donor who has ever been present in a malaria risk area (or areas), for a continuous period of 6 months or more (at any point in their lifetime)</p> <p>Visitor – A donor who has visited or travelled through a malaria risk area (or areas) within the past 12 months</p> <p>Unexplained febrile illness – A donor who had undiagnosed fever (that could have been malaria) while present in, or within four months of leaving, a malaria risk area.</p> <p>Previous diagnosis of malaria – A donor who previously had a confirmed diagnosis of malaria, at any point in their lifetime.</p> <p>Malaria risk area – Risk area for country as defined by the GDRI</p> <p>MAT: Malarial Antibody Test</p> <p>NAT: Nucleic Acid Test (for malaria)»</p>
Obligatory	<p>«Must not donate (if no testing is available): Applies to all groups as defined above»</p> <p>Must not donate if:</p> <p>a) The donor has ever had malaria.</p> <p>b) The donor has had an undiagnosed fever (that could have been malaria) while abroad or within four months of leaving a malaria endemic area.</p> <p>c) The donor has lived in any malarial endemic area for a continuous period of six months or more at any time of life.</p> <p>d) Less than 12 months after last leaving a malaria endemic area.</p>
Discretionary	<p>«1a) Previous Malaria:</p> <p>If less than 4 months have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved, refer to DCSO. See 'Additional Information' section.</p>

	<p>If more than 4 months have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved, obtain a blood sample for MAT and NAT test. See information below in this section.</p> <p>1b) Unexplained Febrile illness:</p> <p>If less than 4 months from the date of recovery of symptoms of unexplained febrile illness that could have been malaria: refer to DCSO. See 'Additional Information' section.</p> <p>If more than 4 months from the date of recovery of symptoms of unexplained febrile illness that could have been malaria: Obtain a blood sample for MAT and NAT. See information below in this section.</p> <p>1c) Resident:</p> <p>If less than 4 months since date last present in a malaria risk area: Obtain a blood sample for MAT and NAT. See information below in this section.</p> <p>If more than 4 months since date last present in a malaria risk area: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release stem cells. See information below in this section.</p> <p>1d) Visitor:</p> <p>If less than 4 months since return: Obtain a blood sample for MAT and NAT. Donors may be accepted with individual risk assessment with expert advice. See information below in this section.</p> <p>If more than 4 and less than 12 months since return: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release stem cells. See information below in this section.</p> <p>If more than 12 months since return: testing not required, accept</p> <p>NB. Please consider T. cruzi or a tropical virus risk if the area is also identified as a risk area for these infections</p> <p>The results of MAT and NAT tests must be reviewed as a part of donor medical clearance to determine the suitability of stem cells for clinical use. If the exposure or, for donors with a history of malaria where treatment was completed and symptoms have resolved, is less than four months prior to donation, NAT must be done and shown to be negative, irrespective of MAT results. If the exposure or, for donors with a history of malaria where treatment was completed and symptoms have resolved was more than four months prior to donation and MAT is negative, NAT is not required. In case of positive MAT results with a confirmed negative NAT test, a risk assessment can be performed for accepting stem cells for clinical release after seeking expert opinion.»</p> <p>1a) Donors who have had malaria diagnosed in the past:</p> <p>If more than three years have passed since anti malaria therapy has been completed and symptoms caused by malaria have resolved and a validated test for malaria antibody is negative, accept.</p> <p>If the donor (with a history of malaria) has revisited a malaria endemic area and at least four months have passed since return and a validated test for malaria antibody is negative, accept.</p> <p>1b) Donors who have EVER had an undiagnosed fever that could have been malaria while in a malaria area or within four months of leaving a malaria endemic area:</p>
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	<p>If at least four months have passed since the donor returned from the malaria endemic area, or from the date of recovery from symptoms (undiagnosed fever) that may have been caused by malaria, whichever is later, and a validated test for malaria antibody is negative, accept.</p> <p>NB, this may have to be increased to six months if the area is also identified as a risk area for T. cruzi or a tropical virus; the longest stipulated deferral period must be applied</p> <p>1c) Donors who have EVER been resident in a malaria endemic area for six months or more:</p> <p>If at least four months have passed since the date of the last potential exposure to malaria, and a validated test for malaria antibody is negative, accept.</p> <p>1d) For all other donors:</p> <p>If at least four months and less than 12 months have passed since return from a malaria endemic area, and a validated test for malaria antibody is negative, accept.</p> <p>If travel to a malaria endemic area is more than 12 months prior to donation and the donor has never been diagnosed with malaria, has never had an undiagnosed fever while abroad or within four months of leaving a malaria endemic area and has not lived in a malaria endemic area for a continuous period of six months or more at any time of life, the donor can be accepted without the need for malaria antibody testing.</p> <p>If the donor does not comply with any of the above, discuss with the Designated Medical Officer who will decide if the donor may be accepted following a documented risk assessment and discussion with the Transplant Centre.</p>
See if Relevant	Geographical Disease Risk Index for countries with a current endemic malaria risk.
Additional Information	<p>«Symptoms and signs of possible malaria include: fever, flu-like illness, (including shaking chills, headache, muscle aches, and tiredness), anaemia, jaundice, nausea, vomiting, diarrhoea and cough.»</p> <p>Cases of malaria transmission have occurred many years after the donor was last at risk of becoming infected with malaria. This is mainly a problem in people who have had repeated episodes of infection with malaria. This is uncommon, but before allowing someone who has had, or may have had malaria to donate, it is safer to test for malaria antibodies rather than to wait a specific length of time. Malaria may be fatal.</p> <p>«For bone marrow/stem cell donors, if it is an emergency and due to the live saving nature of the treatment, donors may be accepted with individual risk assessment and expert advice for interpretation of MAT and NAT results, at any time point following exposure/recovery. If the donor informs of active malaria infection at donor assessment, they could be treated before donation. If the stem cells are not required for life saving treatment immediately, a four-month deferral should apply. Between 4 months and 12 months following recovery, either a negative MAT or a positive MAT/negative malaria NAT and risk assessment should be applied.»</p> <p>Some countries have malaria as well as tropical viral risk. Both risks have to be considered if the donor had symptoms after travel or stay.</p>
Reason for Change	<p>«This guidance was updated based on advice from the SACTTI parasitology sub-group.»</p> <p>The 'Discretionary' entry has been expanded for clarity</p> <p>The interval since last leaving a malaria endemic area for malaria antibody testing has been reduced from 6 to 4 months.</p>

The following changes apply to:

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
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<i>«Definition</i>	<p>Resident – A donor who has ever been present in a malaria risk area, (or areas), for a continuous period of 6 months or more (at any point in their lifetime)</p> <p>Visitor – A donor who has visited or travelled through a malaria risk area, (or areas), within the past 12 months,</p> <p>Unexplained febrile illness – A donor who had undiagnosed fever (that could have been malaria) while present in, or within four months of leaving, a malaria risk area.</p> <p>Previous diagnosis of malaria – A donor who previously had a confirmed diagnosis of malaria, at any point in their lifetime.</p> <p>Malaria risk area – Risk area for country as defined by the GDRI</p> <p>MAT: Malarial Antibody Test</p> <p>NAT: Nucleic Acid Test (for malaria)»</p>
<i>Obligatory</i>	<p>«Must not donate (if no testing is available): Applies to all groups as defined above»</p> <p>Must not donate if:</p> <p>a) The donor has ever had malaria-</p> <p>b) The donor has had an undiagnosed fever (that could have been malaria) while abroad or within four months of leaving a malaria endemic area-</p> <p>c) The donor has lived in any malarial endemic area for a continuous period of six months or more at any time of life-</p> <p>d) Less than 12 months after last leaving a malaria endemic area-</p>
<i>Discretionary</i>	<p>«1a) Previous Malaria: If more than 4 months have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved, obtain a blood sample for MAT and NAT test. See information below in this section.</p> <p>1b) Unexplained Febrile illness:</p> <p>If less than 4 months from the date of recovery of symptoms of unexplained febrile illness that could have been malaria: Obtain a blood sample for MAT and NAT. See information below in this section.</p> <p>If more than 4 months from the date of recovery of symptoms of unexplained febrile illness that could have been malaria: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release tissues. See information below in this section.</p> <p>1c) Resident:</p> <p>If less than 4 months since date last present in a malaria risk area: Obtain a blood sample for MAT and NAT. See information below in this section.</p>

	<p>If more than 4 months since date last present in a malaria risk area: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release tissues. See information below in this section.</p> <p>1d) Visitor:</p> <p>If less than 4 months since return: Obtain a blood sample for MAT and NAT. See information below in this section.</p> <p>If more than 4 and less than 12 months since return: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release tissues. See information below in this section.</p> <p>If more than 12 months since return: testing not required, accept</p> <p>NB. Please consider <i>T. cruzi</i> or a tropical virus risk if the area is also identified as a risk area for these infections</p> <p>The results of MAT and NAT tests must be reviewed as a part of donor medical clearance to determine the suitability of tissues for clinical use. If the exposure event is more than four months prior to donation, and MAT is negative, NAT is not required. If the exposure event is less than four months prior to donation, NAT must be done and shown to be negative, irrespective of MAT results. For donors with a history of malaria where treatment was completed and symptoms have resolved at least four months prior to donation, if MAT is negative, NAT is not required. In case of positive MAT results with a confirmed negative NAT test, a risk assessment can be performed for accepting tissues for clinical release after seeking expert opinion.</p> <p>2. If tissue will be sterilized by irradiation post-donation: Accept – MAT and NAT testing not required.</p> <p>3. Eyes Accept for corneas only – MAT and NAT testing not required.»</p> <p>1a) Donors who have had malaria diagnosed in the past: If more than three years have passed since anti malaria therapy has been completed and symptoms caused by malaria have resolved and a validated test for malaria antibody is negative, accept. If the donor (with a history of malaria) has revisited a malaria endemic area and at least four months have passed since return and a validated test for malaria antibody is negative, accept.</p> <p>1b) Donors who have EVER had an undiagnosed fever that could have been malaria while in a malaria area or within four months of leaving a malaria endemic area: If at least four months have passed since the donor returned from the malaria endemic area, or from the date of recovery from symptoms (undiagnosed fever) that may have been caused by malaria, whichever is later, and a validated test for malaria antibody is negative, accept.</p> <p>NB: this may have to be increased to six months if the area is also identified as a risk area for T. cruzi or a tropical virus; the longest stipulated deferral period must be applied</p> <p>1c) Donors who have EVER been resident in a malaria endemic area for six months or more: If at least four months have passed since the date of the last potential exposure to malaria, and a validated test for malaria antibody is negative, accept.</p>
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	<p>1d) For all other donors:</p> <p>If at least four months and less than 12 months have passed since return from a malaria endemic area, and a validated test for malaria antibody is negative, accept.</p> <p>If travel to a malaria endemic area is more than 12 months prior to donation and the donor has never been diagnosed with malaria, has never had an undiagnosed fever while abroad or within four months of leaving a malaria endemic area and has not lived in a malaria endemic area for a continuous period of six months or more at any time of life, the donor can be accepted without the need for malaria antibody testing.</p> <p>2. If tissue will be sterilized by irradiation post donation:</p> <p>Accept.</p> <p>3. Eyes</p> <p>Accept for corneas only.</p> <p>If the donor does not comply with any of the above, discuss with the Designated Medical Officer who will decide if the donor may be accepted following a documented risk assessment.</p>
See if Relevant	<u>Geographical Disease Risk Index</u> for countries with a current endemic malaria risk.
Additional Information	<p>«Symptoms and signs of possible malaria include: fever, flu-like illness, (including shaking chills, headache, muscle aches, and tiredness), anaemia, jaundice, nausea, vomiting, diarrhoea and cough.»</p> <p>The SaBTO Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation (2011) confirms that irradiation of the tissue can be allowed as an alternative to malaria antibody testing for donors with a travel history.</p> <p>As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.</p> <p>Some countries have malaria as well as tropical viral risk. Both risks have to be considered if the donor had symptoms after travel or stay.</p>
Reason for Change	<p>«This guidance was updated based on advice from the SACTTI parasitology sub-group.»</p> <p>The 'Discretionary' entry has been expanded for clarity.</p> <p>The interval since last leaving a malaria endemic area for malaria antibody testing has been reduced from 6 to 4 months. The 'additional information' section has also been amended.</p> <p>The potential for discretionary acceptance after risk assessment has been explained</p>

The following changes apply to:

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
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<i>«Definition</i>	<p>Resident – A donor who has ever been present in a malaria risk area (or areas), for a continuous period of 6 months or more (at any point in their lifetime)</p> <p>Visitor – A donor who has visited or travelled through a malaria risk area (or areas) within the past 12 months</p> <p>Unexplained febrile illness – A donor who had undiagnosed fever (that could have been malaria) while present in, or within four months of leaving, a malaria risk area.</p> <p>Previous diagnosis of malaria – A donor who previously had a confirmed diagnosis of malaria, at any point in their lifetime.</p> <p>Malaria risk area – Risk area for country as defined by the GDRI</p> <p>MAT: Malarial Antibody Test</p> <p>NAT: Nucleic Acid Test (for malaria)»</p>
<i>Obligatory</i>	<p>«1. Must not donate (if no testing is available) Applies to all groups as defined above</p> <p>2. Must not donate if testing is performed less than 4 months since: Anti-malaria therapy has been completed and symptoms caused by malaria have resolved OR Recovery of symptoms of unexplained febrile illness that could have been malaria OR Last present in a malaria risk area (or areas) OR Since return from a malaria risk area (or areas).»</p> <p>Must not donate if:</p> <p>a) The donor has ever had malaria-</p> <p>b) The donor has had an undiagnosed fever (that could have been malaria) while abroad or within four months of leaving a malaria endemic area-</p> <p>c) The donor has lived in any malarial endemic area for a continuous period of six months or more at any time of life-</p> <p>d) Less than 12 months after last leaving a malaria endemic area-</p>
<i>Discretionary</i>	<p>«1a) Previous Malaria: If more than 4 months have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved, obtain a blood sample for MAT and NAT test. See information below in this section.</p> <p>1b) Unexplained Febrile illness: If more than 4 months from the date of recovery of symptoms of unexplained febrile illness that could have been malaria: Obtain a</p>

	<p>blood sample for MAT and NAT. If MAT negative, NAT is not required to release tissues. See information below in this section.</p> <p>1c) Resident: If more than 4 months since date last present in a malaria risk area: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release tissues. See information below in this section.</p> <p>1d) Visitor: If more than 4 and less than 12 months since return: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release tissues. See information below in this section. If more than 12 months since return: testing not required, accept</p> <p>NB. Please consider T. cruzi or a tropical virus risk if the area is also identified as a risk area for these infections</p> <p>The results of MAT and NAT tests must be reviewed as a part of donor medical clearance to determine the suitability of tissues for clinical use. If the exposure, or, for donors with a history of malaria where treatment was completed and symptoms have resolved, was more than four months prior to donation and MAT is negative, NAT is not required. However, if MAT is positive and NAT is negative, in these donors, a risk assessment can be performed for accepting tissues for clinical release after seeking expert opinion.</p> <p>2. If tissue will be sterilized by irradiation post-donation: Accept – MAT and NAT testing not required.»</p> <p>1a) Donors who have had malaria diagnosed in the past: If more than three years have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved and a validated test for malaria antibody is negative, accept. If the donor (with a history of malaria) has revisited a malaria endemic area and at least four months have passed since return and a validated test for malaria antibody is negative, accept.</p> <p>1b) Donors who have EVER had an undiagnosed fever that could have been malaria while in a malaria area or within four months of leaving a malaria endemic area: If at least four months have passed since the donor returned from the malaria endemic area, or from the date of recovery from symptoms (undiagnosed fever) that may have been caused by malaria, whichever is later, and a validated test for malaria antibody is negative, accept.</p> <p>NB. this may have to be increased to six months if the area is also identified as a risk area for T. cruzi or a tropical virus; the longest stipulated deferral period must be applied</p> <p>1c) Donors who have EVER been resident in a malaria endemic area for six months or more: If at least four months have passed since the date of the last potential exposure to malaria, and a validated test for malaria antibody is negative, accept.</p> <p>1d) For all other donors:</p>
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	<p>If at least four months and less than 12 months have passed since return from a malaria-endemic area, and a validated test for malaria antibody is negative, accept.</p> <p>If travel to a malaria-endemic area was more than 12 months prior to donation, and the donor has never been diagnosed with malaria, has never had an undiagnosed fever while abroad, or within four months of leaving a malaria-endemic area and has not lived in a malaria endemic area for a continuous period of six months or more at any time of life, the donor can be accepted without the need for malaria antibody testing.</p> <p>2. If tissue will be sterilized by irradiation post-donation:</p> <p>Accept.</p>
See if Relevant	<p><u>Geographical Disease Risk Index</u> for countries with a current endemic malaria risk.</p>
Additional Information	<p>«Symptoms and signs of possible malaria include: fever, flu-like illness, (including shaking chills, headache, muscle aches, and tiredness), anaemia, jaundice, nausea, vomiting, diarrhoea and cough.»</p> <p>The SaBTO Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation (2011) confirms that irradiation of the tissue can be allowed as an alternative to malarial antibody testing for donors with a travel history.</p> <p>Some countries have malaria as well as tropical viral risk. Both risks have to be considered if the donor had symptoms after travel or stay.</p>
Reason for Change	<p>«This guidance was updated based on advice from the SACTTI parasitology sub-group.»</p> <p>The ‘Discretionary’ entry has been expanded for clarity.</p> <p>The interval since last leaving a malaria-endemic area for malaria antibody testing has been reduced from 6 to 4 months.</p>



Dr Stephen Thomas
Professional Director – JPAC
jpac@nhsbt.nhs.uk