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Change Notification UK National Blood Services No. 39 - 2022

Hepatitis B

These changes apply to **Whole Blood and Component Donor Selection Guideline**.

Please amend the entry as shown

<i>Definitions</i>	<p>HBV: Hepatitis B virus HBsAg: Hepatitis B surface antigen Anti-HBs: Antibody against hepatitis B surface antigen Anti-HBc: Antibody against hepatitis B core antigen</p> <p>Active hepatitis B infection refers to an individual with circulating HBsAg and/or HBV DNA. This term includes acute and chronic hepatitis B infection. Recovered hepatitis B infection refers to an individual who was previously diagnosed with hepatitis B infection but has subsequently cleared HBV from their circulation. Current exposure refers to an individual who has recent household or sexual contact with an individual with active or recovered hepatitis B infection. 'Recent' is defined as the last 4 months for household contacts or the last 3 months for sexual contacts. Previous exposure refers to an individual who has been a household contact more than 4 months ago, or a sexual contact more than 3 months ago, of someone with active or recovered hepatitis B infection.</p> <p>The longer time period specified for household contact is a requirement of the Blood Safety and Quality Regulations (BSQR).</p> <p>Hepatitis B (HBV) Testing: Unless otherwise stated, HBV testing refers to routine HBsAg and pooled HBV DNA (NAT) testing.</p>
1. Active or recovered hepatitis B infection	
<i>Obligatory</i>	<p>Must not Donate This includes donors who are identified as anti-HBc positive by Blood Transfusion Service testing</p>
<i>Discretionary</i>	<p>a) If more than 12 months from recovery and the history of HBV infection is not certain, take samples for HBV and anti-HBc testing. No donation should be taken.</p> <p>b) If the donor has undergone anti-HBc testing by the Blood Transfusion Service, the donor has been approved to donate by a DCSO, and no new risk is disclosed, accept</p>

<i>Post-session review of results</i>	<p>a) anti-HBc positive donors. Must not donate</p> <p>b) anti-HBc negative donors who reported hepatitis B infection. If more than 12 months from recovery and,</p> <ul style="list-style-type: none"> • The donor is negative for all markers (HBsAg, screening HBV DNA and anti-HBc negative); and, • Review of their clinical history by a DCSO indicates that it is unlikely the donor had HBV infection; <p>accept for donation.</p>
<i>Additional Information</i>	<p>SaBTO have recommended that all donors are tested at least once for anti-HBc, which is a marker of hepatitis B infection. Individuals who have recovered from hepatitis B will remain anti-HBc positive. There is a risk that reactivation of hepatitis B virus in such an individual could give rise to occult hepatitis B infection which is not detected by routine testing. For this reason, donors who are anti-HBc positive are deferred from donation.</p> <p>SaBTO included in their recommendations a discretion that anti-HBc positive donors could be accepted if (1) they have adequate immunity to HBV, as demonstrated by an anti-HBs result of greater than 100 iu/l in a validated assay within 24 months of donation and (2) all of their donations will be tested by individual HBV DNA testing. UK Blood Transfusion Services are not currently implementing this approach. These guidelines will be revised should any service implement this additional testing at a future date.</p> <p>It is likely that donors who are anti-HBc negative have not had hepatitis B in the past. Such donors can be accepted provided their clinical history has been reviewed by a DCSO. They do not require any additional testing once the diagnosis of hepatitis B has been excluded.</p>
2. Individuals with current exposure to someone with active HBV infection	
<i>Obligatory</i>	Must not donate
<i>Additional Information</i>	Donors who have a sexual partner or household contact with active HBV infection may be at risk of acquiring HBV. Current guidelines do not allow a donor with a recent or ongoing risk of exposure to HBV to give blood, even if the donor is fully vaccinated against HBV.
3. Individuals with current exposure to someone with recovered HBV infection	
<i>Obligatory</i>	Must not donate
<i>Discretionary</i>	<p>a) If:</p> <ul style="list-style-type: none"> • it is at least 3 months after a sexual partner recovered from hepatitis B; and/or • it is at least 4 months after a household contact recovered from hepatitis B; <p>take samples for anti-HBc testing, in addition to HBV testing. No donation should be taken.</p> <p>b) If the donor has undergone anti-HBc testing by the Blood Transfusion Service, the donor has been approved to donate by a DCSO, and no new risk is disclosed, accept</p>
<i>Post-session review of results</i>	<p>a) If the donor is negative for HBV and Anti-HBc, the donor can be accepted. Additional hepatitis B testing is not required for future donations unless the donor discloses a new risk.</p> <p>b) If any of HBsAg, anti-HBc or HBV DNA are positive, refer to Section 1: Active or recovered hepatitis B infection.</p>

<i>Additional Information</i>	<p>The risk of acquiring hepatitis B infection from someone who has recovered from hepatitis B is very low. Testing for anti-HBc will rule out the possibility that the donor picked up HBV at an earlier stage when their sexual or household contact may have been infectious.</p> <p>If the sexual or household contact has no history of hepatitis B but has been told they are anti-HBc positive, indicating previous infection only, it is likely that several months have elapsed since the contact cleared the virus from their circulation. The donor can be accepted for anti-HBc testing, as long as their contact has not had an unexplained illness consistent with hepatitis B in the previous 3 months (sexual partner) or 4 months (household contact). There is no requirement to test the sexual partner or household contact.</p>
4. Individuals with previous exposure to someone with active or recovered hepatitis B	
<i>Obligatory</i>	Must not donate
<i>Discretionary</i>	<p>a) If:</p> <ul style="list-style-type: none"> • it is at least 3 months since sexual contact, and/or • it is at least 4 months since household contact, <p>samples should be taken for HBV and anti-HBc testing. No donation should be taken.</p> <p>b) If the donor has undergone anti-HBc testing by the Blood Transfusion Service, the donor has been approved to donate by a DCSO, and no new risk is disclosed, accept</p>
<i>Post-session review of results</i>	<p>a) If the donor is negative for HBV and Anti-HBc, the donor can be accepted. Additional hepatitis B testing is not required for future donations unless the donor discloses a new risk.</p> <p>b) If any of HBsAg, anti-HBc or HBV DNA are positive, refer to Section 1: Active or recovered hepatitis B infection</p>
5. Individuals undergoing Hepatitis B immunisation	
<i>Obligatory</i>	<p>a) Known Exposure: Must not donate.</p> <p>b) No Known Exposure: Must not donate if: Less than seven days since the most recent dose of vaccine was given.</p>
<i>Discretionary</i>	<p>a) Known Exposure: If it is more than 4 months from the date of exposure, samples can be taken for HBV and anti-HBc testing. No donation should be taken.</p> <p>b) No Known Exposure: If it is more than 7 days from the date of the most recent dose of vaccine, accept</p>
<i>Post-session review of results</i>	<p>a) If the donor is negative for HBV and Anti-HBc, the donor can be accepted. Additional hepatitis B testing is not required for future donations unless the donor discloses a new risk.</p>

	b) If any of HBsAg, anti-HBc or HBV DNA are positive, refer to Section 1: Active or recovered hepatitis B infection
<i>See if Relevant</i>	<u>Hepatitis A – 4. Immunisation</u> <u>Immunoglobulin Therapy</u>
<i>Additional Information</i>	Specific HBV immunoglobulin may be used in the management of individuals who have been exposed to hepatitis B. Administration of hepatitis B vaccine can lead to low level reactivity in HBsAg screening assays. For this reason, donors must be deferred until at least 7 days after receiving a dose of vaccine, even if they have not been exposed to HBV. Hepatitis B vaccine is sometimes given in a combined vaccine with hepatitis A vaccine.
<i>Reason for change</i>	All sections of the hepatitis B entry have been revised to reflect SaBTO recommendations for anti-HBc testing of all blood donors



Dr Stephen Thomas
Professional Director - Joint UKBTS Professional Advisory Committee
✉ stephen.thomas@nhsbt.nhs.uk