

Position Statement

March 2026

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Collection of plasma for fractionation from donors who are anti-HBc positive

Background

Since 2022, all blood donors in the UK have been tested at least once for antibodies against hepatitis B core antigen (anti-HBc). This approach was recommended by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) following a review of available evidence and UK data on the frequency of donors with occult hepatitis B infection with low levels of hepatitis B virus (HBV) DNA that could not be detected on NAT screening in pools of 24.¹ Here, occult hepatitis B is defined as donations that are negative for hepatitis B surface antigen (HBsAg) but positive for anti-HBc and HBV DNA. Anti-HBc screening allows donors with past hepatitis B infection to be identified. The UK blood services decided that anyone with evidence of past hepatitis B should be permanently withdrawn from the donor panel because of the ongoing small risk of occult hepatitis B developing in the future.

Unfortunately, the anti-HBc test may give some non-specific reactions including identifying donations with an anti-HBc reactive test but no other positive markers. In the absence of DNA and other markers, e.g. antibody to hepatitis B e antigen (anti-HBe), it may be impossible to resolve whether this reflects hepatitis B infection at some time. As a result, donors with non-specific reactions are also deferred from donation.

Under the current testing regime, donors may be identified in the following categories:

Type of infection	HBsAg	HBV DNA	anti-HBc (total)	anti-HBs	anti-HBe
Acute	+	+	+	-	-
Chronic	+	+/-	+	+/-	+/-
Occult	-	+	+	+/-	+/-
Immunised	-	-	-	+	-
Past	-	-	+	+/-	+/-
Possible non-specific	-	-	+	-	-

UK data from April 2022 to December 2024 indicate that approximately 0.4% of all donations were repeat reactive when screened for anti-HBc and just over 5000 donors were deferred from whole blood and component donation.² Some 32 donors were identified with occult hepatitis B (HBV DNA detected through pooled or individual NAT testing, HBsAg negative).

Implications for collection of plasma for fractionation

Anti-HBc screening was introduced in order to exclude donors at risk of occult hepatitis B, i.e. donors who may have low levels of DNA which is not detected in standard donation testing. In this circumstance, transfusion of a blood component could result in transmission of hepatitis B infection.

Since 2024, UK blood services have also collected plasma for fractionation to manufacture medicinal products, specifically intravenous immunoglobulin (IVIg) and human albumin solution (HAS). This includes recovered plasma from whole blood donations and source plasma collected through plasmapheresis.

The processing undertaken to produce IVIg and HAS will inactivate any residual hepatitis B virus, including any virus present below the level of detection. Therefore, risks relating to occult hepatitis B which are applicable to blood components do not apply when plasma is destined solely for fractionation. It is noted that anti-HBc positivity is not included in the specifications outlined in the UK plasma master file and is therefore not a reason to defer these donors from donating source plasma.

JPAC is content that donors who have non-specific anti-HBc reactivity, or who are anti-HBc positive with non-detectable DNA, would be suitable candidates to donate plasma only. This applies irrespective of their anti-HBs levels. Anti-HBc positive donors who have anti-HBs could also provide immunoglobulins that could be used in hepatitis B prophylaxis. With suitable caveats and controls in place, it may be possible to return some of the previously deferred donors to a dedicated anti-HBc donor panel where donations from these donors could only be used for fractionated plasma. This approach would require agreement with the appointed fractionator prior to implementation.

References

1. Occult hepatitis B infection in UK blood donors. Published 06 April 2023.
Available at <https://www.gov.uk/government/publications/occult-hepatitis-b-infection-in-uk-blood-donors>
2. SaBTO December 2025 minutes.
Available at <https://app.box.com/s/m6or0zdspah90u6kg3r9/folder/321368063361>



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