Proposed Interim Standards for the 34th edition of *Standards for Blood Banks and Transfusion Services* and 12th edition of *Standards for Cellular Therapy Services*

The following proposed interim standards to the 34th edition of *Standards for Blood Banks and Transfusion Services* and 12th edition of *Standards for Cellular Therapy Services* are available for public comment until Sunday, February 22, 2026. At the conclusion of the comment period, the Blood Bank/Transfusion Service and Cellular Therapy Services Standards Committees will meet to review all comments submitted. Following the review of comments received, if the interim standards are approved, the AABB will issue the final language of the interim standard through an Association Bulletin.

Proposed Interim Standards

Interim Standards to the 34th edition of Standards for Blood Banks and Transfusion Services

5.8.5 Tests Intended to Prevent Disease Transmission by Allogeneic Donations

A sample of blood from each allogeneic donation shall be tested for HBV DNA, HBsAg, anti-HBc, anti-HCV, HCV RNA, anti-HIV-1/2, HIV-1 RNA, anti-HTLV-I/II, WNV RNA, and syphilis by a serologic test. Donations collected in states in the United States specified by FDA guidance shall undergo nucleic acid testing for *Babesia* spp.* Each donor shall be tested at least once for antibodies to *Trypanosoma cruzi (T. cruzi).* Blood and blood components shall not be distributed or issued for transfusion unless the results of these tests are negative, except in the case of a test for syphilis that has been shown to have a biological false-positive result. Units with biological false-positive results shall be labeled in accordance with FDA requirements.† Standards 4.3.2.1 and 5.2.4 apply.

*FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019).

†21 CFR 610.40 and 21 CFR 630.3(h).

FDA Memorandum to All Registered Blood Establishments: Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc) (September 10, 1991).

FDA Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion (November 2009).

FDA Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis (December 2020).

FDA Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry (December 2017).

FDA Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, Including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus (October 2012).

FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II (HTLV-I/II) (February 2020).

FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components (December 2017).

FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019).

5.8.5.1 **Facilities not subject to United States laws and regulations shall conform to the following requirements in place of testing donors for West Nile Virus and *T. cruzi* if otherwise not required by their Competent Authority. The facility shall:**
1) Defer all donors who have traveled to WNV endemic areas for a minimum of 28 days.
2) Defer all donors who have tested positive for or have a history of WNV for a minimum of 120 days.*
3) Defer all donors who have traveled to *T. cruzi* endemic areas for a minimum of 28 days.
4) Permanently defer all donors who have tested positive for or have a history of T. *cruzi*.^

***FDA Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection (June 2005)**

^FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Blood and Blood Components (December 2017)

5.8.5.2~~1~~ Testing for *Babesia* spp. is not required if all transfusable components from the donation are prepared using FDA-approved pathogen reduction technology.‡

‡FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019).

5.8.5.3~~2~~ If blood or blood components are distributed or issued before completion of these tests due to urgent need, a notation that testing is not completed shall appear conspicuously on an attached label or tie tag.
Required tests shall be completed and results reported to the transfusion service as soon as possible.

5.8.5.4~~3~~ For a cytapheresis donor dedicated to the support of a specific patient, testing required by Standard 5.8.5 shall be performed at the first donation and at least every 30 days thereafter.*

*21 CFR 610.40(c)(1).

Interim Standards to the 12th edition of Standards for Cellular Therapy Services

5.10.2.8 The following tests shall be performed:

1) Hepatitis B virus (HBsAg; anti-HBc; HBV DNA).
2) Hepatitis C virus (anti-HCV; HCV RNA).
3) Human immunodeficiency virus (anti-HIV-1/2; HIV-1 RNA).
4) Human T-cell lymphotropic virus, type I and II (anti-HTLV-I/II), for viable leukocyte-rich products only.
5) Antibody to cytomegalovirus for viable leukocyte-rich products only.
6) A serologic test for syphilis.*
7) West Nile virus (WNV RNA).

Reference Standards 5.10B, Clinical Evaluation and Laboratory Testing of Living Allogeneic Donors; 5.10C, Clinical Evaluation and Laboratory Testing of Autologous Donors; 5.10D, Clinical Evaluation and Laboratory Testing of Mothers of Cord Blood or Gestational Material Donors; and 5.10E, Clinical Evaluation and Laboratory Testing of Cadaveric Donors, apply.

*FDA Guidance for Industry: Use of Donor Screening Tests to Test Donors of Human Cells, Tissues and Cellular and Tissue-Based Products for Infection with *Treponema pallidum* (Syphilis) (September 2015).

5.10.2.8.1 ~~For~~ **F**~~f~~acilities not subject to US laws and regulations **shall conform to the following requirements in place of testing donors for West Nile Virus, *T. cruzi*, anti-HBc if otherwise not required by their Competent Authority. The facility shall:** ~~, HBV DNA testing is acceptable in place of anti-HBc testing.~~

1) Defer all donors who have traveled to WNV endemic areas for a minimum of 28 days.
2) Defer all donors who have tested positive for or have a history of WNV for a minimum of 120 days.*
3) Defer all donors who have traveled to *T. cruzi* endemic areas for a minimum of 28 days.
4) Permanently defer all donors who have tested positive for or have a history of *T. cruzi*.
5) Have the option of performing HBV DNA testing ~~is acceptable~~ in place of anti-HBc testing**.**

***FDA Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) (August 2007)**

Rationale

These interim standards are geared towards AABB accredited facilities outside the United States specifically surrounding infectious disease testing requirements for *Trypanosoma* cruzi (Chagas) and West Nile Virus (WNV). Incorporation of these interim standards into the editions cited above will limit the majority of all variance requests received and speed up the accreditation process for every facility outside of the United States that are accredited for the BB/TS and CT Standards.

The interim standards proposed would eliminate the need to perform infectious disease testing for Chagas WNV for facilities outside the United States that are not required to do so by their Competent Authority, while enforcing donor deferral periods for individuals who have traveled to countries that are endemic for these diseases, and for individuals who have tested positive for the viruses.

The deferral periods selected are based on FDA Guidances, and current practice among donor centers.

Note the interim standards to the BB/TS Standards, if approved, would be incorporated into the 35th edition of BB/TS Standards.

How to Comment on the Proposed Interim Standards

1. Send comments by February 22, 2026 to the Standards Department via Jotform (https://form.jotform.com/260203665863155) or email: standards@aabb.org.

2. Include name and postal address/fax number/email address, as appropriate.

3. Provide alternative wording if you think it would improve the clarity of the standards. If you agree or disagree strongly with the proposed addition, please state your reasons or submit data.