



Association Bulletin #26-02

Date: April 1, 2026

To: AABB Members

From: Jose Cancelas, MD, PhD – President
Debra BenAvram – Chief Executive Officer

Re: Interim Standards to the 35th edition of *Standards for Blood Banks and Transfusion Services* and 12th edition of *Standards for Cellular Therapy Services*

Association Bulletins provide a mechanism for publication of documents that have been approved by the Board of Directors for distribution to individual and institutional members, such as:

- Standards that were adopted after publication of the most recent edition of *Standards*.
- Statements of AABB policy intended for distribution to members.
- Guidance, recommendations, and reports that have been developed by AABB Committees or National Office staff for distribution to members.

Summary

This bulletin contains new interim standards to the 35th edition of *Standards for Blood Banks and Transfusion Services (BB/TS Standards)* and 12th edition of *Standards for Cellular Therapy Services* focused on infectious disease testing and donor deferrals for facilities outside the United States for West Nile virus (WNV) and *Trypanosoma cruzi* (Chagas disease).

Background

These interim standards were made available for 30-day public and member comment from January 16 to February 15, 2026. A review of the comments received took place with both the Blood Banks/Transfusion Services and Cellular Therapies Standards Committees and with input from AABB's Transfusion Transmitted Diseases Committee.

They are intended for AABB-accredited facilities outside the United States, specifically in countries or facilities where testing for WNV and Chagas disease are not required. Incorporation of these interim standards into the editions cited above will speed up the accreditation and accreditation renewal process for every facility outside of the United States that are accredited for the *BB/TS* and *CT Standards*.



The interim standards of the 35th edition of *BB/TS Standards* will give accredited facilities outside the United States the option to eliminate infectious disease testing for WNV and/or Chagas disease for facilities that are not required to do so by their Competent Authority. In place of testing, the standards require specific 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 the cited FDA Guidance, and current practice among donor centers.

Interim standard 5.10.2.8.2 to the 12th edition of *CT Standards* will give accredited facilities outside the United States the option to eliminate infectious disease testing for WNV for facilities that are not required to do so by their Competent Authority. Such facilities would still enforce 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 virus. The facilities that choose this option would be required to determine the donor to be ineligible for donation during the periods noted in the new standard.

Interim standard 5.10.2.8.3 to the 12th edition of *CT Standards* clarifies expectations for accredited facilities, where testing for Chagas disease is not required, as it relates to determination of donor ineligibility based on their risk factors for potential Chagas disease infection.

The periods of donor ineligibility are based on the cited FDA Guidance and current practices among cellular therapy facilities.

The updates to the 35th edition of *Standards for Blood Banks and Transfusion Services* and 12th edition of *Standards for Cellular Therapy Services* are listed below, including the rationale for their creation.

Please note that the edited standards are indicated by strike-through and bold formatting.

Final Interim Standards

35th edition of *BB/TS Standards*

5.8.5.1 For facilities not subject to United States laws and regulations, and where Competent Authority regulations do not require donor testing for West Nile virus and/or *T. cruzi*, the facility shall:

- 1) Test for WNV or defer for a minimum of 28 days, all donors who have traveled to WNV-endemic areas.**
- 2) Defer all donors who have tested positive for or have a history of WNV for a minimum of 120 days.***



- 3) Test for *T. cruzi* or permanently defer donors who were born in or have resided for 3 consecutive months in *T. cruzi*-endemic areas.[†]
- 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)**

[†] [https://www.who.int/news-room/fact-sheets/detail/chagas-disease-\(american-trypanosomiasis\)](https://www.who.int/news-room/fact-sheets/detail/chagas-disease-(american-trypanosomiasis))

‡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).

12th edition of *CT Standards*

5.10.2.8.1 For facilities not subject to US laws and regulations, HBV DNA testing is acceptable in place of anti-HBc testing. **Standards 1.4, 5.10.7, and Reference Standard 5.10B apply.**



5.10.2.8.2 **Facilities not subject to US laws and regulations shall conform to the following alternatives if testing of donors for West Nile virus is not required by their Competent Authority:**

1) Facilities shall determine all donors to be ineligible for a minimum of 28 days if they have traveled to WNV-endemic areas as determined by the Competent Authority (eg, WHO, CDC, or ECDC surveillance maps).

2) Facilities shall determine all donors to be ineligible for a minimum of 120 days if they have tested positive for or have a history of WNV.[¶]

Standards 1.4, 5.10.7, and Reference Standard 5.10B apply.

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

5.10.2.8.3 **Facilities not subject to US laws and regulations, and where testing for *T. cruzi* is not required by the facility's Competent Authority, shall determine all donors to be ineligible if any of the following apply:**

1) Donors have tested positive for *T. cruzi*.

2) Donors have a history of *T. cruzi* infection.

3) Donors have a health history or environmental risk factors for *T. cruzi* that would be identified by the donor screening process.

Standards 1.4, 5.10.7, and Reference Standard 5.10B apply.

Conclusion

The interim standards listed above will be updated in the AABB Standards Portal and can be implemented by AABB-accredited facilities outside the United States immediately.

Please note, facilities in countries whose Competent Authority requires testing for the diseases cited above should follow the requirements set forth to ensure conformance with those requirements.



Facilities that have any questions concerning the interim standards or their implementation can be directed via email to standards@aabb.org.