



Advancing Transfusion and
Cellular Therapies Worldwide

Association Bulletin #19-03

Date: December 13, 2019

To: AABB Members

From: Beth Shaz, MD - President
Debra BenAvram – Chief Executive Officer

Re: Interim Standards to the 31st edition of *Standards for Blood Banks and Transfusion 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.

This bulletin describes additional requirements included in standards 5.8.5, 5.8.6, 5.8.7, reference standards, 5.1.6A, Requirements for Labeling Blood and Blood Components, 5.4.1A, Donor Qualification, as well as the creation of new standards 5.8.5.1, 5.8.5.2, 5.8.6.1, and 5.8.6.2 as they relate to the FDA Guidance from May 2019, Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis.

On August 30, 2019 the AABB issued the interim standards for a 30 day public comment period, running through September 28, 2019. Following the comment period, the Blood Banks and Transfusion Services Standards Committee (BB/TS SC) reviewed the comments received and adjusted the interim standards where appropriate.

The interim standards below can be implemented immediately; however accredited facilities in states that the FDA has delineated as being where individuals are at risk of transfusion transmitted babesiosis have until May 10, 2020 (the day the Guidance for Industry becomes effective) to achieve compliance with the requirements. It should be noted that the 32nd edition of *Standards for Blood Banks and Transfusion Services* takes effect April 1, 2020, except for the standards cited below, which are effective May 10, 2020.



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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, Zika virus RNA, and syphilis by a serologic test. Each donor shall be tested at least once for antibodies to *Trypanosoma cruzi* (*T. cruzi*). **Donations collected in states specified by FDA guidance shall undergo nucleic acid testing for *Babesia* spp.**[#] Blood and blood components shall not be distributed or issued for transfusion unless the results of these tests are negative **or nonreactive**, 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 – Guidance for Industry (May 2019)

*21 CFR 610.40, 21 CFR 630.3(h)

FDA Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis (September 2014)

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: Revised Recommendations for Reducing the Risk of Zika virus Transmission by Blood and Blood Components (July 2018)

5.8.5.1 The requirement for *Babesia* spp. nucleic acid testing shall have an effective date of May 10, 2020.

5.8.5.2 Testing for Zika and *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 – Guidance for Industry (May 2019)



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5.8.6 Tests Intended to Prevent Disease Transmission by Autologous Donations

Autologous blood or components that will be transfused outside the collection facility 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, Zika virus RNA, and syphilis by a serologic test. **Donations collected in states specified by FDA guidance shall undergo nucleic acid testing for *Babesia* spp.**[#] These tests shall be performed before shipping on at least the first unit collected during each 30-day period.[‡] Each donor shall be tested at least once for antibodies to *T. cruzi*. Standard 4.3.2.1 applies.

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

[‡]21 CFR 610.40(d)

5.8.6.1 The requirement for *Babesia* spp. nucleic acid testing shall have an effective date of May 10, 2020.

5.8.6.2 Testing for Zika and *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)

5.8.7 Quarantine and Disposition of Units from Prior Collections

The BB/TS shall have a process that is in accordance with FDA requirements and recommendations for quarantine and disposition of prior collections when a repeat donor has a reactive screening test for anti-HBc, HBsAg, HBV DNA, anti-HCV, HCV RNA, anti-HIV-1/2, HIV-1 RNA, anti-HTLV-I/II, WNV RNA, Zika virus RNA, *T. cruzi* antibodies, or ***Babesia* spp. DNA.**^{†#}

[†]21 CFR 610.40(a)(4) and (6), 21 CFR 610.46, and 21 CFR 610.47

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



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Reference Standard 5.1.6A – Requirements for Labeling Blood and Blood Components

¹³Biohazard labels for autologous units or allogeneic units from a dedicated donor shall be used for the following test results:

<u>Test</u>	<u>Test Result</u>
HBsAg	Repeatedly reactive
Anti-HBc	Repeatedly reactive
HBV NAT	Positive or reactive
Anti-HCV	Repeatedly reactive
HCV NAT	Positive or reactive
Anti-HIV-1/2	Repeatedly reactive
HIV-1 NAT	Positive or reactive
Anti-HTLV-I/II	Repeatedly reactive
WNV NAT	Positive or reactive
Syphilis	Reactive screening test*
Zika NAT	Positive or reactive

When performed:

<i>T. cruzi</i> Antibody Screening	Repeatedly reactive
<u>Babesia spp. NAT</u>	Positive or reactive[#]

*21 CFR 610.40(h)(2)(ii), and 21 CFR 610.40(h)(2)(iv) apply.

FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019)
The requirement for *Babesia* nucleic acid testing shall have an effective date of May 10, 2020.

Reference Standard 5.4.1A – Requirements for Allogeneic Donor Qualification

15) Relevant Transfusion Transmitted Infections ³	• Reactive test for <i>Babesia</i> spp.	At least 2 years - Donor re-entry in accordance with FDA Guidance ¹⁰
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¹⁰FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019)
The requirement for *Babesia* nucleic acid testing shall have an effective date of May 10, 2020.