



Advancing Transfusion and
Cellular Therapies Worldwide

Association Bulletin #21-03

Date: June 4, 2021

To: AABB Members

From: Dave R. Green, MSA – President
Debra BenAvram – Chief Executive Officer

Re: Emergent Standards for the 32nd 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 updated requirements to Standards 5.8.5, 5.8.5.2, 5.8.6, 5.8.6.2, 5.8.7, Reference Standard 5.1.6A, Requirements for Labeling Blood and Blood Components, and Reference Standard 5.4.1A, Donor Qualification, in the 32nd edition of *Standards for Blood Banks and Transfusion Services (BB/TS Standards)* removing the requirement to perform infectious disease testing on potential donors for Zika Virus (ZIKV).

On Wednesday, May 12, 2021 the Food and Drug Administration (FDA) withdrew the July 2018 ZIKV Testing guidance as “testing for ZIKV, or pathogen reduction as an alternative to testing for ZIKV, is not necessary to comply with the requirements of 21 CFR 610.40(a)(3).” To read more on the FDA’s decision to remove the Guidance (effective since 2016), please click on this link [<https://www.fda.gov/media/148549/download>].

As a result of the withdrawal of the Guidance, AABB is making changes to the *BB/TS Standards* to remove the requirement to perform ZIKV testing for future donations. The discontinuation of testing would require a transition period for most blood collectors; hospitals should be aware that they may continue to receive ZIKV-tested units from their blood supplier during this time, and associated costs may remain in place under the terms of existing contracts. Accordingly, blood collectors may distribute ZIKV tested inventory for the next several months. For facilities planning to discontinue ZIKV testing, please ensure that you are following the requirements articulated in Standard 5.1.1, which states the following:



Advancing Transfusion and
Cellular Therapies Worldwide

5.1.1 Change Control

The BB/TS shall have a process to develop new processes or procedures or to change existing ones. This process shall include identification of specifications and verification that specifications have been met. Before implementation, the new or changed processes or procedures shall be validated. Standard 2.1.2 applies.

32nd Edition of Standards for Blood Banks and Transfusion Services Edits

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. Donations collected in 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, 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)~~

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



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

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

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

§21 CFR 610.40(d).

FDA Guidance for Industry: Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use - Compliance Policy (August 2016)

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)

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

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.*‡

~~*FDA Guidance for Industry: Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components (July 2018)~~



Advancing Transfusion and
Cellular Therapies Worldwide

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

‡21 CFR 610.40(a)(4), 21 CFR 610.40(a)(6), 21 CFR 610.46, and 21 CFR 610.47.

FDA Guidance for Industry: Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (December 2015)

FDA Memorandum to All Registered Blood and Plasma Establishments: Recommendations for the Quarantine and Disposition of Units from Prior Collection from Donors with Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human T- Lymphotropic Virus Type I (HTLV-I) (July 19, 1996)

FDA Guidance for Industry: Donor Screening for Antibodies to HTLV-II (August 15, 1997)

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 6, 2009)

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: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc) (May 2010)

FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion (December 2010)

FDA Guidance for Industry: “Lookback” for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV (December 2010)

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)



Advancing Transfusion and
Cellular Therapies Worldwide

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:

| Test | Test Result |
|---------------------|---------------------------------|
| Zika NAT | Positive or reactive |

Reference Standard 5.4.1A Requirements for Allogeneic Donor Qualification

| Category | Criteria/Description/Examples | Deferral Period |
|--|-------------------------------|---|
| 15) Relevant Transfusion-Transmitted Infections³ | Zika Virus | In accordance with FDA Guidance¹⁵ |

³21 CFR 610.40.

~~¹⁵FDA Guidance for Industry: Revised Recommendation for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components (July 2018).~~