4550 Montgomery Avenue | Suite 700, North Tower | Bethesda, MD 20814 | 301.907.6977 | aabb.org

Association for the Advancement of Blood & Biotherapies

Association Bulletin #24-04

Date: August 2, 2024

To: AABB Members

From: Aaron Tobian, MD, PhD – President
Debra BenAvram – Chief Executive Officer

Re: Emergent Standards for the 11th 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

This bulletin describes updated requirements to the 11th edition of *Standards for Cellular Therapy Services* (*CT Standards*) specifically:

- Reference Standards 5.12B, Clinical Evaluation and Laboratory Testing of Living Donors;
- Reference Standard 5.12D, Clinical Evaluation and Laboratory Testing of Mothers of Cord Blood or Gestational Material Donors; and
- Reference Standard 5.12E, Clinical Evaluation and Laboratory Testing of Cadaveric Donors

These changes remove the requirement to perform screening of potential donors for Zika virus (ZIKV).

Background

On Monday, May 20, 2024 the Food and Drug Administration (FDA) withdrew the March 2016 (which was updated in May 2018) ZIKV donor screening guidance, *Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P)* because "FDA has determined Zika virus (ZIKV) is no longer a Relevant Communicable Disease Agent or Disease (RCDAD) under FDA's regulations." As discussed below, "the available evidence demonstrates that ZIKV no longer has sufficient incidence and/or prevalence to affect the potential HCT/P donor population." To read more on the FDA's decision to remove the Guidance (effective since 2016), please click on this link.

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As a result of the withdrawal of the Guidance, AABB is making changes to the *CT Standards* to remove the requirement to perform ZIKV donor screening from the appropriate Reference Standards. The discontinuation of donor screening can be implemented immediately and does not have a deadline for implementation.

With this update to the *CT Standards*, the Cellular Therapy Standards Committee reminds users of that Standard 5.2.1, Change Control, requires accredited facilities identify the reasons for a change and the need to obtain the approval from the appropriate individual(s) for the change. This would include any training of employes; evaluations of competence for said employees; and/or updates to all affected policies, processes, and procedures. Facilities should also ensure that all documents that require an update or obsolescence are treated in a controlled manner.

To assist facilities in their transition of the updated requirements to *CT Standards*, AABB has created a document on the AABB website, "AABB Resources to Support FDA's Determination that Zika Virus Is No Longer an RCDAD."

Edits to the 11th Edition of Standards for Cellular Therapy Services

Reference Standard 5.12B—Clinical Evaluation and Laboratory Testing of Living Allogeneic Donors

II. Clinical Evaluation to Protect the Safety of the Recipient[3]
History and Behavioral Risk for Exposure to the Following Infectious Agents or Disease[3]:

	Required (Yes/No)[1]
HIV	Yes
HBV	Yes
HCV	Yes
HTLV (viable, leukocyte-rich products only)	Yes
Syphilis	Yes
WNV[5]	Yes
Vaccinia (smallpox vaccine)	Yes
Human TSEs	Yes
Malaria (travel or residence in malaria-endemic areas)[6]	Yes
Trypanosoma cruzi (Chagas disease)[6]	Yes
Sepsis	Yes

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~~**Zika**~~[7]	~~**Yes**~~

III. Laboratory Testing for Allogeneic Donors[3,8]7

	Required (Yes/No)[1]
HIV-1/2	Yes
HBV	Yes
HCV	Yes
Syphilis	Yes
HTLV-I/II (viable, leukocyte-rich products only)	Yes
CMV (viable, leukocyte-rich products only)	Yes
HLA Type, if applicable[9, 10]**8.9**	Yes
ABO/Rh, if applicable[9]**8**	Yes
CBC, if applicable	Yes
WNV[5]	Yes
Trypanosoma cruzi (Chagas disease)[6]	No
~~**Zika**~~[7]	~~**No**~~

~~[7]**In the United States, Zika virus is considered a relevant communicable disease agent or disease as defined under 21 CFR 1271.3(r)(2) by the FDA. Guidance for Industry "Donor Screening Recommendations to Reduce the Risk of Transmission of Zika virus by Human Cells, Tissues, and Cellular and Tissue-Based Products," March 2016, updated May 2018.**~~

[7]**8** In the United States, perform tests for relevant communicable disease agents or diseases as required by the FDA and interpret positive/reactive test results as described in 21 CFR 1271.80(d)(1).

[8]**9**Testing shall be performed whenever this information is necessary for the selection and/or clinical use of a cellular therapy product.

[9]**10**HLA-*A*, *HLA-B*, *HLA-C,* and *HLA-DRB1* loci shall be determined. All typing used for the final selection of the donor shall use DNA-based technologies.

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Reference Standard 5.12D—Clinical Evaluation and Laboratory Testing of Mothers of Cord Blood or Gestational Material Donors

II. Clinical Evaluation to Protect the Safety of the Recipient[2,3]
History and Behavioral Risk for Exposure to the Following Infectious Agents or Diseases[2,3]:

	Required (Yes/No)[1]
HIV	Yes
HBV	Yes
HCV	Yes
HTLV (viable, leukocyte-rich products only)	Yes
Syphilis	Yes
WNV[5]	Yes
Vaccinia (smallpox vaccine)	Yes
Human TSEs	Yes
Malaria (travel or residence in malaria-endemic areas)[6]	Yes
Trypanosoma cruzi (Chagas disease)[6]	Yes
Sepsis	Yes
~~**Zika**[7]~~	~~**Yes**~~

III. Laboratory Testing [3,7~~8~~]

	Required (Yes/No)[1]
HIV-1/2	Yes
HBV	Yes
HCV	Yes
Syphilis	Yes
HTLV-I/II (viable, leukocyte-rich products only)	Yes
CMV (viable, leukocyte-rich products only)	Yes
WNV[5]	Yes
Trypanosoma cruzi (Chagas disease)[6]	No
~~**Zika**[7]~~	~~**No**~~

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~~[7] In the United States Zika virus is considered a relevant communicable disease agent or disease as defined under 21 CFR 1271.3(r)(2) by the FDA. Guidance for Industry "Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products, March 2016, updated May 2018~~

[7][8] In the United States, perform tests for relevant communicable disease agents or diseases as required by the FDA and interpret positive/reactive test results as described in 21 CFR 1271.80(d)(1).

Reference Standard 5.12E—Clinical Evaluation and Laboratory Testing of Cadaveric Donors

I. Clinical Evaluation to Protect the Safety of the Recipient[1]
History and Behavioral Risk for Exposure to the Following Infectious Agents or Diseases[1]:

	Required (Yes/No)[2]
HIV	Yes
HBV	Yes
HCV	Yes
HTLV (viable, leukocyte-rich products only)	Yes
Syphilis	Yes
WNV[4]	Yes
Vaccinia (smallpox vaccine)	Yes
Human TSEs	Yes
Malaria (travel or residence in malaria-endemic areas)[4]	Yes
Trypanosoma cruzi (Chagas disease)[4]	Yes
Sepsis	Yes
~~**Zika[6]**~~	~~**Yes**~~

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II. Laboratory Testing[6~~7~~]

	Required (Yes/No)[2]
HIV-1/2	Yes
HBV	Yes
HCV	Yes
Syphilis	Yes
HTLV-I/II (viable, leukocyte-rich products only)	Yes
CMV (viable, leukocyte-rich products only)	Yes
HLA Type, if applicable[7~~8~~]	Yes
ABO/Rh, if applicable[7~~8~~]	Yes
WNV [4]	No
Trypanosoma cruzi (Chagas disease)[5]	No
~~**Zika**~~[6]	~~**No**~~

[6] ~~**In the United States Zika virus is considered a relevant communicable disease agent or disease as defined under 21 CFR 1271.3(r)(2) by the FDA. Guidance for Industry "Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products, March 2016, updated May 2018**~~

[6~~7~~]In the United States, perform tests for relevant communicable disease agents or diseases as required by the FDA and interpret positive/reactive test results as described in 21 CFR 1271.80(d)(1).

[7~~8~~]Testing shall be performed whenever this information is necessary for the selection and/or clinical use of a cellular therapy or tissue product.