

## Blood DHQ/aDHQ v4.0 References

Donor qualification requirements are located in [21 CFR 630](#) and [21 CFR 640](#) (as revised in the [May 22, 2015 Final Rule](#)) and AABB Standards for Blood Banks and Transfusion Services, current edition.

[AABB Association Bulletin #22-03 Updated Recommendations on Donor Deferral for Use of Antiretroviral Medications for HIV Prevention and Treatment including Long-Acting Injectable PrEP and the Impact on Blood Safety - 9/2022](#)

[Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Blood and Blood Components; Guidance for Industry – 05/2023](#)

[Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry – 05/2023](#)

[Investigational COVID-19 Convalescent Plasma; Guidance for Industry - 1/2022 \(Updated March 13, 2023\)](#)

[Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency; Guidance for Industry - 4/2020 \(updated March 13, 2023\)](#)

[Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry – 12/2022](#)

[Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components; Guidance for Industry \(Updated May 23, 2022\) - 5/2022](#)

[Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis; Guidance for Industry - 12/2020](#)

[Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II \(HTLV-I/II\); Guidance for Industry - 2/2020](#)

[Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Guidance for Industry - 10/2019](#)

[Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry \(This guidance finalizes the draft guidance of the same title dated July 2018.\) - 5/2019](#)

[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; Guidance for Industry \(This document supersedes the guidance of the same title, dated 5/2010.\) - 12/2017](#)

[Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components; Guidance for Industry - 12/2017](#)

[Requalification of Donors Previously Deferred for a History of Viral Hepatitis after the 11th Birthday; Guidance for Industry - 9/2017](#)

[Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus; Guidance for Industry - 1/2017](#)

[Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use - Compliance Policy; Guidance for Industry - 8/2016](#)

[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; Guidance for Industry - 10/2012](#)

[Guidance for Industry: Requalification Method for Reentry of Donors Who Test Hepatitis B Surface Antigen \(HBsAg\) Positive Following a Recent Vaccination against Hepatitis B Virus Infection](#) (This guidance supplements the FDA 1987 Memorandum by providing recommendations for a requalification method for reentry of deferred donors who test repeatedly reactive for HBsAg.) - 11/2011

[Guidance for Industry: Donors of Blood and Blood Components: Notification of Donor Deferral, Small Entity Compliance Guide - 6/2011](#)

[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](#) (This document supersedes the guidance document of the same title, dated August 2007.) - 12/2010

[Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen \(Anti-HBc\) - 5/2010](#)

[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 - 11/2009](#)

[Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods - 12/2007](#)

[Guidance for Industry: Adequate and Appropriate Donor Screening Tests for Hepatitis B; Hepatitis B Surface Antigen \(HBsAg\) Assays Used to Test Donors of Whole Blood and Blood Components, Including Source Plasma and Source Leukocytes - 11/2007](#)

[Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection - 6/2005](#)

[Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components \(including Source Plasma and Source Leukocytes\) to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV - 10/2004](#)

[Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires - 7/2003](#)

[Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine \(Vaccinia Virus\) and Certain Contacts of Smallpox Vaccine Recipients - 12/2002](#)

[Guidance for Industry: Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax - 10/2001](#)

[Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods - Technical Correction February 2001 - 2/2001](#)