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.

Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry
4/2020

Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products - Guidance for Industry
4/2020

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
4/2020

Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency; Guidance for Industry
4/2020

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(This guidance finalizes the draft guidance of the same title dated July 2018.)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

Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry
7/2018

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

Implementation of Pathogen Reduction Technology in the Manufacture of Blood Components in Blood Establishments: Questions and Answers; Draft Guidance for Industry
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

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
5/2016

Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis - Guidance for Industry
(This guidance finalizes the draft guidance of the same title, dated March 2013.) - 9/2014

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

Recommendations for Management of Donors at Increased Risk for Human Immunodeficiency Virus Type 1 (HIV-1) Group O Infection
8/2009

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

Additional requirements may be found in FDA memoranda:

FDA Memorandum, December 4, 1995: Donor Deferral Due to Red Blood Cell Loss during Collection of Source Plasma. (*Supports the Questions related to types of donations*)

FDA Memorandum, July 28, 1993: Deferral of Blood and Plasma Donors Based on Medications. (*Contains requirements for finasteride, isotretinoin, etretinate, human pituitary-derived growth hormone and medical director responsibility to be aware of other drugs*)

FDA Memorandum, April 23, 1992: Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma, and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti HCV) in Blood Establishments. (*Contains requirements related to acupuncture, ear piercing, tattooing in the absence of sterile technique*)