

To: Users of Circular of Information
From: Kendra Reynolds
Director, Quality & Regulatory Affairs
Date: January 23, 2024
Subject: Revised Circular of Information

On March 22, 2022 FDA issued guidance formally recognizing the December 2021 Circular of Information for the Use of Human Blood and Blood Components (Circular) as an “extension of labeling,” which provides specific instructions for the administration and use of blood and blood components intended for transfusion as required in 21 CFR 606.122; this Circular replaces the October 2017 version.

Below are local changes to the December 2021 FDA-Approved Circular of Information, applicable to blood products manufactured by Innovative Blood Resources.

August 2021 – Zika Testing

Blood components collected between 11/13/2017 and 8/11/2021 were tested with a licensed nucleic acid test (NAT) for Zika Virus RNA and found to be nonreactive. (8/2021)

January 2024 – Cryoprecipitate and Plasma Cryoprecipitate Reduced Products

Cryoprecipitated Antihemophilic Factor (AHF) is prepared by thawing whole-blood-derived or PF24 between 1 and 6 C and recovering the precipitate. 1/29/2024

Plasma Cryoprecipitate Reduced is prepared from whole-blood-derived or PF24 after thawing and centrifugation and removal of the cryoprecipitate. 1/29/2024