

To: Users of Circular of Information
From: Kendra Reynolds
Director, Quality & Regulatory Affairs
Date: November 6, 2024
Subject: Revised Circular of Information

On September 25, 2024 the FDA issued guidance formally recognizing the June 2024 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 December 2021 version.

Below are local changes to the June 2024 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)