

# Memo

To: User of Circular of Information

From: Christine Driscoll, Director, Regulatory Affairs and Donna Strauss,  
Executive Director, Core Operations

Date: September 15, 2015

Re: Circular of Information Update

---

In accordance with the AABB's Circular of Information Task Force and liaisons from the Food and Drug Administration (FDA), New York Blood Center is providing an update to the November 2013 version of the *Circular of Information for the Use of Human Blood and Blood Components* (Circular of Information).

The following information is to be considered a part of the Circular of Information as it applies to the *Further Processing* section. New York Blood Center will update the Circular of Information on our website once it is made available. Thank you for your consideration.

## **Pathogen Reduction**

### *Description*

Pathogen reduction is a post-collection manufacturing process intended to reduce the risk of certain transfusion transmitted infections (TTI). Pathogen reduction technology employs a combination of UV irradiation and photosensitizers to damage pathogen nucleic acids, preventing replication and growth.

Psoralen treatment is a specific pathogen reduction technology used to prepare pathogen reduced whole blood-derived pooled plasma, apheresis plasma or apheresis platelets. The platelet source and suspension medium must be in accordance with the pathogen reduction system package insert. Psoralen treatment inactivates a broad spectrum of viruses, as well as gram-positive and gram-negative bacteria, spirochetes, and parasites. In addition, leukocyte activity is reduced. It does not completely inactivate all pathogens; hepatitis A (HAV), hepatitis E (HEV), human parvovirus B19 (B19V), poliovirus, and *Bacillus cereus* spores have shown resistance to the process.

In brief, the inactivation procedure is as follows: A psoralen (e.g., amotosalen) is added to the plasma or platelet product and then transferred into a container that is placed inside an illumination device for UVA treatment. Unreacted psoralen and free photoproducts are subsequently removed with a compound adsorption device.

Following treatment, the plasma product is distributed among two or three plasma bags for use or storage at or below -18 C. Treated pooled whole blood-derived plasma must be placed at -18 C or colder within 24 hours of blood collection. Treated apheresis plasma

must be placed at -18 C or colder within 8 hours of collection. The plasma products must be transfused within 24 hours of thawing.

Treated platelets are transferred to storage container(s) for use or storage at 20 to 24 C with continuous agitation for up to 5 days from the time of collection.

#### *Indications*

Pathogen-reduced blood components have reduced risk for certain types of TTIs and may be used similarly to other products as indicated in the Plasma Components and Platelet Components sections.

#### *Contraindications*

Contraindicated for patients with a history of hypersensitivity reaction to amotosalen or other psoralens.

Contraindicated for neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth less than 375 nm, due to the potential for erythema resulting from the interaction between ultraviolet light and amotosalen.

#### *Side Effects and Hazards*

Psoralen-treated platelets may have an increased risk of causing Acute Respiratory Distress Syndrome (ARDS) compared to conventional platelet components.

In patients with Thrombotic Thrombocytopenic Purpura (TTP) being treated with therapeutic plasma exchange (TPE), amotosalen-treated plasma may cause adverse cardiac events. Patients should be monitored for signs and symptoms of cardiac events during TPE for TTP.

#### *Specific Pathogen-Reduced Components*

The list of blood components that can be further processed using pathogen reduction technology may change as the device manufacturer(s) receives additional approvals from the Food and Drug Administration. A list will be maintained on the AABB web page and additions will be announced in AABB newsletters. Blood components currently suitable for further processing using pathogen reduction technology are listed below. All components resulting from psoralen-based pathogen reduction treatment will bear the labeling attribute "psoralen-treated." Downstream components manufactured at a later time also will bear the labeling attribute "psoralen-treated."

#### Manual collection:

Whole blood-derived plasma

#### Automated collection:

Apheresis Platelets Platelet Additive Solution (PAS-C) Added Leukocytes Reduced Apheresis Plasma