



DONOR HEALTH AND SAFETY CONSIDERATIONS FOR INDIVIDUALS WHO DO NOT IDENTIFY AS MALE OR FEMALE

The Donor Health and Safety Committee (DHSC) has developed the following donor health and safety considerations for the collection of blood from individuals who do not identify as male or female.

1. Predonation Minimum Hemoglobin Value

To protect the health and safety of a donor who does not identify as male or female, consider the use of the most protective minimum hemoglobin of 13.0 g/dL.

2. Estimated Total Blood Volume (EBV) and Apheresis Donor Health and Safety

For specific questions related to apheresis collections of individuals who do not identify as male or female contact the apheresis device manufacturer.

Donor centers may consider the following information:

- To protect the health and safety of a donor who does not identify as male or female, consider the use of the more protective EBV with an automated apheresis device which does not provide a non-binary option for collection. The use of a more protective EBV is intended to protect the health and safety of the donor and reduces the risk of adverse reactions during apheresis collections.
- Some apheresis donor reactions are a function of the volume of blood drawn relative to EBV. Various nomograms for estimating EBV are generally based on an equation using donor height, weight, and gender. EBV calculations are significantly lower for females as compared to EBV calculations for males at the same height and weight.
 - For example, a 150-pound, 5'6" male has an EBV of 4.5 liters and a female of the same height and weight has a 4.1-liter EBV, i.e., a full 10% lower. (See: https://www.mdcalc.com/blood-volume-calculation).
- Donor centers may consider suggesting whole blood donations for a donor who does not identify as male or female if the apheresis device requires the input of gender for the computer calculation of EBV without an override option.

3. Pregnancy – Donor and Patient Safety

The AABB <u>Donor History Questionnaire v4.0 (DHQ v4.0)</u>, formally accepted in FDA <u>guidance</u>, poses <u>all</u> questions to <u>all</u> donors regardless of sexual orientation or gender.

• To protect **DONOR** health and safety, all donors are asked:

DHQ Question #4: "Are you pregnant now?"

This question protects the health and safety of a donor who is pregnant on the day of the donation attempt. For reasons of donor safety, an individual is deferred for 6 weeks from the last date of pregnancy.

 To protect the safety of both the <u>DONOR</u> and the <u>PATIENT</u> all donors are asked the following question for two reasons:

DHQ v4.0 Question 35: "Have you ever been pregnant?"

- 1) This question protects the health and safety of the **DONOR** by identifying a donor who has been pregnant in the past 6 weeks but is no longer pregnant at the time of donation. For reasons of donor safety, an individual is deferred for 6 weeks from the last date of pregnancy.
- 2) This question also protects the health and safety of the **PATIENT** by assessing for a history of pregnancy to mitigate the risk of Transfusion Related Acute Lung Injury (TRALI) caused by HLA antibodies.
 - TRALI is a rare but acute complication of transfusion that is often lifethreatening.
 - The HLA antibodies causing TRALI are most often found in the plasma following pregnancy.
 - This question is used to identify donors who have been pregnant and will need donor testing for HLA antibodies to help prevent TRALI in a **PATIENT** recipient.

For additional information on TRALI risk mitigation, refer to:

- AABB <u>Association Bulletin #14-02</u> TRALI Risk Mitigation for Plasma and Whole Blood for Allogeneic Transfusion
- AABB Technical Manual, 20th edition, Chapter 22 Noninfectious Complications of Blood Transfusion
- AABB Standards for Blood Banks and Transfusion Services, 33rd edition