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Blood Component Quality Control Program for RBC and Apheresis Platelets

Vitalant follows all regulations and recommendations for blood component quality control monitoring. The Vitalant quality control policies and procedures have been reviewed and accepted by the FDA. The SOPs are also reviewed by AABB and other auditors during routine inspections.

Statistical methods are used to ensure adequate numbers of blood components are tested each month for required quality control.

This is in compliance with:

- **AABB Standards for Blood Banks and Transfusion Services, 33rd edition**
  - **Standard 5.7.3.1 Leukocyte Reduction :** Leukocyte-reduced blood and blood components shall be prepared by a method known to reduce the leukocyte number to $<5 \times 10^6$ for Red Blood Cells and Apheresis or Pooled Platelets and to $<8.3 \times 10^5$ for whole-blood-derived Platelets. Validation and quality control shall demonstrate that >95% of units sampled meet this criterion.
  - **5.7.4.9.1 Apheresis Red Blood Cells Leukocytes Reduced:** Apheresis Red Blood Cells Leukocytes Reduced shall be prepared by a method known to ensure a final component containing a mean hemoglobin of $\geq$51 g (or 153 mL cell volume). The sampling plan shall confirm with 95% confidence that more than 95% of units contain $<5 \times 10^6$ leukocytes. At least 95% of units sampled shall have >42.5 g of hemoglobin (or 128 mL red cell volume). Validation and quality control shall demonstrate that these criteria or the criteria specified in the operator's manual are met. FDA criteria apply. Standards 3.3 and 5.7.3.1 apply.
  - **Standard 5.7.4.24 Apheresis Platelets Leukocytes Reduced:** Validation and quality control shall demonstrate with 95% confidence that greater than 75% of units contain $\geq 3.0 \times 10^{11}$ platelets and shall demonstrate with 95% confidence that greater than 95% of units have a pH $\geq$6.2, at the time of issue or within 12 hours after expiration. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $<5 \times 10^6$ leukocytes. FDA criteria apply.

- **FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion, September 2012**

- **FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods, December 2007**

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