



Statement of Compliance

Florida's Blood Centers, Inc's quality system is defined, documented, implemented and maintained in compliance with current good manufacturing requirements and AABB Standards. FBC is accredited by the AABB in donor center activities and immunohematology reference lab (IRL) activities, accredited by the Health Care Financing Administration (HCFA), licensed by the State of Florida Agency for Health Care Administration (AHCA), and licensed and registered by the U.S. Food and Drug Administration, U.S. Department of Health and Human Services.

FBC's Laboratory Director approves all methods used by each laboratory; where applicable FDA-licensed or approved test kits and reagents are used. Performance of testing and interpretation of results are in accordance with manufacturer's instructions. As required by CLIA rules in 42 CFR 493, all testing personnel are qualified and deemed competent to perform high complexity testing and the laboratory participates in a proficiency testing program for each tested analyte. FBC has agreements in place for outsourced activities and monitors compliance with these agreements through supplier qualification audits.

Statement of Compliance with Bacterial Detection Requirements

In compliance with AABB Standards for Blood Banks and Transfusion Services 5.1.5.1 for a method to detect bacteria in platelet components, all Florida's Blood Centers platelets, pheresis and whole blood derived pre-pooled platelets are cultured using the Biomerieux BacT/Alert Microbial Detection System, an FDA approved testing method.

Richard R Gammon, M.D.
Medical Director