

SAN DIEGO BLOOD BANK CAPABILITIES TO SUPPORT RESEARCH AND CLINICAL STUDIES

The San Diego Blood Bank is well known in the area of blood banking, supplying not only blood needed for transfusion, but is also now expanding into providing blood and blood derived products, and services to support research and clinical studies.

SDBB has the following capabilities in addition to standard blood-banking:

- **Cell Therapy Research Laboratory**
- **Development and Research Services (DRS)**
- **Reference Laboratory Testing and Procedures**
- **A large state of the art, clean room/lab facility**
- **Clinical and Regulatory Certifications**

A. Types of draws / blood collections:

- **Whole Blood:**
 - 500mL whole blood collected in CPD anticoagulant plus AS-1 Red Cell Additive
 - 500mL whole blood collected in CPDA-1
 - 450mL whole blood collected without anticoagulant, for production of serum
- **Apheresis:**
 - Single donor platelets
 - Concurrent plasma by apheresis
 - Concurrent red cell by apheresis with AS-3 Red Cell Additive Solution
 - Double red cells by apheresis (Trima or Haemonetics) with AS-3 Red Cell Additive Solution
 - Plasmapheresis (plasma only donation on Trima)
- **Specials Apheresis:**
 - Leukapheresis for MNC's (healthy donors)
 - Leukapheresis for MNC's (on donors/patients selected by researcher)
 - Leukapheresis for Granulocytes

B. Blood Products Collected by either Whole Blood or Apheresis:

- Whole blood
- Red Blood Cells
- Plasma from either whole blood or apheresis donations
- Serum from whole blood donations
- Platelets only from apheresis
- Cryoprecipitate Singles and Cryoprecipitate Pools (5 single units / pool)
- Buffy Coats (single soft centrifugation, premium 50mL product as source WBC's)
- LRS-WBC's (8 – 9mL product as source of WBC's)

C. “5th Tube” or extra tube collections (we can collect 1 or more extra tubes per each WB donation to provide to researchers):

- EDTA (purple top)
- Clot tube (red top)
- Clot tube with serum separator
- ACD tube (yellow top)
- Heparin tube (green top)
- Citrate tube (blue top)
- Any other special order tube provided by researcher or ordered by SDBB
- Process tubes upon request for added charges (spin, separate, aliquot, freeze)
- Provide small numbers of tubes or large numbers over time
- Collect tubes by race, gender, age, etc
- Provide demographic info at extra cost per item on each tube

D. Testing (for requirements by FDA for donor suitability screening):

- | | |
|----------|---|
| • ABO/RH | ABO & Rh Blood Groups |
| • HBsAg | Hepatitis B Surface Antigen |
| • HIV | Antibody to Human Immunodeficiency Virus 1 / 2 |
| • HCV | Antibody to Hepatitis C Virus |
| • NAT | Nucleic Acid Testing for HIV 1 / HCV |
| • NAT3 | Nucleic Acid Testing for HIV1 / HCV / HBV |
| • HTLV | Antibody to Human T-lymphotropic Virus I and II |
| • HBC | Antibody to Hepatitis B Core |
| • STS | Syphilis Test |
| • WNV | Nucleic Acid Testing for West Nile Virus |
| • ABS | RBC Antibody Screen |
| • CMV | Antibody to Cytomegalovirus |
| • TCRZ | Antibody to Trypanosoma cruzi (Chagas disease) |

E. QC lab testing:

- Complete CBC
- CBC with Differential
- WBC counts on leukoreduced blood products
- Use of the flow cytometer (limited use based on validation of protocols, can be expanded)
- Equipment validation (validation writing and execution for centrifuges, refrigerators, freezers, RT incubators, thermometers, scales, temperature monitoring systems, etc)

F. Component Production (cGMP Manufacturing):

- Centrifuges that can be operated at selected refrigerated temperatures or at Room Temperature
- Sterile tubing heat sealing
- Sterile tubing welders or connection devices to attach bags in a closed system
- Cell Washers to perform saline wash of cellular components
- Blast or “flash” freezers for rapid freezing of plasma, serum or other components
- Freezers for -30°C frozen storage
- Freezers for -80°C Ultra Cold frozen storage
- Laminar flow hood to provide aseptic work space at the bench
- Dockable leukoreduction filters for RBC’s

G. Reference Laboratory Capabilities

- Full reference laboratory testing service
- Cross-matching
- Antibody identification
- Problem resolution
- Rare RBC unit frozen inventory
- DNA extraction from whole blood and limited PCR testing, currently related to blood typing.

H. Cell Therapy Research

- Harvest, process and store cord bloods
- Ficoll separation of MNC’s.
- Fresh unprocessed cord blood units consented for research use
- Frozen processed cord blood units consented for research use
- Cord blood plasma consented for research use
- IDM, CFU, TNC, CD34 and sterility analyses and testing of cord blood units

I. Clean room/lab facility

- Space available for expansion of research facilities
- Opportunity for incubation of start-up companies conducting blood-based research.

J. Clinical and Regulatory Certifications

- CLIA Certification
- FDA (cGMP) registered facility
- EU certification
- AABB accredited