## 

**Cellular Therapies Redefined** 

A portfolio of products and services brought to you by:





## Celluvative

## cell·u·va·tive /'sel-yōō-vā-tiv/ noun

- 1. a partnership between BloodCenter of Wisconsin and San Diego Blood Bank created to enable advances in cellular therapies
- 2. a portfolio of products and services combining properly sourced biological material from diverse populations with decades of clinical and contract laboratory medicine expertise

## **Your Cellular Therapies Partner**



## Comprehensive

Celluvative provides high quality blood and cell products, esoteric diagnostic testing, and clinical trial support to the biopharma, diagnostics, and medical device industries, as well as academic researchers.

Our portfolio includes:

· Blood product collection

Cord blood and tissue, whole blood, platelets, plasma, leukocytes, peripheral blood, mononuclear cells

- · GMP cell manufacturing
- · Sterility and infectious disease testing
- · Donor recruitment for investigational studies
- · Clinical diagnostic testing

HLA, malignant hematology, immunohematology, hemostasis, platelet neutrophil immunology, and hematology genetics

- 510(k), IVD, and therapeutic clinical trial support
- Custom assay development and validation
- Regulatory pathway consultation including protocol evaluation
- · Medical and technical consultation

## **Expertise**

Whether you are developing a treatment, therapy, drug, or medical device our Medical and Scientific directors offer unmatched expertise to ensure that product and process requirements all align to meet desired outcomes on time and within budget.

## Our experts in

Cell Sorting, Enrichment, Analysis, Banking

Cell Processing

Donor Recruitment

Hematology Diagnostics and Genetics

**HLA Immunology and Typing** 

Quality/Regulatory Processes

Transfusion Medicine and Immunohematology

## Help you with

Access to Characterized Samples

Clinical Interpretations and Medical Consultations

Custom Assay Development and Validation

**Custom Reporting** 

IRB Submission

Pre-clinical to Phase IV

## Quality

Celluvative products are backed by rigorous regulatory compliance and a continuous improvement culture. Our stringent quality managements systems combined with state-of-the-art facilities produce results you can trust.

- FDA Licensed
- · CLIA, CAP, AABB, FACT, ASHI, NY, CA Accredited
- · GLP, GMP and GCP Compliant
- Six Sigma and Lean

## Celluvative Products

## **Cord Blood Products**

- Fresh Cord Blood, Processed or Unprocessed
- Frozen Cord Blood, Processed
- Frozen Cord Blood Plasma
- CD34<sup>+</sup> Enriched Cell Fractions from Cord Blood

## Whole Blood Products\*

- Whole Blood
- Red Blood Cells
- Platelets

- Leukopheresis for MNCs or Granulocytes
- Plasma, Serum and Cryoprecipitate from Whole Blood
- Ficoll Enriched MNC Isolates from Whole Blood

## **Cellular Analysis**

- ABO Typing
- Antibody Testing
- Blood Products Sterility
- CBC

- CD34<sup>+</sup> Enrichment
- CFU Assav
- Flow Cytometry Analysis for Various CD Markers
- Infectious Disease Screening
- TNC Assay

## **Cell Culture Products**

- Clearsate: A cGMP-manufactured high quality platelet lysate media supplement offering cost reduction due to use at lower concentration and less frequent feeding. Human-based material, fully tested according to FDA regulations with no animal-related immunogenicity and no mycoplasma or endotoxin contamination.
- \* Select products can be supplied under cGMP guidelines to support clinical use on a custom basis.

# Celluvative Clinical and Contract Research Services

## **CLINICAL DIAGNOSTIC TESTING**

## **HLA and Transplantation**

- HLA Antibody Detection
- HLA Antibody Identification Class I & II
- HLA Typing High, Intermediate & Low Resolution – A,B,C,DP,DQ,DR
- Disease Association A29, B27, B51, Narcolepsy, Celiac
- Pharmacogenetic Risk B\*15:02, B\*57:01
- KIR Genotyping

- Cell Enrichment for Chimerism Testing
- · Chimerism Testing
- Erythroid Chimerism

## **Malignant Hematology**

- ASXL1 Mutation Analysis
- BCR-ABL Breakpoint Analysis
- BCR-ABL Kinase Mutation Analysis
- BCR-ABL Quantitative Analysis
- CALR Mutation Analysis
- CEBPA Mutation Analysis
- DNMT3A Exon 23 Sequence Analysis

- FLT3 Mutation Analysis
- IDH1 & 2 Exon 4 Mutation Detection
- JAK2 Exon 12 Mutation Analysis
- JAK2 V617F Mutation Analysis
- KIT D816 Mutation Analysis
- KIT Exons 8 and 17 Mutation Analysis
- MPL Exon 10 Mutation Analysis
- NGS HemeOnc Panel
- NPM1 Mutation Analysis
- NRAS Mutation Analysis
- RUNX1 Acquired Mutation Analysis
- TP53 Mutation Analysis
- WT1 Mutation Analysis

## Non-Malignant Hematology

- Non-Malignant Hematology
- Antiphospholipid Antibody Detection
- ADAMTS13 Activity, Inhibitor & Antibody
- aHUS/DDD Genetic Evaluation
- Anticardiolipin Antibody
- Antithrombin Activity & Antigen
- Drug-Dependent Neutrophil Antibody
- Drug-Dependent Platelet Antibody

- Factor II, V, VII, VIII, IX, X, XI,
   °XII Activities & Inhibitors
- Fibrinogen Activity & Antigen
- Hematology Genetics –
   ELANE, HAX1, MPL, MYH9,
   RUNX1, WAS, Factor V Leiden,
   Prothrombin Gene Mutation,
   Factor VIII, Factor IX, von
   Willebrand Factor
- Heparin-Dependent Platelet Antibody
- Lupus Anticoagulant

- Neutrophil Antibody Screen & Identification
- Platelet Antibody Screen & Identification
- Platelet Autoantibodies
- PNH (Paroxysmal Nocturnal Hemoglobinuria)
- Porcine FVIII Inhibitor
- Protein C Activity & Antigen
- Protein S Activity & Antigen
- Serotonin Release Assay
- von Willebrand Disease
   Evaluation

# Celluvative Clinical and Contract Research Services

## **CLINICAL DIAGNOSTIC TESTING CONTINUED**

## **Transfusion Medicine**

- Red Cell Genotyping
- Antibody Identification & Screen
- Antigen Typing

- Autoimmune Hemolytic Anemia Evaluation
- Drug Dependent RBC Antibody Study
- Partial D Analysis
- Transfusion Reaction Evaluation

### **CELLULAR ANALYSIS**

- ABO Typing
- Antibody Testing
- Blood Products Sterility
- CBC

- CD34<sup>+</sup> Enrichment
- CFU Assay
- Flow Cytometry Analysis for Various CD Markers
- Infectious Disease Screening
- TNC Assay

### RESEARCH USE ONLY TESTING

- Autologous In Vivo Recovery and Survival Monitoring (red cells and platelets)
- ATP

- P-selectin (CD62P) Expression
- PAC-1 Expression
- Plasma Hemoglobin
- Prothrombin Fragment F1+2
- Thrombin/Anti-Thrombin III Complex
- 2.3 DPG

### **CLINICAL TRIAL SERVICES**

- · Project management
- Study design
- Custom reporting
- Direct data transfers
- Sample storage
- IRB submission
- Donor recruitment
- Assay design and validation
- Clinical interpretations and Medical consultations

## Celluvative

## **Cellular Therapies Redefined**

BloodCenter of Wisconsin and San Diego Blood Bank introduce Celluvative, a portfolio of products and services designed to enable advances in cellular therapies. These leaders in cord blood banking and diagnostic laboratory testing combine properly sourced biological material, from diverse populations, with decades of clinical and contract laboratory medicine experience. Celluvative will serve biopharma, diagnostics and medical device industry, and academic researchers with blood and cell products, esoteric diagnostic testing, and clinical trial support.

We offer over 300 products and services ranging from ready to ship to fully customized

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