

SAMPLE PROCESSING LABORATORY SERVICES

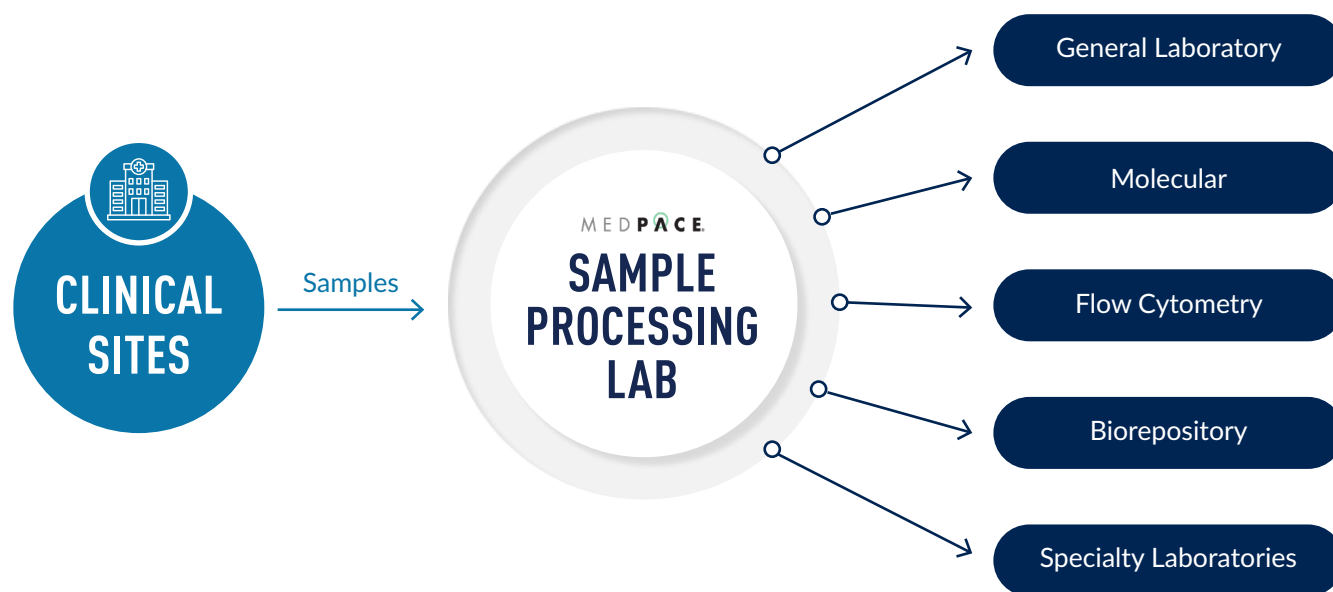
GLOBAL EXPERTISE IN CONTROLLED SAMPLED PROCESSING

As a full-service contract research organization (CRO) model, Medpace offers experienced Sample Processing Laboratory (SPL) teams at our central laboratories across the world (Belgium (BE), Singapore (SG), China (CN) and the United States (US)), overseen by PhD-level scientists. Medpace has over 20 years of experience in processing samples.

SPL provides expertise in the controlled isolation of samples prepared and/or treated to make them suitable for downstream analyses. This involves sample aliquoting and storage, isolation and purification of peripheral blood mononuclear cells (PBMCs), bone marrow mononuclear cells (BMMCs), leukocytes from various material sources, such as whole blood, bone marrow, plasma, serum, bone marrow aspirate (BMA), urine, and stool.

Centralized testing in sample processing is crucial to ensure consistency, reduce variability, and improve the reliability of results in clinical trials. By processing all samples with standardized methods and equipment, it minimizes errors and facilitates accurate data analysis, leading to more reliable results.

Our SPLs provide the foundation for accurate and reliable downstream analysis by preparing samples in a controlled and standardized manner.



SAMPLE PROCESSING AND ANALYSIS

Standardized instrument settings, global Standard Operating Procedures (SOPs) and shared acquisition templates on the instrument are applied per process to globally harmonize standards, ensuring consistently high yields, viability, and recovery.

The lab employs various techniques to isolate, purify, and concentrate specific components from the sample, depending on the intended analysis. This might involve samples handling, cryopreservation, analysis in addition to:

- PBMCs Processing
- BMMCs Processing
- Leukocytes Processing



The SPL can process samples from different matrices (e.g. whole blood, bone marrow aspirate (BMA) using a variety of tube types and anticoagulants (e.g. Cell Preparation tube - CPT™, with sodium heparin and sodium citrate anticoagulants, sodium heparin, lithium heparin, EDTA and acid citrate dextrose (ACD)) or Sponsor-approved tube types. SPL also welcomes custom validation of Sponsor methods.

All procedures are performed with adherence to aseptic technique. Sample and/or reagents are handled following strict guidelines to ensure sterile under the biosafety cabinet.

INSTRUMENTATION

The Cytex® Guava® Muse® cell analyzer is implemented worldwide at BE, SG and US Medpace central laboratories. The instrument is a laser-based fluorescence detector equipped with a microcapillary fluorescent technology to detect cells using optimized kit for count and viability.

To guarantee uninterrupted analysis and data continuity, each of our laboratories is equipped with at least two fully validated instruments. In the unlikely event of a technical or quality issue, a back-up instrument—cross-validated across laboratories—can be immediately activated. This redundancy underscores our commitment to operational excellence, data consistency, and meeting the expectations of our clients without compromise.

QUALITY CONTROLS

During PBMC isolation, the lab performs quality control of the instrument, measures cell count yield, and viability and ensure the purity, concentration, and integrity of the extracted materials.

All processes are performed following SOPs to globally harmonized standards ensuring consistently high yields, viability, and recovery across facilities. Our staff members are highly trained and regularly participate in external proficiency testing for PBMC processing which is performed through the Integrated Biobank of Luxembourg.



STORAGE AND SHIPPING

Post isolation, PBMC samples can be freshly analyzed or stored in ultralow (e.g. -75°C +/- 10°C freezers) or liquid nitrogen (<-145°C dewar tanks) storage units, under appropriate conditions, to maintain their quality at one of Medpace's global biorepositories for further batch analysis.

Custom aliquoting requirements are implemented into clinical trials as appropriate.

If Medpace is not performing the downstream testing, it provides services to ship frozen PBMCs on dry ice or nitrogen cryo-shippers to other specialty labs.

DATABASE MANAGEMENT

Data obtained by our SPL can be seamlessly integrated into a dedicated study portal within the ClinTrak® Lab system. This ensures secure and real-time access to study data for both the Sponsor and the CRO, facilitating transparency and efficient project oversight.

Results generated by Cytex® Guava® Muse® cell analyzers and undergo a thorough review by experienced and qualified laboratory technologists. After review is completed, data is validated, and the results are released to view on ClinTrak Lab, ensuring the highest standards of data integrity and reliability.

PROCESSING SERVICES

PROCESS	INITIAL MATRIX	TUBE	METHOD	DOWNSTREAM ANALYSIS
PBMCs isolation	Whole blood	- Ethylenediaminetetraacetic acid (EDTA) - Acid-citrate-dextrose (ACD) - Sodium heparin - Lithium heparin - Sodium heparin or sodium citrate in Cell Preparation Tubes (CPT™)	- Ficoll-Paque in SepMate™ tubes - Cell Preparation Tubes (CPT™) - Accuspin	- Molecular - Flow Cytometry - Cell Culture - Immunoassays (e.g. ELISA, ELISPOT)
BMMCs isolation	Bone Marrow aspirate (BMA)	- EDTA - ACD - Sodium heparin - Sodium citrate - Lithium Heparin	Ficoll-Paque in SepMate™ tubes	- Molecular - Flow Cytometry - Cell Culture - Immunoassays (e.g. ELISA, ELISPOT)
Leukocyte isolation	- Whole blood - BMA	EDTA	- Red Blood Cell (RBC) lysis - Double-density gradient centrifugation	- Molecular - Flow Cytometry - Cell Culture
Plasma isolation/purification	Whole blood	Streck Cell-Free DNA BCT	High-speed centrifugation (~16,000 × g)	- Circulating tumor DNA (ctDNA) - Cell-free DNA (cfDNA) extraction
Buffy coat isolation	Whole blood	Streck Cell-Free DNA BCT	Centrifugation	- Molecular - Flow Cytometry - Cell Culture
Cell counting and viability assessment	- Freshly isolated cells - Cryopreserved cells	Microcentrifuge tubes	Guava® Muse® Cell Analyzer	- Molecular - Flow Cytometry - Cell Culture - General Laboratory



PROCESS	INITIAL MATRIX	TUBE	METHOD	DOWNSTREAM ANALYSIS
Samples aliquoting	• Plasma • Serum • Whole blood • BMA • Urine • Stool and other	• Cryovials	• Multiple aliquots for storage or distribution • Manual or semi-automated pipetting systems	• Molecular • Flow Cytometry • Cell Culture • General Laboratory
Preparation and distribution of correlation samples	• Plasma • Serum • Whole blood • Urine	• 15mL or 50mL conical tubes	• Multiple aliquots for storage or distribution	• Chemistry • Immunology • Hematology • General Laboratory
Samples Cryopreservation, Thawing and recovery	• Whole blood • BMA	• Cryovials	• Freezing and long-term storage using controlled-rate freezing	• Molecular • Flow Cytometry • Cell Culture
Controlled slow freezing	• Whole blood	• PAXgene Blood DNA or RNA Tubes	• Slow and progressive decrease of the temperature to ultra-low storage (-80C)	• Biorepository
Reagents preparation/aliquoting	• Multiple chemical reagents	• Variable	• Reagent dilution, mixing and preparation • Final aliquots dispensed to ensure consistency and traceability, with assigned new lot numbers and expiry dates • Manual or Semi-Automated Pipetting Systems	• Logistics • Clinical sites

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

