

PERIPHERAL BLOOD MONONUCLEAR CELL (PBMC) PROCESSING SERVICES

Human peripheral blood mononuclear cells (PBMCs), isolated from anticoagulated blood for use in preclinical and clinical research, are any blood cell with a round nucleus including lymphocytes, monocytes, natural killer cells (NK cells) or dendritic cells. The analysis of immune cells has gained increasing significance in the past years due to their insights into the immune response patterns, making them valuable biomarkers for clinical use and precision medicine.

The Medpace central laboratory facilities situated in Belgium, Singapore, and the United States possess the capabilities to process PBMCs from whole blood.

In clinical trials, blood sample transportation to central laboratories can increase the time between blood collection and PBMC isolation. To ensure the PBMCs' integrity, Medpace built a robust and comprehensive global courier network that efficiently transports samples from clinical sites to the nearest Medpace laboratory facility.

PBMC PROCESSING METHOD

Medpace sample processing laboratories validated different PBMC processing methods to meet the needs of Sponsors. Existing methods for isolating PBMCs include using SepMate™ Tubes and Cell Preparation Tubes™ (CPT).

SepMate™ Tubes

SepMate™ Tubes are innovative tubes that facilitate and enable consistent PBMC isolation by density gradient centrifugation:

- SepMate™ Tubes simplify the isolation protocol for blood received in another vacutainer (K2 EDTA, lithium-heparin, sodium-heparin).
- Suggested for bone marrow aspirate and whole blood processing.
- Upon receipt at Medpace, the blood is transferred to SepMate™ Tubes that have a separating insert that allows users to quickly layer blood over the density gradient medium for good separation of PBMCs from red blood cells.
- SepMate™ Tubes allow for more expedient processing of PBMCs than the traditional Ficoll® overlay process and minimize variability between users.

Cell Preparation Tubes™

Cell Preparation Tubes™ (CPT) are evacuated tubes for direct whole blood collection and following separation of mononuclear cells:

- CPT™ are straightforward for PBMC isolation and require limited sample handling.
- These provide a single-step, standardized method for the isolation of PBMCs.
- CPT™ are collected at the site, mixed 8-10 times, centrifuged within 2 hours from collection at site, and submitted unopened, ambient to Medpace.
- Blood is drawn directly into CPT™ preloaded with anticoagulant (Na Heparin or Na Citrate), with a Ficoll™ Hypaque™ density fluid and polyester gel. The gel barrier keeps PBMCs separate.
- The processing time is shorter than traditional Ficoll-Paque method.
- Medpace provides an [instructional collection video](#) for clinical sites to follow.

PBMC QUALITY CONTROLS

During PBMC isolation, cell count yield, purity, and viability are monitored. Cell yield range is typically 0.8 to 3.2 x 10⁶ cells/mL of blood.

Medpace is well qualified to perform PBMC isolation. To ensure quality and standardization, we participate in external proficiency testing for PBMC processing which is performed yearly through the Integrated Biobank of Luxembourg.

Post isolation, the isolated PBMC samples can be used fresh, for downstream real-time testing (e.g. Flow Cytometry assays) or kept in ultralow (e.g. -75°C +/- 10°C freezers) or liquid nitrogen (<-145°C dewar tanks) storage units at one of the Medpace global biorepositories. Custom aliquoting requirements are implemented into clinical trials as appropriate.

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

TESTING APPLICATIONS WITH PBMC

Assays using PBMCs can be categorized into:

- Assays not requiring viable cells
 - DNA-based genomic analysis
 - RNA-based gene expression analyses
- Assays requiring intact or viable cells, such as immunophenotyping and functional assays
 - Functional assays
 - Chromosome-based analysis (chromosome aberration assays) for the detection of genotoxicity, chemotaxis assays
 - Natural killer (NK) cytotoxicity assays
 - Antigen-specific response assays such as lymphocyte proliferation assays, intracellular cytokine staining
 - ELISPOT is important for vaccine studies, enabling quantification of IgG-secreting B cells and the assessment of memory B cell activity
 - Flow cytometry
 - Advantages include the ability to perform batched analysis on stable samples
 - Batching helps avoid potential run-to-run effects and is more economical for Sponsors, reducing reagents consumption and labor time by minimizing multiple runs

For more information on Medpace and PBMC processing, please visit our [website](#) or download the whitepaper [“Processing Peripheral Blood Mononuclear Cells \(PBMC\) for Clinical Studies: Points to Consider for Quality Results.”](#)

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.

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