

PERIPHERAL BLOOD MONONUCLEAR CELL (PBMC) PROCESSING SERVICES

Peripheral blood mononuclear cells (PBMCs), including monocytes and lymphocytes, are often isolated from anticoagulated blood for use in preclinical and clinical research. The Medpace central laboratory facilities situated in Belgium, Singapore, and the United States possess the capabilities to process PBMC from whole blood and BMMC from bone marrow. To ensure the PBMCs' integrity, it is crucial to transport the samples promptly to one of Medpace's regional central laboratory locations. Medpace has a robust and comprehensive global courier network that efficiently transports samples from clinical sites to the nearest Medpace laboratory facility.

PBMC PROCESSING METHOD

Existing methods for isolating Peripheral Blood Mononuclear Cells (PBMCs) include using Cell Preparation Tubes (CPT), SepMate™ Tubes, and the conventional Ficoll overlay method.

Cell Preparation Tubes (CPT)

Cell Preparation Tubes (CPT) are straightforward for PBMC isolation and require limited sample handling.

- CPTs are preloaded with anticoagulant (Na Heparin or Na Citrate), cell separation matrix and polyester gel.
- The benefit is that blood is drawn directly into the tube that contains all of the required anticoagulants and separation materials without having to use Ficoll density gradient.
- CPT tubes are collected at the site, mixed 8-10 times, centrifuged, and submitted unopened, ambient to Medpace Central Labs. A barrier keeps PBMCs separate.
- This method yields good cell viability and a good response to super antigen stimulation.
- The processing time is shorter than traditional Ficoll-Paque method.
- Medpace provides an [instructional collection video](#) on Medpace.com for clinical sites to follow.

Sepmate™ Tubes

SepMate™ Tubes are used when blood is received in another vacutainer like K2 EDTA, lithium-heparin, sodium-heparin, or sodium-citrate.

- K2 EDTA collection tubes are less expensive than CPT tubes. Depending on downstream testing, sponsors may have other reasons for choosing K2 EDTA.
- Upon receipt at Medpace the blood is transferred to SepMate™ tubes that contain a plastic insert that is filled with ficoll.
- SepMate™ tubes have a separating insert that allows for good separation of PBMCs from red blood cells.
- SepMate™ tubes allow for more expedient processing of PBMCs than the traditional Ficoll overlay process.

Ficoll-Paque Method

Ficoll-Paque method of isolation takes advantage of the differences between PBMC and red blood cell density.

- This traditional Ficoll overlay method can be performed at Medpace upon the Sponsor's request.
- Anticoagulation tubes (EDTA, lithium-heparin, sodium-heparin, sodium-citrate whole blood) are collected at sites and shipped to Medpace for further processing.



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 are stored in ultralow storage units (e.g. -75°C +/- 10°C freezers or <-145°C liquid nitrogen dewar tanks) at one of Medpace's global biorepositories, or PBMC samples are used fresh, for downstream real-time testing (Flow Cytometry). If Medpace is not performing the downstream testing, Medpace provides services to ship frozen PBMCs on dry ice or nitrogen cryoshippers to other specialty labs.

TESTING APPLICATIONS WITH PBMC

Assays using PBMCs can be categorized into assays not requiring viable cells, such as DNA-based genomic analysis and RNA-based gene expression analyses, and assays requiring intact or viable cells, such as immunophenotyping and functional assays.

Functional assays include 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, and enzyme-linked immunospot (ELISPOT) assays. ELISPOT is important for vaccine studies, enabling quantification of IgG-secreting B cells and the assessment of memory B cell activity.

Medpace laboratories use PMBCs in flow cytometry when the cell type supports it. The advantages of this approach include the ability to perform batched analysis on stable samples. Batching helps avoid potential run-to-run effects and is more economical to Sponsors by reducing reagents and labor time on performing 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.

