ALTASCIENCES

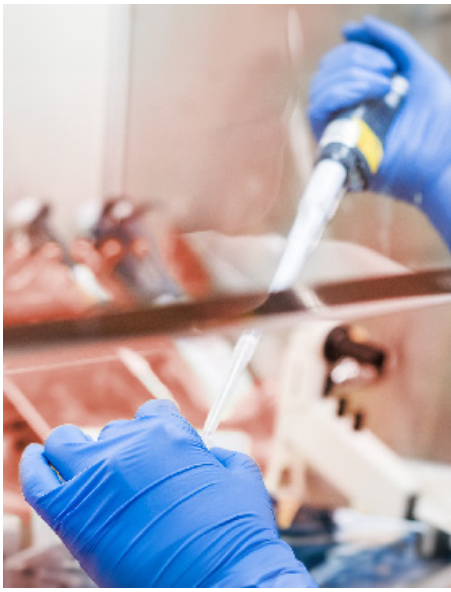
FLOW CYTOMETRY AND PERIPHERAL BLOOD MONONUCLEAR CELL (PBMC) ISOLATION

Bioanalytical support is essential in clinical trials for accurate and timely assessment of primary, secondary, and exploratory endpoints involving immunological markers and cellular responses.

Our clinical facilities are integrated with state-of-the-art flow cytometry laboratories, equipped with advanced platforms and staffed by an in-house team of experts proficient in regulated cellular analysis. We specialize in developing and validating assays tailored to your specific program requirements, ensuring efficient, timely, high-quality support for your clinical trials.

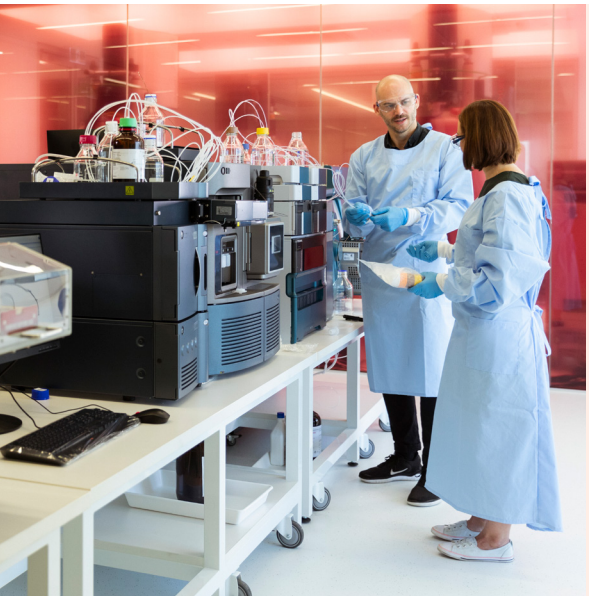
BENEFITS OF FLOW CYTOMETRY IN YOUR CLINICAL TRIALS

Flow cytometry analysis used in clinical trials for **exploratory and secondary endpoints** provides information on counts, cellular properties, and cellular classification. Primarily **used to identify and measure cellular biomarkers within complex subpopulations**, it enables rapid, in-depth analysis of the immune system, such as immunophenotyping, activation, exhaustion, proliferation, or phosphorylation.



Flow cytometry is used for receptor occupancy (RO) assays to quantify therapeutic drug binding to cell surface targets. We ensure reliable, high-quality RO data through meticulous assay design and execution. By analyzing RO results alongside pharmacokinetic (PK) data, we enhance our understanding of the drug profile following administration. This PK/RO modeling correlates drug concentration with its effects, providing comprehensive insights into drug behavior.

We actively provide comprehensive validation services to meet regulatory requirements emphasizing **fit-for-purpose validation (FFPV)** tailored specifically to your program's needs.



THE CRUCIAL ROLE OF PBMC ISOLATION IN CLINICAL TRIALS

Flow cytometry assays can utilize either whole blood or cryopreserved PBMCs—an essential cell population with applications in numerous fields of clinical research. Often a key focus on immunology, PBMCs can be used for many different purposes, such as infectious diseases and autoimmune disorders.

The protein expression levels of PBMCs provide valuable insights into disease states and potential biomarkers. Through harvesting, processing, and analysis of PBMCs, our researchers can **evaluate immune responses** to therapeutic agents, and gain a **deeper understanding of immune system functions**, pre-dose, post-dose, and throughout other integral stages of testing.

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OPTIMIZING FLOW CYTOMETRY ANALYSIS WITH CRYOPRESERVED PBMCs

We excel in using cryopreserved PBMCs as a matrix for flow cytometry. Our processes ensure **cell viability and protein stability**, which is directly linked to the quality of the data generated—especially in rare cell populations, such as deep immune cell subsets.

Isolation and cryopreservation processes require two core components: **quality and timely sample processing**. Our clinics and laboratories in the U.S.A. and Canada are located in close proximity to ensure seamless transitions and swift sample analysis.

Montréal Clinic

~15-minute drive
to our bioanalytical laboratory* in Greater Montréal, QC

*on-site testing can be arranged.

Kansas Clinic

~2-hour drive
to our bioanalytical laboratory* in Columbia, MO

Los Angeles Clinic

In-house
dedicated laboratory to process PBMCs; samples can be shipped to laboratories as needed, based on validated stability data.

2 hours to our Seattle laboratory

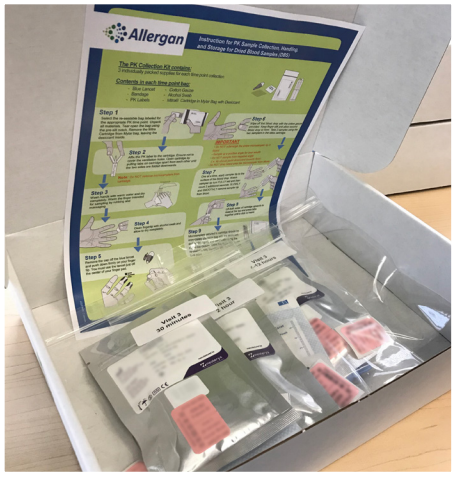
Flow cytometry analysis is also conducted in whole blood, offering several advantages, including:

- absolute counts of blood subpopulations
- fast assay procedures
- ability to meet short stability time frames for certain rare cell populations, or those susceptible to cryopreservation

For samples susceptible to cryopreservation process, such as RO assessment, we can offer **custom assay design**; while for samples with a narrow window of stability, we design panels in whole blood and have an array of strategies to extend sample stability. Our off-the-shelf whole blood TBNK panel has been validated for 11 days of stability, allowing for appropriate analysis from multiple clinical sites worldwide.

THE BENEFITS OF OUR CLINICAL SAMPLE KITS

Our custom clinical sample kits are adapted to meet the specific requirements of your study, ensuring **sample stability** during transport. These kits eliminate the need for a central laboratory, significantly reducing turnaround time, especially for stability-sensitive endpoints. By utilizing our sample kits, you can keep samples within our tracking system, ensuring a **seamless transition from the clinic to the laboratory,** for **rapid analysis and reporting**.



For more information on our flow cytometry capabilities, consult this fact sheet:

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