International PBMC Network

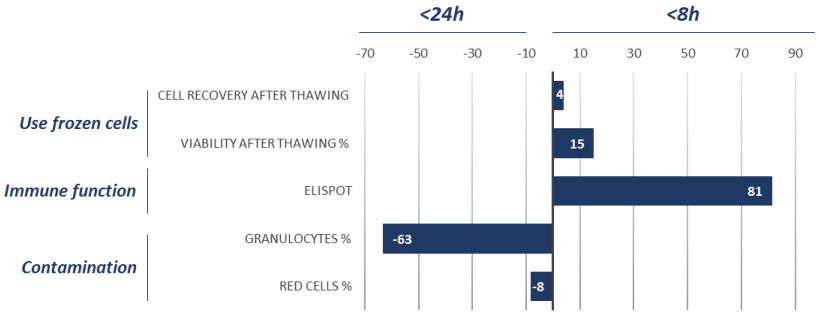
Using peripheral blood mononuclear cells (PBMC) for cell-based immunological assays is a powerful tool to understand and characterize immune mechanisms related to immunotherapies. With many 1000's of ongoing clinical trials in progress worldwide, monitoring immune functions to validate clinical relevance of treatments is a critical and major challenge. Preserving cell integrity to provide high quality samples is consequently a necessity.

To address this critical need, ABL has developed a network of international laboratories for timely and high quality PBMC processing & storage using harmonized SOPs and training. Our priority is to offer a standardized, qualified and controlled sample processing method to preserve cell integrity and cell immune functions across broad geographic regions. To accompany this service, ABL offers a wide range of scientific and technological solutions to monitor the immune response within clinical trials.

Performance of the method based on rigorous scientific data

ABL has set-up an internal program to optimize and validate a standardized method for PBMC processing taking into account:

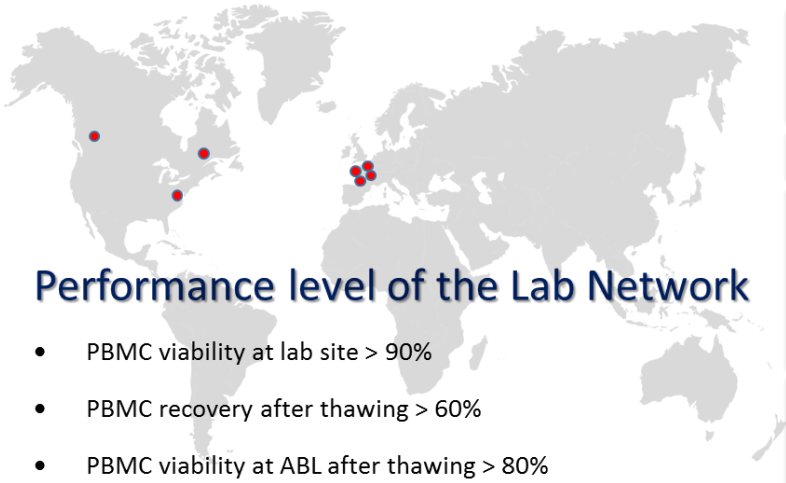
- PBMC counts per mL of blood after isolation
- Cell viability and cell recovery after PBMC freeze/thaw cycles
- Enumeration of Immune cells (T, B and NK cells)
- PBMC Purity (granulocytes & red blood cells contamination)
- Functionality of PBMC as measured by ELISpot IFN-γ



Impact of PBMC time-processing on cell integrity (Cell viability and cell recovery), cell purity (Granulocytes & red blood cells contamination) and cell immune capability (ELISpot). Processing PBMC within less than 8 hours following venipuncture favors cell integrity and cell immune functions with the added benefit of limiting risk of contamination. Mean results from three independent testing series.

Quality assessment program

ABL has set up a qualification process for selection, training and qualification of laboratories involved in its PBMC Network. Seven PBMC reference laboratories are currently available in Canada, USA and Europe. New laboratories can be implemented within 3 to 6 months.



Performance level of the Lab Network

- PBMC viability at lab site > 90%
- PBMC recovery after thawing > 60%
- PBMC viability at ABL after thawing > 80%
- High polyclonal immune response analysis by ELISpot assay

Laboratory pre-selection
- Confidentiality agreement
- Lab capabilities' questionnaire

Laboratory approved by sponsor

Audit & technical Training on site
- PBMC processing under ABL supervision
- Unassisted PBMC processing
- Quality environment evaluation

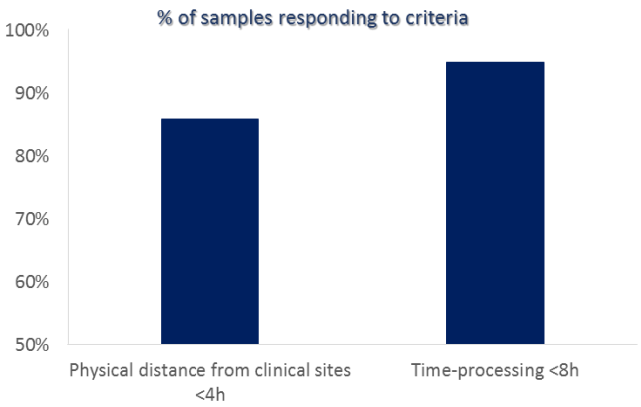
Laboratory Qualification
- Evaluation by ABL of PBMC processed by the lab
- Audit & training Qualification report

Performance of the PBMC Network

ABL's PBMC Network is currently used to harvest and store samples in support of several clinical trials. Critical parameters such as physical distance from the clinical sites and turnaround time to PBMC processing are known to influence performance, and are integrated within our Quality Assessment Program. Excellent correlation between cell viability and specific immune responses have been observed and are continually monitored during clinical trials.

Key success factors

- Physical distance from clinical site to PBMC laboratory < 4h
- Time-processing of PBMC < 8h
- Harmonization of procedures: ABL provides laboratories with kits and SOPs for PBMC processing
- Specific Quality Control & positive criteria for data interpretation
- ABL is in charge of training, management, logistics and supply



ABL PBMC Network

Get the utmost from your clinical samples

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