



FOCUS Immunology

on

Prenanalytical Services

In own GLP-certified laboratories FOCUS Immunology performs functional analysis of immune parameters **be it for discovery/translational medicine or for regulatory-type studies.**

Studies are performed by using blood samples from a local pool of healthy volunteers or from volunteers / patients participating in clinical studies world-wide.

Additionally, blood and tissue samples are collected from animal studies, e.g. from mice, rats, dogs and monkeys, shipped to our laboratories and analyzed for immunological parameters.

For the successful performance of a project aspects of preanalytics are of great importance. These comprise standardized methods for sample collection and sample processing as well as sample shipment. FOCUS Immunology has established sample specific pre-analytical procedures in order to ensure that valuable samples arrive in our laboratories resembling the starting material, i.e. the freshly collected sample as closely as possible.

We rely on established products for sample transport, for example BD Biosciences CPT-tubes for fresh transport of Peripheral Blood Mononuclear Cells (PBMC) or we have adapted proven protocols e.g. for cell freezing for our purposes. Especially for the latter we have placed great emphasis on procedures that are reliable, reproducible, easy to perform and **do not require all too sophisticated equipment.**

In particular in multi-center clinical trials it is not reasonable to expect that every participating site will have a dedicated and fully equipped cell culture facility with personnel trained in many different cell isolation techniques.

Accordingly, our protocol for collecting and freezing PBMC for functional analysis in our laboratories is based on blood collection in the afore mentioned CPT-tubes, a **simple centrifugation step**, collecting of the upper layer containing the cells, a simple **washing step and an equally simple cell freezing procedure** using our own, validated cryo-solution. All reagents and tubes, buffers and the cryo-solution as well as protocols are supplied with pre-printed labels by us in order to offer **maximum convenience and ease of use for the clinical sites.**

For sample transport we work together with courier services offering proven quality. The choice of which to use for any particular transport problem depends on several factors including complexity of the transport (is an airport in the vicinity of the clinic, is a direct flight to Frankfurt available, are problems with customs to be expected, etc.), time constraints and not to forget the prize. It is well known that World Courier offers an exceptional service but it is equally well known that this service has its price. **For simple transports there are more cost effective solutions.**

Every new project has its own challenges and needs to be carefully planned ahead. Therefore, together with you, we strive to find the best solutions for your specific samples. **The following lists several examples from our collection of preanalytical procedures.** It is important that **every new parameter to be tested is validated before start of the study** using the chosen preanalytical method to ensure reliability of the resulting data.

Collection and transport of fresh cells from blood donations:

This procedure is based on the collection of blood in the already mentioned CPT-tubes, their centrifugation on site and transport of the unopened tubes to our laboratories.

This allows maximum simplicity for the participating site. The vacutainer system, on which also the CPT-tubes are based, is used worldwide and the single centrifugation step has never presented a problem.

Tubes are then shipped at room temperature overnight. This procedure is particularly useful if cell freezing has to be avoided or if it is mandatory that cell analysis is performed as quickly as possible. It is probably not the best choice if only a very small number of samples are collected per day at any site since this drives up the transport costs.

Collection and transport of frozen cells from blood donations:

This procedure has already been outlined briefly above. It is a very convenient method **if only a few samples are collected** per day and may be stored frozen on site for collective shipment at a later point in time.

Collection and transport of tissue samples:

Frozen tissue samples may be shipped on dry ice at any convenient point in time. For fresh tissue samples we choose a direct transport service for immediate delivery.

Collection and transport of serum / plasma samples:

Dependent on the results of the validation experiments showing stability of the biomarker to be measured from serum or plasma samples, such samples may be shipped fresh by overnight transport or frozen.

Collection and transport of fixed whole blood samples for flow cytometry analysis:

This is a particularly convenient method to perform flow cytometric studies, e.g. to determine changes in lineage distribution of leukocytes during clinical studies but also for other flow cytometry applications.

Whole blood is immediately mixed with a special solution resulting in fixing of the cells. These may then be easily stored and shipped and used in our laboratories for staining with the required fluorescence-labelled antibodies and analysis on a flow cytometer.

The sole prerequisite for this type of study is the availability of antibodies recognizing fixed epitopes but this is the case for an ever growing list of important markers.

The above provides a brief overview of our preanalytical services. If you are interested in more information or if you want to discuss a specific problem, please contact:

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