



SAFETY ASSESSMENT

Additional Clinical Services

- Protocol design and medical writing
- Bioanalysis
- Microbiology, biomarkers, flow cytometry and pharmacokinetics
- Central laboratory services
- Data management and biostatistics
- Vaccine manufacturing and testing
- Process manufacturing support
- Scientific and regulatory consulting
- Contract staffing
- Educational and training programs

Clinical Sample Kits

Backed by more than 40 years of experience, Charles River's clinical sample management kits are designed to facilitate collection, storage and shipment of valuable clinical samples in support of Phase I-III clinical trials. The shipment of clinical samples is pivotal to the success of any clinical program. For this reason, Charles River Laboratories offers clinical sample kits in support of clinical programs around the world. Failure in maintaining sample integrity could result in delays in a product development program and, in extreme cases, the need to repeat a clinical trial. Biological samples lost due to inadequate material or identification and delays in border processing due to missing or inadequate documentation are examples of problems that can arise and compromise a clinical study. Charles River's Clinical Services can help prevent sample loss and facilitate faster, safer delivery of samples to their destinations.

Kit Description

Our clinical sample kits are specifically designed to allow storage and shipping of different matrices such as plasma, urine, serum and whole blood. Kits commonly include the following materials:

1. Collection tubes, vacutainers and storage tubes appropriate to the type of matrix.
2. Storage containers to hold the storage tubes during transit and appropriate tube labels. Clients pre-approve a draft of labels before they are printed with desired criteria. Clinical site personnel affix prepared labels on tubes with the required information.
3. Duplicate storage tubes and labels for the collection of a second aliquot of each sample, for better sample security.
4. Laboratory manual detailing specimen identification, sample processing, and matrix collection methods (pre-approved by the client).

EVERY STEP OF THE WAY

Our clinical sample kits also include the following documentation and support services to ensure rapid transfer of samples through all aspects of shipping:

1. Shipping coolers and labels that comply with the latest International Air Transport Association (IATA) regulations.
2. Preparation and shipping instructions (available in different languages) with import and export permits for biological samples.
3. Completed international waybills, instructions for specialized couriers such as FedEx or World Courier, completed commercial invoices, and instructions.

Our team customizes each clinical sample kit to suit even the most challenging requirements. Kits are sent as requested directly to the clinical site(s) or to the client's facility, in one or more shipments.

Services and Kits Designed to Optimize Delivery Time of Samples

Our clinical sample kits and related services are specifically designed to optimize all stages of the sample shipment process:

1. Kits include all the necessary documentation to ensure international shipment is as straightforward as domestic shipments.
2. Dedicated customs brokers are located at key international airports to ensure rapid transport of clinical samples to our facility.
3. Samples can be received during normal business hours throughout the year, and special accommodations can be made for receipt of samples after hours and on weekends.

Partnering with You Every Step of the Way

Planning and assembly of clinical sample kits requires a considerable amount of knowledge and resources; even the easiest steps can involve a considerable effort.

Companies who partner with Charles River for clinical sample management benefit not only from our ability to provide the right materials for the task, but from the deep experience of sample management experts employed across all of our sites. Dedicated staff is available to ensure that all steps involving sample handling are performed efficiently, and is ready to answer questions, and resolve any problems that may occur.

Additional services that are available and have been requested by our clients include:

1. Review of the client's protocol, planning, and assembly of sample kits based on the matrix to be tested (obviating the need for the client to consult product catalogues and contact suppliers). Recommendations are incorporated into the laboratory manual, which is developed in collaboration with the client and sent to the clinical site(s).
2. Coordinate responsibility for all sample shipments by overseeing communications between the clinical site, courier and customs broker to ensure safe and efficient sample transfer from the clinical site to the intended destination. We track the samples during shipment and confirm arrival of the samples to the client in writing.
3. Upon receipt of samples, our Clinical Services group can review the samples and sample manifests for discrepancies that might delay analysis of the samples and then work with the sites and clients to resolve issues that might otherwise delay the readiness of samples for analysis.