

A photograph of several glass test tubes containing liquids of various colors (green, yellow, orange) held in a white laboratory rack. The background is slightly blurred, showing more test tubes and laboratory equipment.

CLINICAL KITS AND CLINICAL LOGISTICS SERVICES

Intertek Pharmaceutical Services

Clinical Kits and Clinical Logistics Services

Comprehensive sample handling and management services provide the proper resources and expertise for collecting, processing, packaging, and shipping samples

Proper collection, processing, packaging, and shipping is crucial to maintaining the integrity of pharmaceutical samples. When submitting samples for analysis, certain protocols and methods must be followed to comply with regulatory standards. Pharmaceutical companies can find it challenging to ensure the proper procedures for collecting samples, as well as packaging and shipping them to the testing site have been followed. If the proper procedures are not implemented, samples may be compromised in transit resulting in a sample that can no longer be analyzed.

Intertek offers comprehensive sample handling and management services to provide the proper resources and expertise for collecting, processing, packaging, and shipping samples. Our clinical logistics provide support across an entire study, offering a fast and efficient path to market. Our staff of trained professionals provides a quality support service and customized approach, with materials designed specifically for each clinical or preclinical study. Through the development of study specific sampling manuals, sample collection kits, shipping kits, and additional materials, we provide assurance that procedures are carried out in accordance with the study protocol, applicable regulations, and validated methods.

We specialize in domestic and international cold chain logistics from single to multi-site studies. Our clinical logistics team works directly with our bioanalytical validation teams or other collaborators to ensure consistency with validated parameters, providing assurance that the sample will comply with applicable FDA, GLP, and OECD regulations.

Our comprehensive solutions include small phase I to phase III clinical studies; barcode sample handling; custom label development; a clinical tracking database; automatic re-supply services on request; and access to the Watson LIMS™ system for effective and efficient management of pharmaceutical studies.

Intertek has pharmaceutical labs around the world, providing convenience to clients wherever they are located. This worldwide reach provides total quality assurance for small, mid-size, and large pharmaceutical companies.



Clinical Kits and Clinical Logistics Services

Sample collection kits designed to meet your specific needs

Laboratory Manuals

We specialize in taking complex study designs and study protocol layouts and transferring the details into easy to use instructions for clinical sites. Our laboratory manuals offer text instructions and graphics to help users follow sample collection procedures. These manuals include a study overview and collection time point charts; as well as instructions for sample collection, processing, sample storage and shipment from the collection sites to the testing sites. Study specific sample collection forms are also included.

To ensure quality, all lab manuals undergo a QC review prior to finalization.

Intertek lab manuals provide collection and processing instructions for a diverse group of assignments, including:

- Pharmacokinetics (PK)
- Pharmacodynamics (PD)
- Immunogenicity
- Biomarker
- Cytokines
- Ribonucleic Acid (RNA)

Sampling Kits/Bulk Supplies

Sample collection kits are designed for each client's specific needs. Kits can be generic, patient specific, or interval specific. If a study requires a specialty collection tube containing additional additives or stabilizers, specialty collection tubes can be included in kits as well.

A common collection kit includes:

- Sample collection tubes
- Polypropylene cryovials
- Transfer pipettes
- Study specific cryo-labels
- Sample collection sheets

Shipping/Packing Materials

Proper packing and shipping materials ensure your samples will maintain appropriate conditions throughout transport. Common supplies include:

- Insulated shipping containers
- Dual temperature shippers, which can ship both frozen and ambient samples in the same shipment
- DOT required labels/packaging materials/cryo-storage boxes
- Packing tape and Sharpie pens
- Coordination and delivery of dry ice

Support Services

Our clinical logistics provide guidance and support for your transportation challenges and ensure access to markets throughout the globe, with services, including:

- Coordination of shipping
- Access to preferred logistics carriers
- Import/export services to help minimize potential shipping delays

Did You Know?

Clinical Trials Day is May 20th

In recognition of James Lind, who many credit for conducting the first randomized clinical trial aboard a ship on May 20, 1747.

About Intertek

Intertek is a leading Total Quality Assurance provider to industries worldwide. Through our network of more than 1,000 laboratories and offices and over 42,000 people in more than 100 countries, the Group is re-defining the industry with our Total Quality Assurance proposition.

We go beyond physical quality control to provide total peace of mind through our innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise is delivered consistently, with precision, pace and passion, enabling our customers to power ahead safely.



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