



LKF

Laboratorium für Klinische Forschung

Contact

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LKF

Laboratorium für Klinische Forschung

Laboratory for Clinical Trials
Laboratoire des Essais Cliniques
Laboratorio de Ensayos Clínicos



Introducing ourselves

LKF - Laboratorium für Klinische Forschung GmbH – was established in 1991. The founder, Prof. Dr. W. Junge, M.D., after 6 years' experience of clinical trials in his medical routine laboratory, recognized the necessity and advantage of forming a separate and specialized medical laboratory unit dedicated exclusively to supporting clinical trials of phases I – IV. Today, LKF has more than 50 employees and is owned by four partners of different medical backgrounds.

Services

We offer a broad spectrum of services covering all aspects of the laboratory part of clinical trials – from planning to completion. Our team has considerable experience and expertise in a variety of clinical indications, their diagnosis and therapy.

LKF has supported more than 600 national and international clinical trials with some thousand investigator sites in Western and Eastern Europe, the U.S., Canada, Australia, Israel, South Africa and several South American and Asian countries. Specimens from approximately 40,000 patient visits are processed annually.

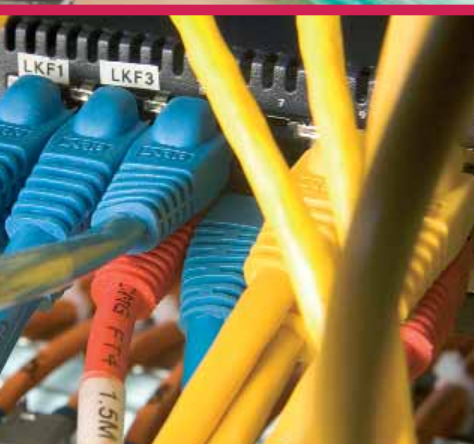
To provide fast and high quality global services, LKF executed a formal alliance with the Mayo Central Laboratory for Clinical Trials (MCLCT) in 2002. In an extensive cross-validation study with actual patient samples, equivalence of methodology, of reporting formats and of reference intervals was verified. A continuous quality control programme ensures the long-term consistency of the analytical results of both laboratories.





Communication

From the start, we have always been aware of the importance of providing continuous and timely information to all those responsible for, and involved in, a clinical trial – and we are convinced that communication is one of our biggest strengths. Our multilingual project team – you may contact us in German, English, French, Spanish, Dutch – comprises experienced personnel with different professional backgrounds. It provides immediate and reliable information to everyone concerned – e.g. trial manager, investigator, study nurse, monitor and biometrist. Consultation and assistance are offered for protocol development, test selection and interpretation of results



Quality Management

LKF has implemented a stringent quality management system, based on the international guidelines GCP/GLP and ISO 17025 and certified according to DIN EN ISO 9001. This ensures excellent quality of performance and enables LKF to prove the quality required for conducting clinical trials at any time. Analytical quality is regularly certified by participation in proficiency testing programmes, e.g. NGSP (Level I Certificate for HbA1c), or INSTAND e.V., a government approved institution which organizes quarterly ring trials as required by German law.



Trial preparation

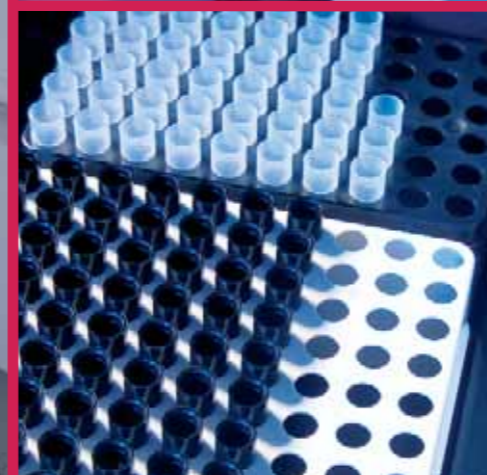
LKF provides various customized services for setting up a trial:

- a dedicated study manager assigned to each study
- a trial-specific project and data management plan
- a laboratory manual written in any major European language with detailed instructions for specimen processing and shipment
- laminated collection charts
- visit-specific kits for specimen collection
- pre-printed trial-specific requisition forms, ID-labels and (air) waybills
- on-site training for investigators, CRAs and study nurses
- presentations on investigator and/or monitor meetings
- test data transfer

Specimen accessioning process

On receipt of a patient visit kit, several items of information are recorded on a special protocol form, before specimens are brought into the analytical process. These data include:

- name of courier service company (e.g. TNT, DHL, FedEx)
- (air) waybill number
- elapsed time between blood collection and delivery
- number and type of tubes (e.g. serum, EDTA-blood, citrated plasma, urine)
- centrifugation of each plasma or serum sample to exclude minor cellular contamination
- sample quality assessment (e.g. lipemic, haemolytic, clotted)
- check of appropriate specimen volumes
- result of data verification of tube ID-labels and requisition forms



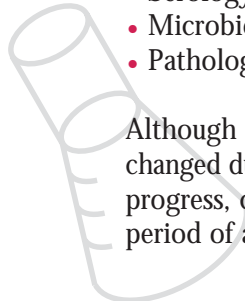
Analyses

LKF offers a comprehensive clinical laboratory testing programme. Whenever possible, the methods and procedures applied are those recommended by international scientific societies, e.g. IFCC, ECAT, or traceable to approved reference material. Furthermore, LKF has expertise in the development, evaluation and reference interval establishment of new methods.

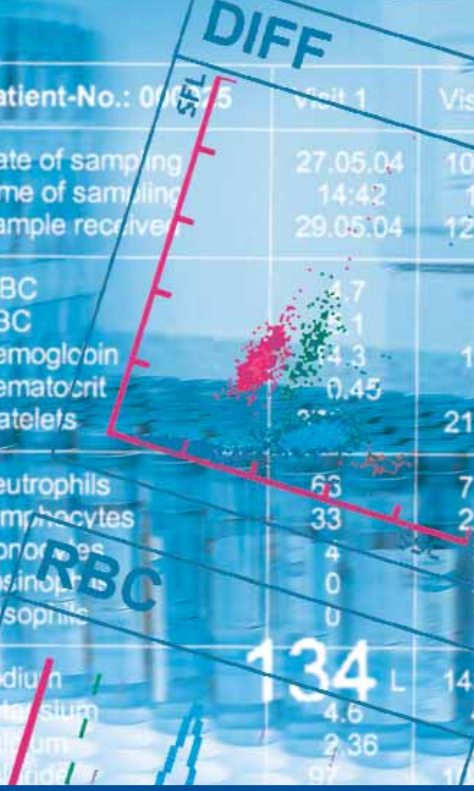
Analyses are performed in a timely and accurate manner. The measurement of routine and safety parameters, including reporting of test results, is usually completed on the day of specimen receipt, six days a week.

LKF provides analyses in the following sub-specialties:

- Clinical Chemistry
- Haematology
- Coagulation
- Endocrinology
- Immunology
- Serology
- Microbiology
- Pathological Anatomy/Cytology



Although laboratory methods are frequently modified or changed due to technical developments and/or methodological progress, consistency of methods is provided for the entire period of a trial.



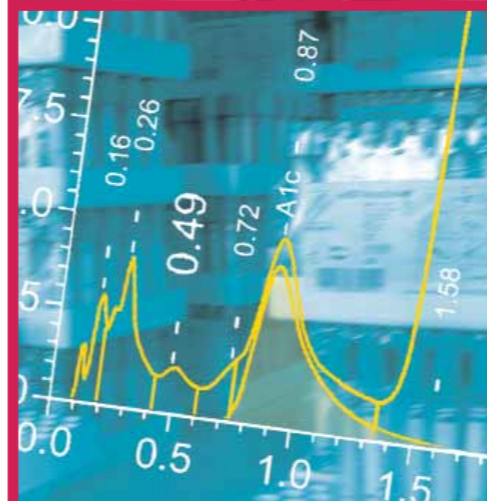
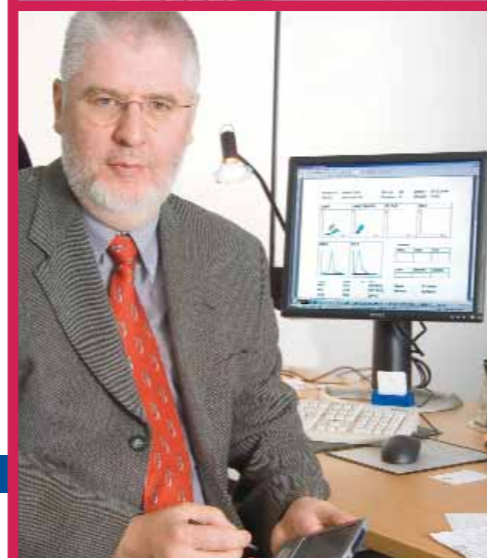
Reporting

After review by experienced staff, test results are reported immediately via fax to investigators and other persons concerned. The lab report contains the dates of specimen collection and delivery at the LKF, demographic data and reference intervals. Results are flagged according to the specifications defined by the the study protocol, e.g. outside reference interval, alert values, exclusion/inclusion criteria. Patient results can be transmitted as single and/or cumulative reports by fax, e-mail, regular mail or courier.

A special report form designed for our clients, called OVERVIEW, is an Excel file containing a compilation of relevant information about the current status of a study, e.g. demographic data, missing information, site- or country-related visit and enrolment of patients. The OVERVIEW is available at any time on request, or it can be submitted automatically on a regular basis at agreed intervals. Encryption software, e.g. PGP, is generally used for the transmission of this document.

Archiving

LKF runs an archive designed and equipped for the secure storage of all study-related documents and records in compliance with GLP requirements. Electronic records are archived according to 21 CFR Part 11.



Data Management

LKF has developed and continues to develop a data management system dedicated to the requirements of a medical laboratory dealing with clinical trials. Our reliable and flexible software complies with international standards (GCP/GLP, 21 CFR Part 11) and is tailored to our clients` needs. For each trial a study-specific database is created and validated as defined by the protocol. A test data transfer will be executed prior to the start of the study.

As a member of the Clinical Data Interchange Standards Consortium (CDISC) LKF supports the CDISC-XML standard.

LKF's data management system includes the following key features:

- blinding of laboratory data
- electronic archiving of source data, e.g. request forms, analyser printouts.
- import of external laboratory data
- export of multiple output formats (ASCII, XML)
- accommodation of different data structures (CDISC, OC, SAS or client specific)
- incremental or cumulative data transfer
- support of eCFR and EDC systems by daily data transfer
- automated data encryption





Specimen management services

Post-analytical storage of study specimens

LKF has created a sophisticated specimen retention and retrieval system, which provides various items of information on each sample, e.g. the remainder volume, ensures accurate tracking and enables instant access wherever additional or repeat-testing is necessary. After completion of the analytical process, the specimens are stored frozen for as long as the client wishes. Specimens are disposed of only on the client's written request. Disposal is documented according to ICH-GCP.

Management of specimens for third parties

LKF offers the retrieval, handling, storage and transportation of specimens to be analysed by a referral laboratory, e.g. for pharmaco-kinetic or DNA/RNA assays. In co-operation with clients, LKF has established special procedures for the management of DNA samples for genetic testing including a reliable de-identification step to ensure full protection of data privacy.

