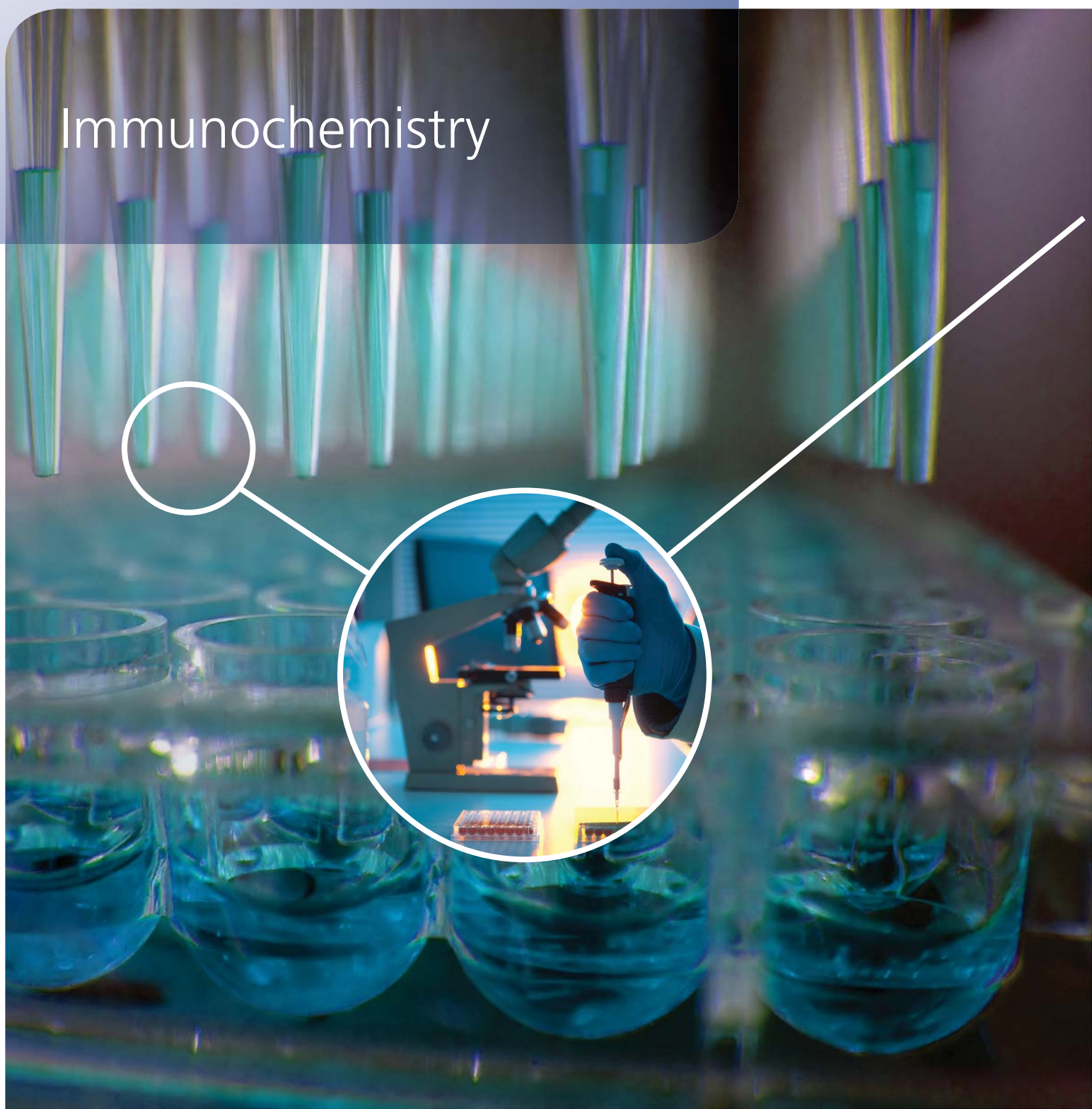
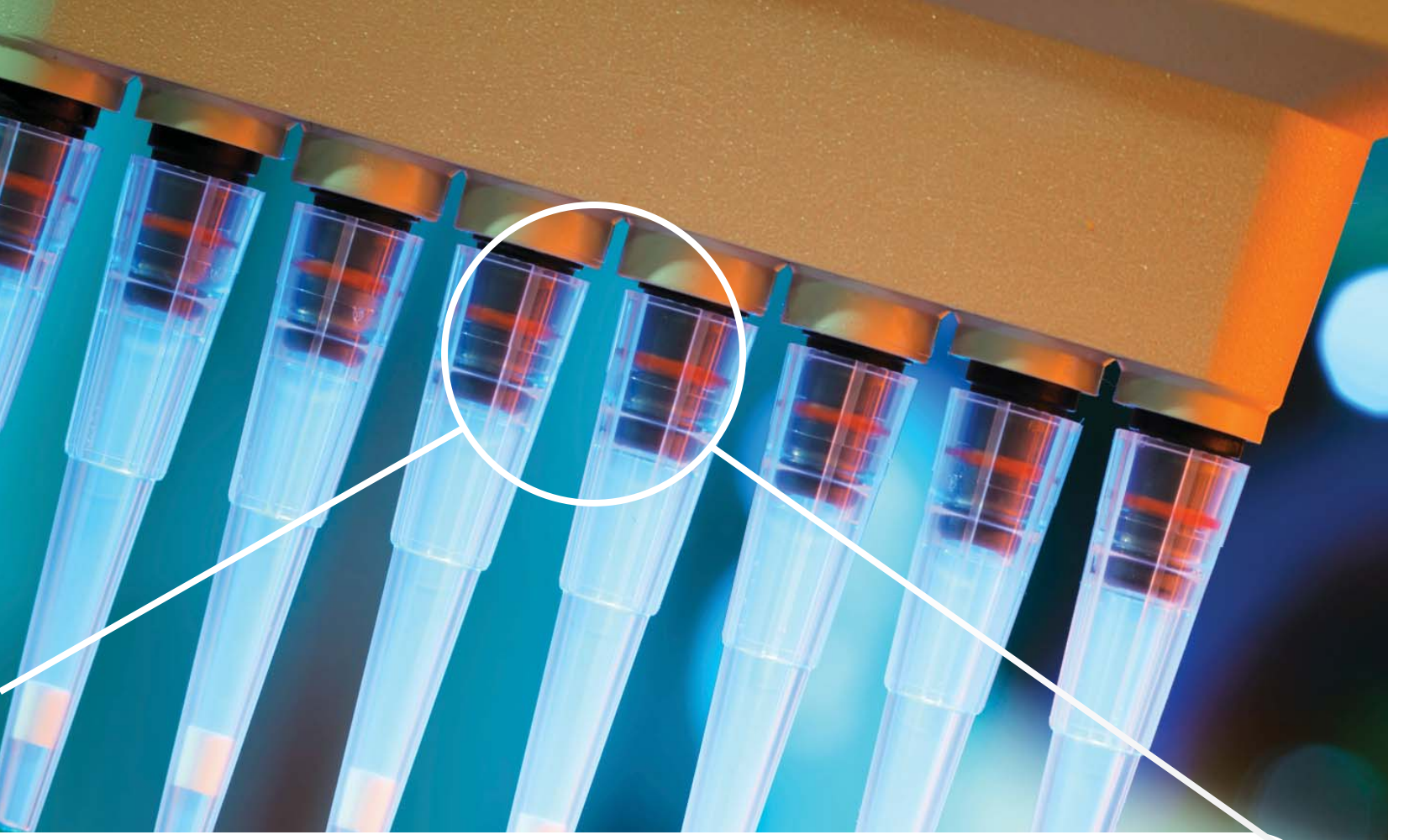
Pharmaceutical Services

Intertek

Valued Quality. Delivered.

Immunochemistry





Immunochemistry Services

Intertek has extensive experience in the development, validation and sample analysis of quantitative and qualitative GLP and Non-GLP immunoassays in support of clinical and preclinical studies for the measurement of therapeutic drugs, synthetic peptides, humanized monoclonal antibodies, chimerics, conjugated drugs, various growth factors, hormones, cytokines and biomarkers.

- Intertek provides a team of specialists that work exclusively with the project.
- Project Manager/Principal Investigator is the single point of contact for all the work performed during the course of the study.
- Intertek's Quality Assurance Unit has a vast array of experience to ensure the quality and integrity of the studies that go through their review.
- Intertek is an FDA registered laboratory that has been regularly audited by the Food and Drug Administration.

Special Services:

- Anti KLH (IgG & IgM) analysis
- Anti TT (IgG & IgM) analysis
- SPEAD ELISA
- SPEAD ECL
- Radioimmunoassays
- In-house Statistician to perform Statistical Evaluation of Validation Data
- Neutralization Cell-Based Assay (with high level of drug tolerance)
- Scientific Biopharma Consultant available
- Biotinylations and Ruthenium Labeling capabilities
- Enzymatic Assays
- Fluorometric Assays
- Ocular Tissue Bioanalysis
- Biosimilar expertise
- Complex large molecule expertise (ADC, fusion protein, pegylated, *etc.*) and Peptide experience

Our Immunochemistry Capabilities

Quantitative Ligand Binding Assays

- Development and validation of quantitative ELISAs for proprietary compounds.
- Development and Optimization of assays followed by validation.
- Transfer and validation of an existing method.
- Intertek Project Manager (Principal Investigator), with support from a team of Analysts and a Project Coordinator will ensure that the method will be developed, validated and the samples associated with this method will be analyzed, and reported with quality, integrity and efficiency.
- Quality control checks performed by this team as well as Quality Assurance Unit will ensure accurate raw data and data tables.
- Our staff ensures adequate sample security, temperature, and document tracking are maintained at all times.
- Our practices and procedures are designed to meet FDA GLP standards.
- Our top priority is always scientific integrity.

Biomarker Assays

Intertek has a dedicated team with expertise in the qualification and validation of biomarkers using ELISA and ECL platforms (including multiplexing, prototypes and custom multiplexing from MSD™) in multiple matrices and anticoagulants. The list of validated assays is constantly changing, so please contact the lab for the latest assay list. Examples of validated or qualified biomarkers include:

- Anti-KLH IgG and IgM
- Anti-tetanus toxoid (TT) IgG and IgM
- Avastin
- E-Selectin
- FGF
- HGF
- ICAM-1
- IL-6
- IL-8
- IP-10
- Leptin
- MCP-1
- MMP-3
- MMP-9
- TNF-alpha
- VCAM-1
- VEGF C
- VEGF
- VEGF R2
- Multiplexing (Vascular Injury I, Vascular Injury II)

Immunoassays

Immunoassays for the Detection of Antibodies to Specific Compounds

- Development, validation and sample analysis of Anti-drug antibody assays (sandwich, bridging or SPEAD formats) using ELISA and ECL platforms (includes screen, titer and specificity testing) along with statistical analysis by an in-house statistician.
- SPEAD/BEAD ECL - expertise in the development and validation of immunogenicity assays faced with the need for increased drug tolerance. SPEAD and BEAD (acid dissociation) assays for increased drug tolerance, utilizing both ELISA and ECL formats are offered across multiple teams.
- Development and validation of cell based assays for use in determining the presence of neutralizing antibodies.
- Development and validation of ligand binding receptor assays.
- GLP sample analysis utilizing various cell based assay readouts - cell proliferation, cell death, or an ELISA readout.

Our ultimate goal is to provide the sponsor with a sensitive, robust and reliable immunogenicity assay that performs as reproducibly in the third year of a lengthy clinical trial as it did during the first year.

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Intertek is the leading quality solutions provider to industries worldwide. From auditing and inspection, to testing, training, advisory, quality assurance and certification, Intertek adds value to customers' products, processes and assets. With a network of more than 1,000 laboratories and offices and over 35,000 people in more than 100 countries, Intertek supports companies' success in a global marketplace. Intertek helps its customers to meet end users' expectations for safety, sustainability, performance, integrity and desirability in virtually any market worldwide.

For more information please contact us:

Americas
t: +1 (858) 558 2599
Pharma-americas@intertek.com

Europe
t: +44 (0) 161 721 5247
Pharma-europe@intertek.com

Asia
t: +86 (532) 8099 3568
Pharma-asia@intertek.com

pharma-americas@intertek.com

http://www.intertek.com/pharmaceutical