



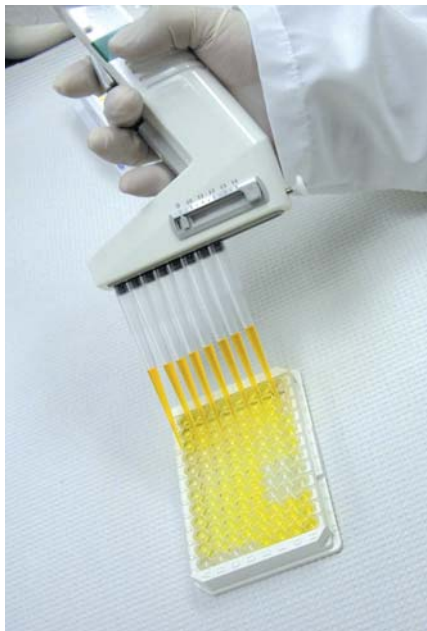
**Intertek**

**ALTA  
Immunochemistry  
Services**

# One Location for All Your Immunochemistry Needs.

Alta Immunochemistry has experience in the development and validation of quantitative immunoassays for the measurement of therapeutic drugs, synthetic peptides, humanized monoclonal antibodies, chimerics, various growth factors, hormones, cytokines, and various biomarkers. We work closely with sponsors to determine the needs of the assay, regulatory requirements, turn around times, report requirements, and make every effort to work within their budgetary restrictions.

Alta is also very experienced in the development and validation of quasi-quantitative methods for the measurement of antibody responses to their specific drug (immunogenicity studies). The challenge of developing and validating cell-based assays for neutralizing antibody evaluation is also a strength of our immunochemistry lab. Each client, each assay, each compound, is evaluated on an individual basis with regards to the approach to development and the approach to providing a comprehensive and scientifically sound validation.



Alta Immunochemistry has a history of keeping pace with the requirements of industry and the expectations of the FDA to assure reliable assay development and validation, and has constantly made every effort to improve the Quality Control systems to provide clients with reliable and robust assays for both preclinical and clinical studies.

# Quantitative Ligand Binding Assays

## **ALTA Immunochemistry is experienced in:**

- *Development and validation of quantitative ELISAs for proprietary compounds*
- *Transfer and validation of an existing method*
- *Optimizing a method and then validating*
- *Validation of an existing kit assay*

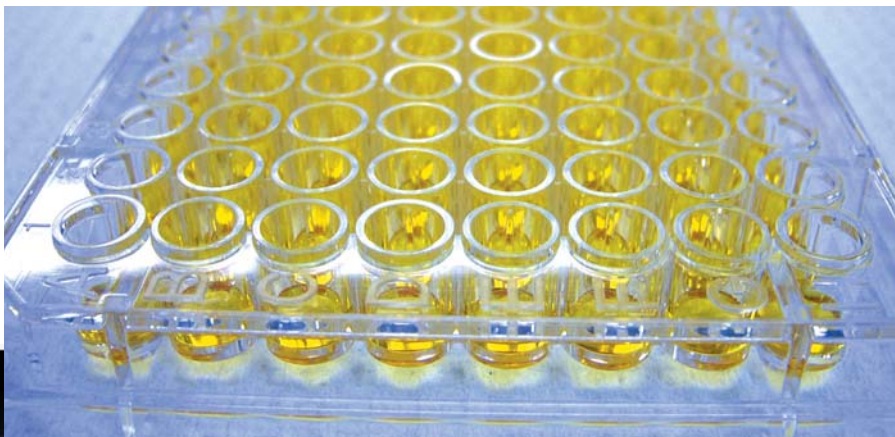
Projects that are brought into our lab are handled by a project manager (principal investigator), with support from a team of analysts, and a project coordinator. This team assures that the method will be developed, validated and the samples associated with this method will be accessioned, analyzed, and reported in the most efficient way possible. Quality Control checks performed by this team will assure clean raw data and data tables are handed over for the final check with the Quality Assurance department at the lab.

**Sample control designed to meet FDA GLP standards**

**Provide sample security, temperature maintenance and document tracking**

**Pro-active team with regards to assay development and validation guidelines**

**Competitive pricing and quality work, with the top concern being scientific integrity**



# Immunoassays for the Detection of Antibodies to Specific Compounds

The development and validation of qualitative ELISA assays for the measurement of antibodies directed against a specific compound, or biological product has become an expertise of the Intertek Immunochemistry group. The group has several approaches to ELISA assay format (sandwich ELISA, bridging format) as well as ECL (Meso Scale Discovery™) methodologies. When immunogenic responses are identified, cell-based neutralization assays can be specifically designed to detect the presence of anti-drug antibodies that interfere with the intended pharmacologic activity of the biologic drug entity.

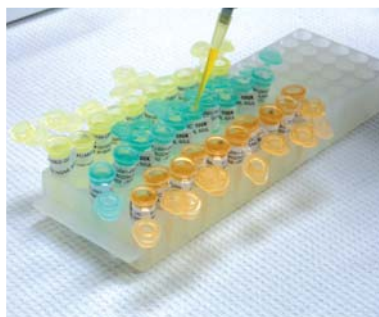
Because each project offers its own set of challenges and requirements, the project managers work closely with clients to exceed their expectations, while keeping a close eye on regulatory requirements for a fully validated assay suitable for regulatory submissions.

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

## Cell Based assays

**Development and validation of cell based assays for use in determining the presence of neutralizing antibodies**

**GLP sample analysis utilizing various cell based assay readouts – cell proliferation, cell death, or an ELISA readout**



# Biomarker Assays

Alta has validated a select group of biomarkers that might be useful in the selection of a lead compound, determining the mechanism of action of a compound, used as a surrogate endpoint for demonstrating efficacy, or for identifying intermediate endpoints of success to decrease follow-up time with a specific treatment. The assays are fully validated for use in GLP-compliant preclinical and clinical study designs. The list of validated assays constantly changing, so please contact the lab for the latest assay list. Examples of previously validated biomarkers include the following:

CD-44	MCP-1
E selectin	MMP-2
P selectin	MMP-9
FGF	TNF-alpha
HGF	VCAM-1
ICAM-1	VEGF
IL-2	Adiponectin
IL-6	Leptin
IL-8	
IL-18	



*service at a higher level*



**Quantitative Immunoassays**

**Immunogenicity Assays**

**Cell Based Assays**

**Biomarkers**

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