



*Sciences, Inc.*

Contract R & D Laboratory

**Customized Contract Laboratory Services**



## Products

TGA Sciences, Inc. offers specimen collection kits for our clients clinical sites to assist in sample collection, preparation and shipment. A typical collection kit includes the following components:

- Vacutainer collection tubes
- Polypropylene transfer tubes
- Specimen labels
- Specimen sample forms
- SOP's for collection methods
- Shipping containers
- Shipping airbills

All kits are customized for the particular study or client and can be purchased in bulk or individually. Clinical site training for specific collection techniques is also available, as is telephone support.



## Sample Handling / Storage



TGA Sciences, Inc. offers an in-house Quality Assurance program and efficient sample handling. We provide a high a high quality, professional service which is precise, reliable and confidential.

- Specimen coding (manual or barcode).
- Sample storage includes validated temperature sensitive chambers that are in complete compliance with cGMP guidelines.
- Sample preparation techniques developed in response to the client's requirements for a precise and accurate analysis.
- Clinical sample handling and analysis are performed in accordance with cGMP guidelines.
- In-house Quality Assurance documentation system.

For sample storage rates per month or year, please contact us at: [info@tgasciences.com](mailto:info@tgasciences.com)



## In Vivo Animal Studies

TGA Sciences, Inc. offers the client experience in the production of customized antibodies for research and clinical applications. Working as an extension of the client's laboratory, we offer customer consultations and progress reports at each phase of production. TGA Sciences, Inc. is AAALAC accredited, USDA registered, OLAW licensed and maintains an internal Institutional Animal Care and Use Committee (IACUC) in accordance with USDA and HHS regulations and guidelines. TGA Sciences, Inc. also provides access to our surgical suite for clients interested in performing their own studies. Please call for suite availability.

### In Vivo Mouse Studies

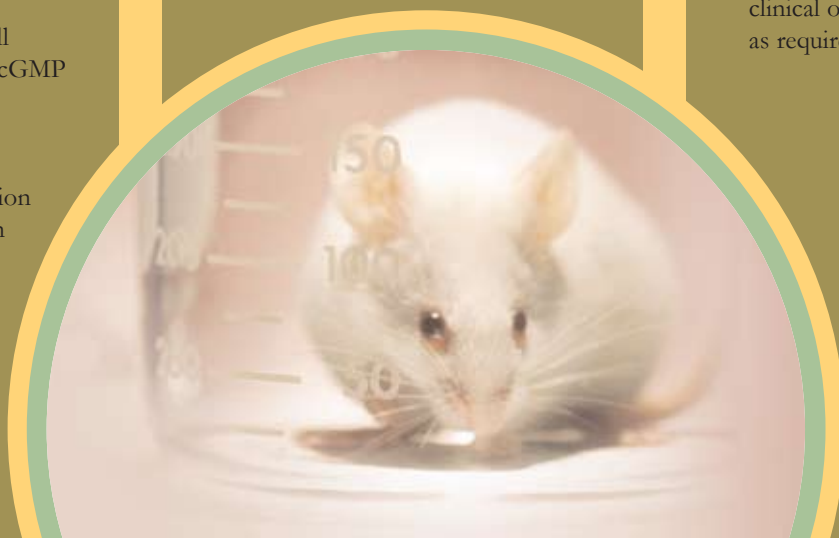
- The development and performance of in vivo mouse studies for the optimization of vaccine immunization schedules, dosing and adjuvant screening.
- Immunogenicity testing for the release and stability studies of bulk and finished clinical product, as well as raw material screening.
- Antibody production tailored to the specific requirements of each R&D project or clinical study.
- Complete antibody development programs are available from immunization to purification, all performed in compliance with cGMP requirements.
- The development of specific screening assays for the evaluation of titer, isotype characterization and tissue culture services.

### Rat Toxicology Testing

- The development of toxicology studies and quantitation for Pharmacokinetic studies.
- Dose ranging studies.
- Bioequivalence and bioavailability studies.

### GPMT Testing

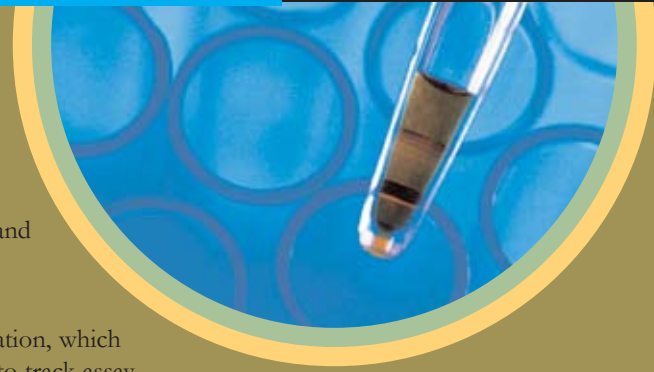
- The offering of in vivo guinea pig maximization test using the method developed by Magnusson and Kligman for dermal sensitization testing for identifying contact allergens in humans.
- Performed in compliance with cGMP requirements.
- Guinea pigs are housed in single-unit ventilated caging systems.
- Temperature and humidity are monitored on a daily basis and clinical observations are performed as required.



## Immunoassay Validation

TGA Sciences, Inc. provides a complete immunoassay validation package that is in compliance with FDA review. All work is performed under good laboratory practices (21 CFR Part 58) and follows the basic parameters set by FDA CDER.

- Performance Characteristics – Reproducibility, operator-to-operator variation, sample parallelism, sensitivity, specificity, beginning to end variation, assay ruggedness, spike and recovery, freeze-thaw effects and cutoff analysis can be performed to evaluate the performance of the particular assay.
- Assay Acceptability Criteria – Acceptability parameters are established from the validation, which then are used for the determination of assay acceptability. Control charts are utilized to track assay performance and trends that may occur over time.
- Supporting Documentation – Standard Operating Procedures (SOP's), worksheets and reagent logs are generated and incorporated into the TGA Sciences, Inc. QA documentation system, resulting in full traceability of all analysis.
- Database Formation and Handling – Specific macros are tailored to each project to ensure that all raw data is electronically transferred during database generation and statistical analysis, thereby eliminating manual input errors.



## Immunoassay Development

TGA Sciences, Inc. offers the client a complete package of development and optimization of qualitative or quantitative immunoassay systems utilized in pre-clinical through Phase IV studies, all in compliance with GLP and cGMP requirements.

- Measurement of small molecules, peptides, and large proteins from research grade to cGMP compliance quality.
- Immunoassays for monitoring antibody or protein levels throughout a clinical study (direct binding assays, competitive techniques, HACA and HAMA).
- Development of an Immunoassay-based screening protocol against your lead compound.
- Assay design and detection systems for antibodies with unique specifications.
- Quantitative detection systems for the determination of contaminants in highly purified products.
- Immunoassays utilized for the detection of cytokines or cell surface markers.
- Use of commercial kits under cGMP guidelines.
- Monoclonal antibody screening (Western blot or ELISA).

## Multiplex Assay Systems

TGA Sciences, Inc. offers the multiplex assay system which allows the simultaneous analysis of up to 100 markers in a single sample, as well as the customization of specific markers for our client's requirements. Currently, we offer multiplex assays in the following areas:

- Genotyping
- Transcription Factors
  - Apoptosis
  - Endocrine
- Metabolic Markers
  - Autoimmune
  - Cytokines
  - Isotyping
  - Tissue Typing
- Kinase/Phosphorylated Proteins

## Immunoassay Consultation

TGA Sciences, Inc. offers the client consultation services in the areas of assay methodology, monoclonal antibody development, purification and other immuno-chemistry techniques, as well as product development aspects of project management. Our in-house experts are available for one-on-one consultation, or to speak to larger groups. Please contact the company for more information.



## FACScan Analysis

TGA Sciences, Inc. can assist the client in creating the necessary analysis and options that ensures the accurate identity of specific cell populations by pheno-type and function.

- Immunocytochemical staining for apoptosis studies, tissue culture cell staining studies, phenotyping or in vivo blood cell staining using high throughput FACScan techniques.
- Immunoglobulin screening and staining.
- R&D of sample preparation systems and analytical techniques.

## Bioassay Analysis

TGA Sciences, Inc. offers bioassays for the toxicity screening of chemicals, compounds and reagents. The general types of bioassays that are currently being utilized are presented below, however, customized bioassays are available upon request:

- Growth factor and interleukin bioassays.
- Proliferation bioassays using various cell types:
- Collagen bioassays
- Normal Human Epidermal Keratinocytes
- Normal Human Epidermal Melanocytes
- Determination of interleukin levels or cell viability following the bioassay using commercially available kits or other assays (Neutral red, Alamar Blue, MTT or MTS) as an analytical readout of bioassay performance.
- Other specialized bioassays:
- UVB cell survival bioassays
- H<sub>2</sub>O<sub>2</sub> cell survival bioassays
- R&D bioassays developed for specific analysis



## Research & Development Protocols

TGA Sciences, Inc. offers general laboratory support for academic institutions, virtual biotechnology companies and small to mid-sized Pharmaceutical companies. Our flexibility allows our technicians to work with clients as an extension of their laboratories. Services offered in the past include:

- Method development for laboratory protocols
- Antibody purification and titration
- IEA analysis
- Western Blot – used for the determination of Mab screening to molecules of interest.
- Use of commercial kits under cGMP guidelines.
- HLA typing
- LAL endotoxin analysis
- Specialized sample preparation techniques
- Customized animal protocols – immunogenicity testing
- Maintenance of cell lines.
- Protocol/documentation generation





## Accreditations

AAALAC Accreditation

USDA Registered

OLAW Licensed

Registration of Drug Establishment  
Labeler Code Assignment -  
FDA (20001222-758)

Drug Enforcement Administration - (DEA) Licensed  
Federal and State registrations (schedules I-V)



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