IVD Development Services

Creative Diagnostics Service

Always a Move Ahead in IVD Assay

Partnering to Advance Human Health, Your Global Partner for Full Range of IVD Development Services

CD Creative Diagnostics®

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About Us

Creative Diagnostics provide resources and expertise for pharmaceutical and diagnostics industries. As your complete diagnostics partner, we have clinical and research laboratories in Europe and the USA, enabling us to support global studies. We offer a comprehensive range of in vitro diagnostic services and capabilities to augment your needs, such as:

- Integrated discovery, development, validation through regulatory approval
- Custom projects, all diagnostic areas
- Complete clinical trial services

Your project is unique — we tailor to fit your needs.

Communication, speed and efficiency are just a few of the benefits gained through dedicated project management in a controlled, quality-compliant environment.

Your project is in capable hands.

With scientific and medical expertise to support all areas of IVD diagnostics, we ensure your project is designed, implemented and on-target with your goals and schedules.

Reagents Development Service

Creative Diagnostics is well-equipped and versed in reagent development to assist our customers' IVD research and project development. We have established advanced antibody and antigen development platforms to support the discovery and production of high quality IVD reagents based on customized applications.

Range of Platforms

We offer the flexibility of a range of platforms for clients to choose from with experience in satisfying different application needs. Diverse cutting-edge technologies, such as hybridoma technology, phage display technology, antigen-specific single B cell sorting technology, and analysis technology LC-MS, BLI, SPR, etc., have been employed within our reagent development platforms.

Figure 1. Single-B-Cell-Antibody-Discovery

Production Systems

Creative Diagnostics has established systematic animal immune, recombinant express, and protein purification procedures, especially offering chicken IgY antibodies and camel VHH antibodies generation. We also help you maximize the success rate of your projects with multiple recombinant protein expression systems including *E. coli*, *Pichia pastoris*, HEK293/CHO cell, Baculovirus-Insect cell, etc.

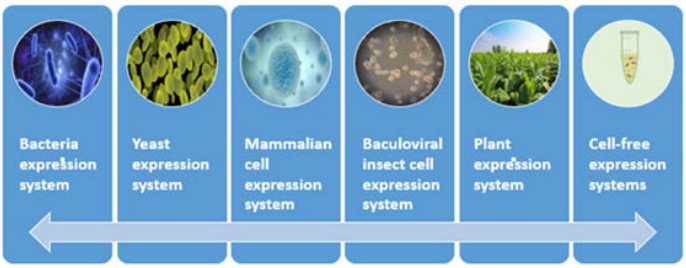

Figure 2. Expression systems for recombinant protein production

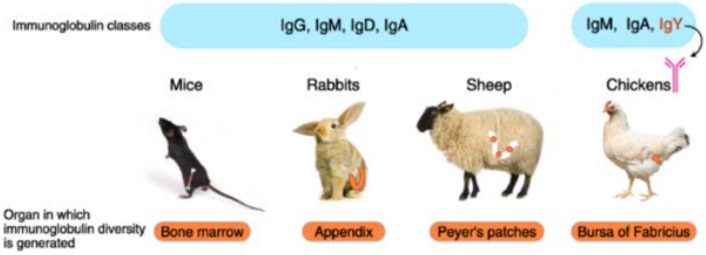

Figure 3. Host animals

Sample Management

Creative Diagnostics offers a full range of sample management services including sample sourcing, receipt and accessioning, sample preparation & QC, LIMS reporting, storage, logistics and downstream processing capabilities.

Kit and Methodology Development

Creative Diagnostics offers one-stop IVD kit and assay development services. We are backed by years of experience and state-of-the-art facilities. Whether you are developing an ELISA, CLIA, or lateral flow assay, our services are equipped with optimal procedures and high-performance formulations that provide a quicker path to commercialization.

ELISA Kit Development

Creative Diagnostics helps our clients develop different ELISA kits for infectious disease detection, drug testing and impurity detection purpose.

- Infectious disease detection

  Creative Diagnostics offers a broad range of infectious disease ELISA kits development service for the detection of human IgG, IgA and IgM antibodies to bacterial, viral, fungal and parasite antigens featured with high sensitivities and specificities.
- Impurity detection

  The manufacturing of recombinant drugs requires comprehensive monitoring of process-related impurities, such as HCPs. We provide HCP assay development service, various orthogonal methods, including 2D Western Blot/2D DIGE analysis and MS , to complete the analytical puzzle.

- ADA/PK assay development

  Creative Diagnostics delivers novel assay methods development and ADA/PK ELISA kit development. Our services include custom development of key reagents, such as antibody pairs, positive antibodies, anti-idiotypic and neutralizing antibodies for ADA/PK analysis, high-quality ADA assay validation, custom immunogenicity testing for preclinical/clinical method development and sample analysis, etc.

Lateral Flow Assay (LFIA) Development

Creative Diagnostics develops lateral flow assays with different labels, such as gold, magnetic beads, and colored latex nanoparticles, that are widely applied in hospitals, biological and clinical laboratories. These assays are used to detect analytes including pathogens and biomarkers in humans or animals, or contaminants in foodstuffs, water supplies, or animal feeds.

Conjugation Service

Creative Diagnostics offers a full range of antigen and antibody conjugation services to meet the specific requirements of our global clients. With years of experience, we are able to provide custom conjugation of an antibody to a variety of labeled materials, such as HRP, biotin, or a fluorophore, either from an antibody in our catalog or as a stand-alone service for customer-supplied material.

Case Study

ADA ELISA Kit Development

The Customer Requirement: ADA screening assay kit development (sensitivity: 100ng/ml)

Procedures:

1. Preparation of positive control standard:
   Immunization of 5 rabbits
   Serum collection and titer> 1:100,000
   Affinity purification
2. ADA screening assay development, detection method: Bridging ELISA.
3. Bridging ELISA method validation including Sensitivity, Screening cut point, Hook effect, Drug tolerance, Precision.

Results: A ready-to-use ADA screening ELISA kit with a sensitivity of 3.7314 ng/ml is available.

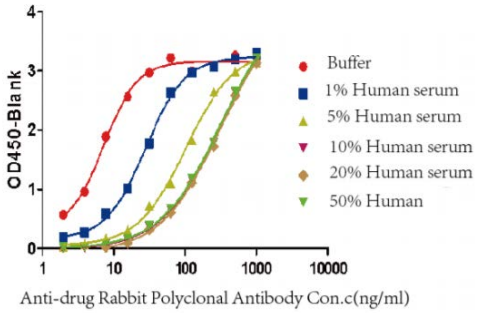

Figure 4. The effect of different serum concentration on the bridge-ELISA

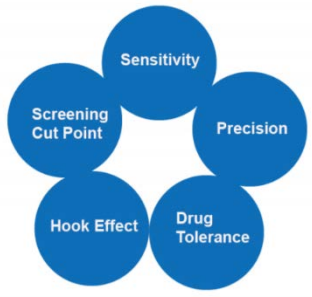

Figure 5. Methodology Validation

CHO-K HCP Residue Detection ELISA Kit Development

The Customer Requirement: CHO HCP detection assay kit development coverage>70%

Procedures:

1.S ample preparation
   Protein of mock CHO cell supernatant culture fluid: >200mg,
   Protein of mock CHO cell lysate: >100mg, all provided by the client, samples are in the mixture of three independent batches.
2. Preparation of detection antibodies
   Immunization of 14 rabbits and 6 goats.
   Serum collection and titer> 1: 50,000, WB evaluation of serum.
   Affinity purification.
3. 2D-WB evaluation for coverage
4. HCP detection assay development, detection method: ELISA
5. ELISA method validation including Coverage, Accuracy, Standard curve and Sensitivity.

Results: Ready-to-use HCP detection ELISA kits, Coverage 74.65%, Accuracy 93.47%-117.68%.

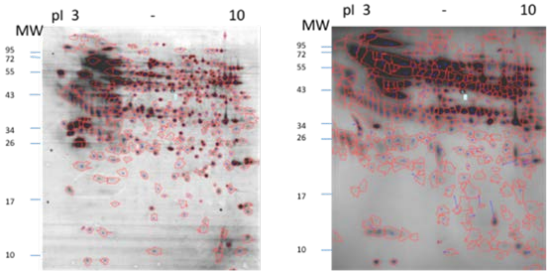

Figure 6. 2-D WB coverage evaluation

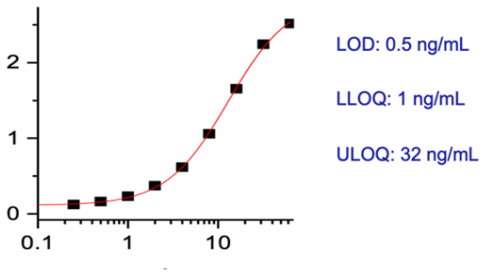

Figure 7. ELISA kit linear analysis

Testing Service

Affinity Test Service

Assessing the structure-activity relationship of antibodies via affinity testing is now a hotly contested area of research and bioengineering. Creative Diagnostics provides SPR/BLI analytical services to our valued customers.

Figure 8. Affinity test platform and device

In Vitro Antibody Activity Test Service

Reliable and high quality ADCC & CDC assays have assumed greater significance with the growing importance in medicine of bio-engineering antibodies and their role in combating cancers. By implementing strict QC standards, Creative Diagnostics® can perform high quality assays for ADCC/CDC.

Pseudovirus Neutralizing Antibody Detection Service

Virus neutralization has become the gold standard to determining antibody efficacy. To optimize and improve this test further, psuedoviruses have been employed. Pseudoviruses possess the essential components for cell entry and viral infection, without the risk of self-replication due to lack of nucleic acid, thus making it a powerful tool. Creative Diagnostics can handle pseudovirus packaging and neutralization detection of SARS-CoV-2, MERS, HPV and influenza viruses.

Regulatory and QA Support

From the fundamental research and discovery phase, to development and validation, conducting clinical trials and the manufacturing of test kits or lab developed tests, to patient sample testing. With expert supporting services teams in Design Control, Project Management, Data Sciences and Quality & Regulatory Affairs we ensure that your individual program objectives are met on time, within budget and to high quality standards.

Project Management

Our experienced project management team work with clients throughout the lifecycle of their project to provide a comprehensive service from initial study design and planning, all the way through to the commercialization of a diagnostic test. We recognize that each IVD development project is unique and has its own challenges. Creative Diagnostics establishes a dedicated project manager to ensure that all key deliverables and timelines are met and that regular communication updates are provided. We foster a collaborative working partnership with our clients through transparency and flexibility to achieve shared goals.

Data Sciences

Our Data Sciences' team partners with clients throughout their IVD development programs, fully supporting the discovery, development and delivery of each project. Our team has a substantial understanding of bioinformatics, biostatistics, and data management, aiding for analysis and demonstration of IVD development research data.

Regulatory Affairs

Our Regulatory Affairs team has significant expertise, built up over many years, to help pharma, diagnositic companies, biotech clients navigate the regulatory landscape in key global territories. Creative Diagnostics currently supports regulatory plans for diagnostic tests in multiple global regions including USA, Canada, Europe, Japan.

We provide regulatory support solutions including: global regulatory strategies for IVD development, IVD pre-submissions, IDE submissions, IVD performance evaluation registration, device classification assistance, analytical and clinical protocol design, regulatory submissions, regulatory agency liaison, and post-market support.

Manufacturing and Commercialization

Manufacturing

Our dedicated IVD manufacturing team and processes follow high-level quality control processes. These processes ensure consistent assay component supply, adequate reagent/kit release processes for analytical validation studies, and a robust assay assembly, labelling, release, and monitoring process for final commercialization.

Commercialization

Creative Diagnostics has years of manufacturing and global distribution experience to support your IVD commercialization needs. Our commercialization team will partner early with your commercial team to ensure your assay will be suitable for the target market. Our team agrees a joint commercialization plan and work in partnership throughout the lifecycle of the product.

CONTACT

CREATIVE DIAGNOSTICS

45-1 Ramsey Road, Shirley, NY 11967, USA

Tel: 1-631-624-4882 (USA) 44-161-818-6441 (Europe)

Fax: 1-631-938-8221 | Email: info@creative-diagnostics.com

www.creative-diagnostics.com