

# Assay Development

## Top of the Line ISO 13485 Certified Assay Development

Using our controlled manufacturing environment, we produce custom multiplex ELISA kits with lyophilized reagents for long-term stability and controls used for standard curve generation. Our manufacturing environment focuses on maximizing stability and minimizing lot-to-lot variability.

We have experience developing sensitive and reliable multiplex assays for a variety of research areas:

- Autoantibodies
- Cancer
- Diabetes
- Immunology
- Nutrition
- Angiogenesis
- Complement Cascade
- Hormone
- Infectious Diseases
- Serology

Our highly efficient system allows us to keep costs low and assay accuracy high. Costs to develop a custom assay will vary depending on the availability of reagents, the types of biomarkers desired, and the time involved to develop, optimize, and validate the ELISA.

## Collaborate with Experts

You will be guided through our four-phase assay development process with a team of expert technical consultants, researchers, and development scientists who will meet with you and your team to understand what you need from immunoassays from concept to production.

We will work together as partners and collaborators throughout the process. We value regular discussion and feedback to make this development the best it can be.



### Phase I

*2-4 weeks*

- Feasibility testing
- Reagent functionality tested
- Cross-reactivity tested
- Foreground to background determination
- Rough outline of assay design



### Phase II

*8-10 weeks*

- Optimization of assays: array, reagents, and protocols
- Characterization: precision, linearity, recovery, sensitivity, cross-reactivity, backfit, drift, edge effect, sample correlation, and inference



### Phase III

*8-12 weeks*

- Design verification
- Design transfer to the Production team
- Verify Phase II specs: precision, linearity, recovery, sensitivity, cross-reactivity, backfit, drift, edge effect, sample correlation and inference
- Stability (real-time and accelerated)



### Phase IV

*8-10 weeks*

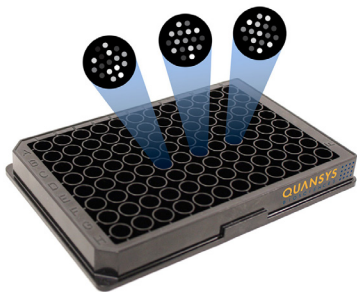
- Prepare plates and reagents
- QC testing and release
- Validate design against user requirements
- Commercial release of the product
- Marketing material produced

## Additional Custom Services

### Custom Q-Plex™ Kits

The Q-Plex™ Custom Assays are fully quantitative ELISA-based Chemiluminescent kits allowing the concurrent measurement of up to 18 biomarkers or analytes.

With over a hundred different unique and validated assays, we can build the array for your specific research application. Each kit comes with a pre-spotted plate and all necessary buffers, reagents, and instructions for your specific multiplex ELISA.



### Custom Plate Printing

Customize a fully quantitative ELISA-based Chemiluminescent assay plate that allows the concurrent measurement of up to 18 biomarkers or analytes.

We have developed capabilities to print assays with high levels of precision. Each printed assay undergoes a rigorous quality assurance process before it is approved for release. Our printing expertise includes antibodies, proteins, peptides, and cell lysates for reverse phase arrays.

### OEM Manufacturing

We work with you to create custom, retail-ready multiplex kits and other products. The development and manufacturing of plates and kits are performed in compliance with agreed-upon guidelines and specifications. This includes applying your specific content to a private labeled multiplexed array.

Our focus on customer service and expertise in array development and custom printing make Quansys a natural choice for OEM partners.



#### Quansys Biosciences

365 North 600 West  
Logan, UT 84321  
www.quansysbio.com

Fax: 435-750-6869  
Phone: 435-752-0531  
Toll Free: 888-QUANSYS (782-6797)



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