

## YOUR TRUE PARTNER IN ASSAY DEVELOPMENT

ZeptoMetrix® is the most trusted partner for assay manufacturers across the assay development process. Our scientists provide the most comprehensive product and custom services portfolio to help you reach your assay development goals.



## **SINGLE SOURCE PARTNER FOR QUALITY CONTROLS AND MICROORGANISMS**

At ZeptoMetrix®, we partner with assay developers like you through all the stages of assay development —from assay concept and design to the development of custom controls for product development as well as ready-to-use external quality controls and panels for labs.

### **EXPLORE OUR DIVERSE PORTFOLIO FOR IVD DEVELOPMENT EXCELLENCE**

- Organisms for analytical testing
- Custom controls and validation materials for internal testing (batch release)
- Controls for studies
- Organism sourcing
- Recombinant generation
- Proficiency testing surveys
- Antibodies and reagents for immunoassay development
- Design history/technical file support

## YOUR PARTNER ACROSS ALL FOUR STAGES OF DEVELOPMENT

With over 20 years of experience working with top diagnostic assay manufacturers, we have the expertise and portfolio required for total cycle support.

### 1 CONCEPT & FEASIBILITY

Rapidly demonstrate project viability and proof of concept.

### 2 ANALYTICAL VALIDATION

Generate data for regulatory submission.

### 3 DEVELOPMENT & MANUFACTURING

Scale-up growing operations without delay.

### 4 COMMERCIALIZATION & LAUNCH

Facilitate quick and easy adoption.

- **EXPANDING PORTFOLIO:** LIBRARY OF 1,200+ ORGANISMS
- **INNOVATION & DEPTH:** TWO BSL-3 LABS AND MULTIPLE BSL-2 LABS
- **COMPLIANCE:** IVD & RUO CAPABILITIES
- **TRUSTWORTHINESS:** OVER 25 LARGE GLOBAL PARTNERS





# 1

## CONCEPT & FEASIBILITY

### RAPIDLY DEMONSTRATE PROJECT VIABILITY AND PROOF OF CONCEPT

Demonstrating early-stage feasibility is a critical step of an assay development project. Using high-quality materials in proof-of-concept studies can save time and money and ultimately avoid project delays.

#### WHAT YOU NEED

- Qualified materials to aid in development
- Stable and consistent supply

#### WHAT WE OFFER

- Early-stage discussions with our team of experienced scientists
- Expansive library of over 1,200 microorganisms
- Strain characterization by whole genome sequencing
- High quality, well characterized strains
- Ability and expertise in organism sourcing through domestic and international resources
- Recombinant generation for nonculturable organisms

#### KEY SOLUTIONS

- Live organisms (e.g., viral culture fluids, titered bacterial cultures)
- High-titer materials
- Quantitated (e.g., TCID50, CFU/mL)
- Inactivated organisms (e.g., chemical, heat)

#### CASE STUDY

An assay developer needed a custom feasibility panel for developing a multiplexed molecular assay. ZeptoMetrix® delivered a panel that used organisms from our library as well as several uncultured organisms, which used generated recombinant solutions. The panel ultimately helped the assay developer demonstrate the assay’s feasibility and bring it to market.

**“ *ZeptoMetrix scientists have become a key part of our development process.* ”**

- Research scientist from a global assay developer

# 2

## ANALYTICAL VALIDATION

### GENERATE DATA FOR REGULATORY SUBMISSION

Regulatory submissions require manufacturers to demonstrate assay performance through a series of rigorous testing protocols. High-quality materials help streamline these studies and generate accurate, reproducible data.

#### WHAT YOU NEED

- Whole organisms
- Well qualified materials
- Necessary organisms for cross-reactivity studies

#### WHAT WE OFFER

- Extensive catalog of organisms in live and safe-to-use, inactivated formats
- Well characterized, high-titer materials
- Development of custom analytical panels
- ISO 13485:2016 Certified
- IVD and CE-IVD capability

#### KEY SOLUTIONS

Live and inactivated organisms used for:

- Cross reactivity
- Sensitivity/specificity
- LOD/LOQ
- Interference
- Custom growth and titering
- Custom testing services
- Infectivity testing
- Quantitation

#### CASE STUDY

A company was developing a multiplexed PCR-based assay for the detection of common GI pathogens. ZeptoMetrix® was able to provide a comprehensive panel of microorganisms for use in their interference and cross-reactivity studies. This involved the sourcing and quantitation of several new organisms, which ZeptoMetrix was able to accommodate without delaying the project.

**“ We rely on input from the ZeptoMetrix team to help us navigate regulatory labeling decisions related to our go-to market strategies. ”**

- Product manager from a global assay developer

# 3

## DEVELOPMENT & MANUFACTURING

### SCALE-UP OPERATIONS WITHOUT DELAY

Transitioning from validation to manufacturing scale can be a challenging process. A consistent supply of critical materials for internal QC can help ensure an efficient and effective transition while adhering to rigorous quality standards.

#### WHAT YOU NEED

- A trusted supplier
- Materials to support manufacturing and QC
- Supply chain dependability

#### WHAT WE OFFER

- Custom and OEM materials manufactured under rigorous quality standards
- Vertically intergraded structure ensures consistent, on time delivery
- Collaboration and flexibility
- Strong IP and know-how

#### KEY SOLUTIONS

Custom and OEM products for:

- Internal QC
- Batch release testing
- New to market: PROTrol™ for antigen assays

#### CASE STUDY

An assay manufacturer evaluated the ZeptoMetrix® NATtrol™ MS2 product for use as an internal control for a new molecular assay. Happy with the product, they decided to implement NATtrol MS2 as the internal control for all new assay development projects. ZeptoMetrix was able to seamlessly scale production to keep up with the increased demand.

# 4

## COMMERCIALIZATION & LAUNCH

### FACILITATE QUICK & EASY ASSAY ADOPTION

Having verification panels and quality control products that are designed to work on your assay and available to your customers can greatly simplify this process and facilitates rapid and easy adoption of your assay.

#### WHAT YOU NEED

- Verification panels to support assay installation and training
- Independent, external quality controls for day-to-day monitoring of assay performance
- Lot-to-lot consistency
- Supply continuity

#### WHAT WE OFFER

- NATtrol™, the preferred brand of molecular products
- Catalog products optimized for your assay
- Global distribution network
- Consistent stock/product availability

#### KEY SOLUTIONS

- PROtrol™: non-infectious whole organism controls designed for antigen testing

- NATrol: non-infectious whole organism controls designed for molecular QC
- System and assay agnostic
- Ready-to-use format
- Refrigerator storage and shipping
- Designed to mimic a patient sample
- Starter packs: custom configuration of everything a customer needs to adopt an assay
- Custom verification panels and external quality controls
- Custom proficiency testing and External Quality Assessment (EQA) panels

#### CASE STUDY

ZeptoMetrix® has a long history of developing custom validation panels in partnership with leading assay manufacturers worldwide. These products are launched under the ZeptoMetrix brand and recommended to clinical laboratories by the assay manufacturer to support the validation of the assay in their laboratory.

## WHAT MAKES US DIFFERENT

The foundation of our success is based upon a sincere partnership approach with collaborators and subject matter experts in both industry and academia as well as a dedicated team to support through the full development process.

### AREAS OF EXPERTISE

- Bacteriology, mycology, and parasitology
- Virology
- Molecular biology
- Immunology
- Oncology

### BREADTH OF PORTFOLIO

- Extensive library of 1,200+ organisms
- 60+ new products launched each year
- Products designed for use across the spectrum from high-complexity tests to point of care (POC)
- Global distribution network

### INNOVATION & DEPTH

- Multiple BSL-2 and BSL-3 labs
- PhD level scientists
- Strong IP and technical expertise
- Array of product modalities and configurations (e.g., liquid, frozen lyophilized, swab)

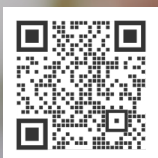
### COMPLIANCE

- IVD, CE-IVD and RUO
- ISO 13485:2016
- FDA 21 CFR part 820
- IVDD 98/79/EC
- IVDR 2017/746

### TRUSTWORTHINESS

- 25+ large global partners
- High volume capabilities
- 2 million tubes filled annually

**ZEPTOMETRIX®**  
**YOUR TRUSTED PARTNER IN  
IVD ASSAY DEVELOPMENT**



LET'S GET THE  
CONVERSATION  
STARTED

+1 800 274 5487  
[zeptomatrix.com/  
assaydevelopment](https://zeptomatrix.com/assaydevelopment)

**ZeptoMetrix®**  
an antylia scientific company