

# on diagnostics

**2021 Volume 3** 

**Application and Resource Library** 





Welcome to the latest News on Diagnostics! This edition looks at the technical resources we have available for all things diagnostics. Whether you're looking for technical support with a particular technique, or looking to develop a new method, our application and resource tech note, video, and webinar library pulls all the relevant information into one place, with clickable links for ease of navigation.

## **IMMUNDASSAYS**

Whether you are developing a new assay, scaling up to prepare for manufacturing, mass producing an IVD kit, or just exploring alternative options for your applications, our vast selection of fit-for-use products and innovative support services can accelerate your time to market. We offer the quality, consistency and documentation necessary for every step of your IVD commercialization process.

Note: You may need to scroll to the bottom of the webpage to fully access these resources.

# **CLIA**

#### Webinars



CLIAs Based on Magnetic Beads

# **Application/Technical Notes**



Development of a Chemiluminescent Immunoassay (CLIA) Using Estapor® Magnetic



Antibody Purification Using Protein A, Protein G, or Protein L Agarose



Procedure for Conjugation of Alkaline Phosphatase to Antibodies and Other Proteins



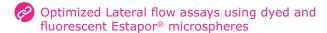
Enzymatic Assay of Peroxidase (EC 1.11.1.7)

Note: You may need to scroll to the bottom of the webpage to fully access these resources.

# **Lateral Flow**

#### **Webinars**





Optimized Lateral Flow Test Strips:Design Considerations for Optimal Performance

Development of Latex Enhanced Immunoassays

#### Other resources

Performance of Estapor® Microspheres and Hi-Flow™ Plus Membranes in a Lateral Flow Assay for Human Chorionic Gonadotropin (hCG) Bed Volumes of SureWick® Pad Materials

# **Application Notes**

Getting Started with IVD Lateral Flow Assay Development

IVD Lateral Flow – Sample, Conjugate and Absorbent Pad Basics

# **ELISA**

#### **Webinars**

The Secret to ELISA-based Diagnostic Test Success: Know Your Water

The Secret to ELISA-based Diagnostic Test Success: Know Your Detection Method

The Secret to ELISA-based Diagnostic Test Success: Know Your Antibody

## Other resources

ELISA Troubleshooting Guide



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# CMO

IVD manufacturers appreciate the flexibility of customization we offer based on our extensive global in-house manufacturing experience and comprehensive network of suppliers.

#### This includes:

**Bulk and Custom Packaging:** Supply of bulk raw materials in configurable pack sizes. Manufacture of custom formulations in a variety of formats, including aqueous or ethanolic solutions, dry powder blends and tabletting options.

**Custom Reagent Formulations:** Custom manufacturing of raw materials, including the further development of existing products or de novo synthesis.

**Custom QC:** Custom QC on existing or new materials, to ensure that raw materials are tested with your intended application in mind.

## **Case studies**

- Accelerating Time to Market Using Custom Lateral Flow Membranes
- A Move to Outsourcing Access Scale-Up Capacity and Custom Kit Development
- Outsourcing for Efficiency The Need for Increased Manufacturing Capacity
- Outsourcing for Security Sustainable Supply Chain for Consumables
- Hazardous Material Handling Streamlining Complex Regulatory and Compliance Issues

- Custom Manufacturing and Kitting for Next Generation Sequencing Index Adaptors
- 10 Strategic Considerations When Outsourcing Production of *In Vitro* Diagnostics
- Custom Blood Typing Increase Market Share by Selecting the Right OEM Part
- Outsourcing Security The need to ensure consistency and continuity of supply in IVD Kit Manufacturing

## **CMO** videos



# RISK MITIGATION

Risk mitigation is a core focus for IVD manufacturers, driven by commercial best practices and regulatory requirements. Assessment of critical raw material performance, supply and quality is important to minimize risk. Risk must be assessed and mitigated throughout the entire IVD commercialization process.

## **Case studies**

EU Regulation on In Vitro Diagnostics

Preparing for Unannounced Audits

Supply Chain Risk Mitigation

ISO 13485 & Supplier Management

Note: You may need to scroll to the bottom of the webpage to fully access these resources.

# Molecular biagnostics

From PCR to CRISPR to Next-Gen Sequencing, molecular tools are becoming increasingly valuable in the development, assessment, and production of in vitro diagnostic assays. Optimizing your techniques can take considerable time and we have the molecular biology support and expertise to speed your assay research, development, and production.

#### **Webinars**



CRISPR Tools and Technologies for Accelerating Research



Library Preparation Methods and Application Specific Kits



NGSO (Next-Gen Sequencing Oligos) for Consistent and Proper Sequence Assembly



NGS Application: Integrated Services for Microbiome Discovery

# Emerging biagnostics technologies

# Microfluidic devices and systems for diagnostic assays

30 years after the introduction of the concept of the "miniaturized total chemical analysis system (µTAS)" and about 20 years after the gold digger's frenzy about how this technology would revolutionize all aspects of chemical, biological or diagnostic applications, it is worth having a look at how this technology has matured (or gone awry). Here we provide you with a broad overview of all aspects of microfluidic devices and systems as an enabling technology for new product development in diagnostics and the life sciences.



Microfluidic Devices and Systems: A Two-Part Webinar Series

