NEWS on diagnostics

2023 Rapid Point of Care Workshop Special Edition

13-15 June, Cork, Ireland

In this issue....

- Lateral Flow Membranes
- Estapor® Beads
- ProClin Preservatives
- Antibodies
- Quality
- Risk Mitigation

Welcome to this special edition of News on Diagnostics for the 2023 RPOC Workshop. The long path to developing a new *in vitro* diagnostic device need not be rocky. Our three-day workshop covers the development and manufacture of a lateral flow test including raw materials, research, and development considerations. Workshop attendees will become familiar with each aspect through lectures, discussions, and hands-on practical sessions.

Along the way, you'll learn about technical challenges, future technologies, regulatory issues, and market trends from industry leaders with discussion sessions and excellent networking opportunities.

Topics include:

- Design considerations
- Critical raw materials selection & sourcing
- Troubleshooting

Read on to discover a few of the topic areas that will be discussed at the RPOC.

Lateral Flow Membranes

Accelerate time to market with products from Merck offering the quality, consistency, and documentation necessary for every step of your IVD LFA development and manufacturing needs.

Hi-Flow™ Plus Membranes for speed and consistency

- 5 flow ranges to suit any assay sensitivity
- Consistent performance speeds assay design and simplifies troubleshooting
- Available as membrane cards to simplify your manufacturing design process and production

SureWick® Pad Materials for use as sample, absorbent, and conjugate pads

- Glass fibre conjugate pads have low extractables and excellent consistency
- 100% pure cellulose fiber sample and absorbent pads have no binders or glues to interfere with assay performance

Hi-Flow™ Plus Lateral Flow Membranes

As part of our renewed commitment to your success in developing and manufacturing IVD assays and kits, we are pleased to announce improvements that will provide a consistent and reliable pipeline of membranes to meet your research and production needs. Discover the benefits of our increased capacity of Hi-Flow™ Plus membranes, our workflow expertise, and ancillary product portfolio.

Estapor® Beads

Estapor® Microspheres are a leading brand of polymeric supports for *in vitro* diagnostics, life sciences, biotechnology, cosmetics, electronics and environmental applications. Merck manufactures, develops, produces and provides more than 200 different types of microspheres worldwide.

Magnetic, white, dyed or fluorescent microspheres are key components for reagent producers in clinical diagnostics, life sciences, food and environmental industries.

Learn more about our portfolio **here**

Europium Microspheres:

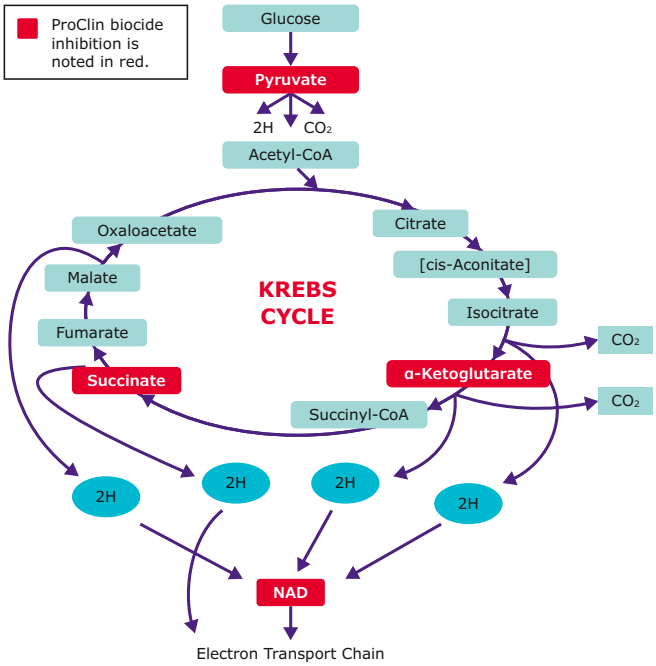
- Significantly improve lateral flow assay sensitivity
- Reduce background fluorescence
- Make assays easier to read and quantify
- Exihibit a longer Stokes shift than traditional fluorescent labels
- Exihibit an enhanced fluorescent quantum yield facilitating a low detection limit
- Functionalized with carboxylated surface for protein conjugation
- Available in three different size options

On-Demand Estapor® Technical Resources

If you're interested in learning more about how Estapor® magnetic microspheres can be used to aid in the separation process of CLIA protocols, please visit **SigmaAldrich.com/BiomagneticSeparationProcesses** SeparationWebinar to review our recent webinar hosted by Dr. Lluis Martinez of SEPMAG.

Other webinars are available at **SigmaAldrich.com/webinars** covering a wide range of topics including Next Generation Sequencing, Immunoassay Development, and Contract/Custom Manufacturing capabilities.

ProClin Biocide Preservatives



ProClin preservatives are water-soluble formulations of biocides that are among the most effective biocides in the IVD industry, used in over 1,000 FDA registered IVD kits from industry-leading diagnostic manufacturers. At low working concentrations, ProClin products help extend the shelf life of IVD reagents by effectively and immediately inhibiting a broad spectrum of microbes.

ProClin biocides attack the Krebs cycle at four key points: the enzymes pyruvate dehydrogenase, α-ketoglutarate dehydrogenase, succinate dehydrogenase, and NADH dehydrogenase. Because all bacteria and fungi possess at least part of the Krebs cycle, they are broad spectrum in their activity.

Unlike other biocides, ProClin preservatives present reduced health hazards, toxicology problems, and disposal issues at recommended usage levels. We offer four unique formulations, ensuring a variety of options to meet a wide range of specific needs. Learn more about our ProClin products. We provide the ProClin™ biocide product range with different characteristic formulations in multiple pack sizes to suit your specific needs.

Antibodies

More than 700 diagnostic antibodies & related products

- Primary Antibodies
- Secondary Antibodies
- Antibody Controls
- Blockers
- Animal Serums
- Primary manufacturer with multiple sites offering flexibility and customization

Our comprehensive portfolios of monoclonal and polyclonal primary antibodies are focused on cell and molecular targets in neurobiology, cancer, cardiology, and immunology. Secondary antibodies targeting multiple host IgGs are conjugated to alkaline phosphatase, peroxidase, biotin, FITC and other labels.

Improving antibody reproducibility

While vendors are responsible for reagent quality, researchers also share responsibility, as personal incentives for reproducible research are high. Taking several small steps can reduce the risk researchers unknowingly have when running an experiment. Some of these steps are simply asking smart questions before purchasing products or recording product information as reagent boxes are opened. Other steps fit into toolboxes of validation strategies to ensure critical reagents match experimental requirements for identity, function and structure. Visit **SigmaAldrich.com/antibodies** for more information, or download our detailed white paper on Improving Reproducibility: Best Practices for Antibodies at **SigmaAldrich.com/antibody-reproducibility**

Reagent Quality and Compliance

Quality is embedded in everything we do, and we provide quality documentation for our products at various levels to address your compliance reporting needs.

Our M-Clarity™ Quality Program

- Enhance your understanding of IVD regulatory landscapes and implications for critical raw materials
- Discover factors and controls to reduce overall risks in supply chain
- Optimize your selection of appropriate products

Industry-driven regulations require that products of higher criticality or those used in highly regulated industries, such as pharma or *in vitro* diagnostics manufacturing, need enhanced supplier quality support.

The quality segments of the M-Clarity™ Program provide transparency so that you can choose, with confidence, suitable products that meet your needs with respect to:

- Compliance with the appropriate quality and regulatory standards
- Portfolio transparency
- Change notification service
- Documentation and support
- The M-Clarity™ matrix includes six quality segments from MQ100 to MQ600 defining the quality attributes and the notifiable changes in each level.

Find out more at **SigmaAldrich.com/mclarity**

Sign up for News on Diagnostics at **SigmaAldrich.com/newsondiagnostics**

Risk mitigation

Risk Mitigation Checklist

- □ Do you have change control notification for critical raw materials?
- □ Do your suppliers have compliant quality management systems?
- □ Are you aware of your suppliers' quality policies?
- □ Can your supplier provide manufacturing and supply chain records?
- □ Can you validate your suppliers' testing of raw materials?
- □ Are you and your suppliers prepared for unannounced audits?
- □ Are you confident that your suppliers' raw materials will perform consistently?

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.

Your critical raw materials require active risk mitigation to ensure:

- Manufacturing continuity
- Lot-to-lot consistency
- Regulatory compliance
- Clinical test reliability

The pillars of risk mitigation are:

- Supply chain
- Quality
- Risk assessment
- Contract manufacturing

Our experts can help you evaluate your risk mitigation needs through our risk mitigation workshop.

Please contact your local account manager for more information.

MK_NL12206EN Ver. 1.0
46854
05/2023