NEWS on diagnostics

**2023 IVD Conference,
21-22 March, Rome, Italy
Special Edition**

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Welcome to this special edition of News on Diagnostics for the 2023 IVD Conference. International experts and scientists addressed critical aspects of IVD immuno- and molecular assay development including:

- Design considerations
- Critical raw materials selection & sourcing
- Analytical controls
- Magnetic separation technology
- Risk mitigation

In this issue, we explore some of the technology and challenges in diagnostic assay development that were discussed in this year's IVD Conference.

MilliporeSigma is the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany.

Lateral Flow Membranes

Accelerate time to market with fit-for-use products from MilliporeSigma 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

Estapor® Beads

Estapor® Microspheres are a leading brand of polymeric supports for *in vitro* diagnostics, life sciences, biotechnology, cosmetics, electronics and environmental applications. MilliporeSigma 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.

Find the right beads for your application **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** 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.

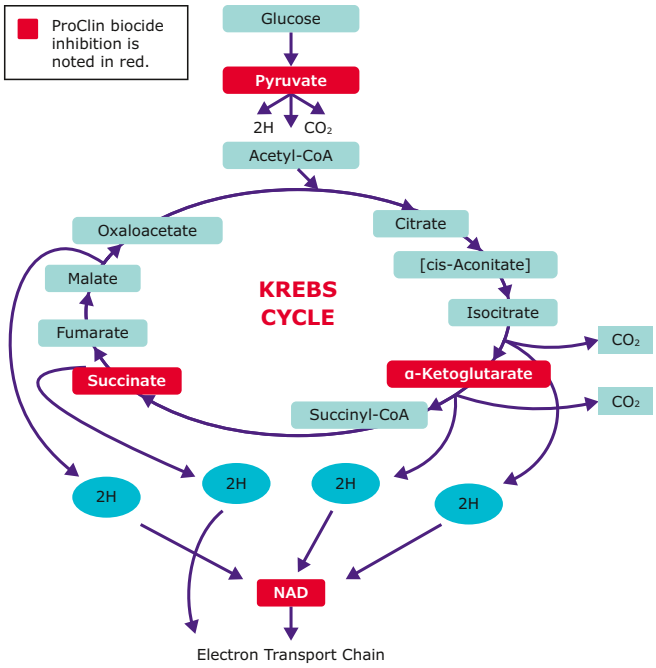
ProClin Biocide Preservatives

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.



ELISA Design Troubleshooting

An ELISA (Enzyme-Linked Immunosorbent Assay) is a multi-well plate-based immunoassay within which one of the assay components, typically an antibody or sample, is adsorbed onto a solid surface, in this case, a plate. Offering rapid, quantitative and sensitive analyte detection at relatively low cost, ELISAs represent one of the simplest assay formats to perform. Furthermore, the ease of adapting an ELISA to a higher throughput screening method enables researchers to test large sample numbers in a single run.

ELISA Troubleshooting Guide

Preforming enzyme-linked immunosorbent assays (ELISA) requires multiple assay components and steps, and therefore, there is often a need for troubleshooting and optimisation. In our troubleshooting guide, we have listed solutions to some of the most common sources of problems for assay development.

Learn more in our **article here**

Customer care and reliability are in our DNA. Accelerate your success, from concept to market, with our custom oligonucleotide expertise and collaborative service approach.

For more information on our portfolio please visit **SigmaAldrich.com/compliantoligos**

Learn more

Our M-Clarity™ Quality Program

Quality is embedded in everything we do, meaning we provide quality, compliance and business support in the most effective and efficient way for the entire portfolio of our life science business.

- 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 fit-for-use products

The M-Clarity™ Matrix

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 Roadshow and Workshop**.

Contact your account manager for more information.

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