NEWS on diagnostics

2022 IVD Conference Special Edition

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Welcome to this special edition of News on Diagnostics for the 2022 MilliporeSigma IVD Conference. International experts and scientists address the critical aspects of IVD immuno- and molecular assay development including:

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

Hear about current and future IVD technologies, market trends, both now, and post-COVID, from industry leaders, while taking advantage of networking opportunities and a supplier exhibition.

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.

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

We are committed to communicating new developments with our customers. As a result, we have webinars available on demand. An introduction to our portfolio can be found at **SigmaAldrich.com/EstaporWebinar**

In conjunction with a collaborative partner, Anteotech, we are delighted to present a webinar on our new Europium microspheres. Please visit **SigmaAldrich.com/anteotech** webinar to access this information.

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/Biomagnetic** 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.

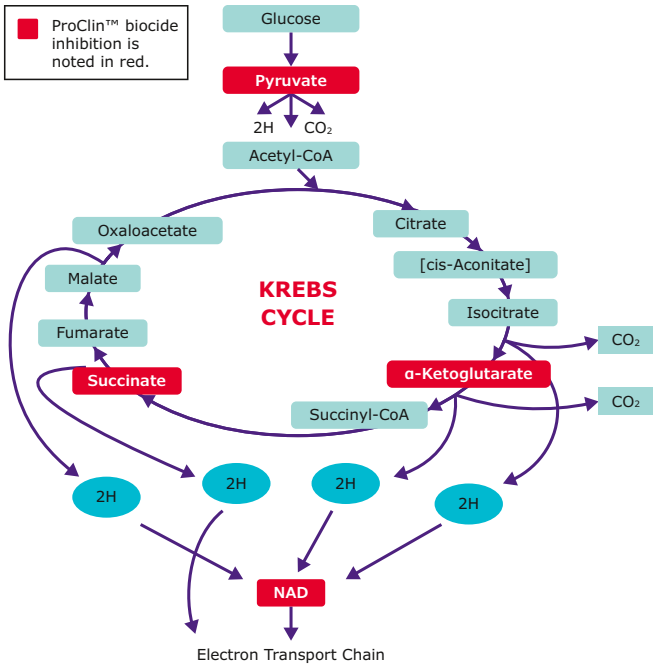
ProClin™ Biocide Preservatives

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.



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**

IVDR Update

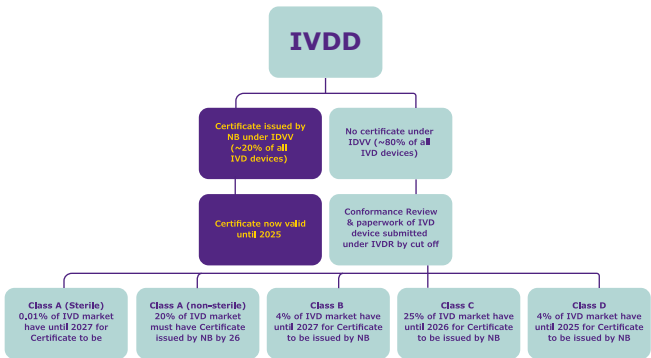
The EU Medical Devices and In Vitro Diagnostics Regulations from 2017 are the biggest change in European regulations related to medical devices and *in vitro* diagnostics (IVDs) since the introduction of the current EU CE marking directives.

This has huge implications to the medical device industry in Europe, impacting all “economic operators” (i.e., manufacturers, importing or distributing devices into Europe, authorized representatives, notified bodies and competent authorities). Critical suppliers to medical device and IVD manufacturers will also feel the impact of the new regulations. The two new regulations were published in May 2017 with a three-year transition period for the Medical Device Regulation (MDR) and a five-year transition for the In Vitro Diagnostic Regulation (IVDR). The longer transition time for the IVDR, is due to the major change in classification from the old IVDD to the new IVDR and the subsequent impact this will have on IVD manufacturers.

The regulations introduce a number of new requirements and changes. Some of the major changes include:

- Changes in the classification of IVDs which will lead to a greater number of IVDs requiring notified body conformity assessments
- New requirements for performance evaluation for IVDs including performance evaluation reports
- Introduction of a person responsible for conformity of the device before it is released
- Identification and traceability - introduction of Unique Device Identification Mandated (UDI)
- Strengthening of the position of Notified Bodies in relation to manufacturers including introduction of unannounced inspections

Our Life Science business has implemented a global project based around a core multi-functional global team providing expert project management, strategy, procedures/templates and guidance/training to local site teams and sub-teams to implement site specific project plans to meet the deadlines for the new regulations.



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 MQ levels 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 6 MQ levels from MQ100 to MQ600 defining the quality attributes and the notifiable changes in each level.

Find out more at **SigmaAldrich.com/M-Clarity**

Sign up for News on Diagnostics at
SigmaAldrich.com/news-on-diagnostics

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**.

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