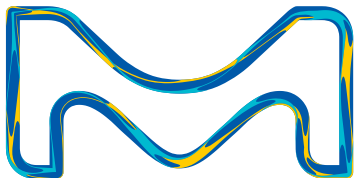


NEWS

on diagnostics

2023 Volume 1



In this issue....

- Engaging your CMO
- Lateral Flow Assay Support - LFADS
- Upcoming IVD event

Welcome to the first issue of News on Diagnostics for 2023. Last year, we discussed what you should consider when looking for a CMO partner. Once that decision has been made, what next?

What services can we offer to support your projects?

This volume of News on Diagnostics explores your options from full contract manufacturing, to troubleshooting steps, to expert technical workshops for your staff.

Diagnostics Elevated



Merck has launched a new program, Elevate, designed to provide manufacturers with products that meet the ever-changing regulatory landscape. Elevate will help navigate your application needs, by providing high quality products for your medical device, which includes audit-ready documentation, site support, and a growing portfolio of products to be included to the program.

SigmaAldrich.com/Elevate-Quality-Program

Getting the Most From your CMO

Our quality systems and regulatory expertise combined with a full range of custom and contract manufacturing (CMO) services provide a global solution for the diagnostics industry with a focus on customer satisfaction. We are proud to partner with the world’s largest diagnostics manufacturers as well as helping new diagnostics companies navigate compliance requirements and launch the products that

will transform healthcare. We offer a comprehensive array of services to meet the development and production needs of medical device manufacturers and diagnostic organisations worldwide.

The table below details the manufacturing sites we have available for your projects, the individual site expertise, and includes the quality certifications each site holds.

Diagnostic Solutions Manufacturing Facilities

Manufacturing Sites		Strengths			Certifications (ALL SITES ISO 9001)		
					USDA	ISO 13485	cGMP
St. Louis, Missouri, U.S.	Ewing	Assay Production	Large Scale Buffers	Molecular Biology Reagents	●	●	●
	Cherokee	Tableting	Pouching	Custom process	●		●
	Dekalb	Proteins & Enzymes	Detergents, Resin, carbohydrates	Formulation & packaging	●	●	
California, U.S.	Temecula	Antibody Purification & Conjugation	Lyophilization	Media	●	●	
	Rocklin	Antibodies small scale	IHC Reagents	Control Slides		●	
Illinois, U.S.	Kankakee	BSA Production	Protein Purification	Enzymes	●		
Ohio, U.S.	Cleveland	Synthesis of powders	Buffer derivatives	Purification of amino acids			
Wisconsin, U.S.	Milwaukee	Chemical Packaging	Custom Packaging	Rare Chemical Library			
	Sheboygan	Organic Chemistry	Further Purification of raw materials	OEM Packaging			
Ohio, U.S.	Norwood	High Purity Solvents & ACS Solvents	DNA Reagents	Returnable drums/ recyclers			
Texas, U.S.	The Woodlands	Basic Primers	qPCR probes/primers	SYBR Green and NGSO		●	
Ireland	Cork	Membranes	Analytical Devices Millex	Chromatography Media Glass		●	
U.K.	Livingston	Antibodies large scale	Blood Typing Antibodies	1000 L in clean room		●	●
Israel	Jerusalem/ Rehovot	Fermentation to 4000 L (GMP)	Fermentation to 1000 L	Antibiotics		●	●

Key: ● Site Specific ● Product Specific ● Rehovot only

Packaging Capabilities

We have extensive manufacturing capabilities with a secure supply-chain and global footprint to give you the reliability, consistency, and flexibility to meet your needs.

- Sterile filtration
- Hazardous materials
- Automated torque and weight checks
- Environmentally-controlled suites
- Molecular biology-grade environments

We can support your project with both powder fill and liquid fill capabilities, from small scale (10 µg/10 µL), accurately weighed ampoules and vials, to larger scale (Kg/L) boxes, bags and Cubitainers™.

Our tableting and pouching capabilities are also available, should your assay development needs require it. To explore the full range of options when using our CMO services, including a customer case study library. For more information about our CMO offering, please visit [SigmaAldrich.com/cmo](https://www.sigmaaldrich.com/cmo)

Leverage our Scientific Expertise for Novel Product Development and Manufacturing

Partnering with us means access to our research and development teams. We have successfully helped clients at all stages of product development and have expertise with reagent reformulation, assay

development, scale-up, and tech transfer. As a raw material manufacturer, we have an extensive offering of fit-for-use raw materials that are aligned with regulatory requirements and supply-chain secure.

Our key technologies include:

● Molecular Amplification

- Oligos, probes, amidites
- DNA/RNA enzymes
- Molecular-grade buffers, formulations
- Nucleic acid purification

● Conjugation

- Large molecules to beads/resins
- Linkage chemistry
- Detection reagents

● Bio-organic Reagents

- Detergents
- Resins
- Carbohydrates
- Buffers & solutions
- Hazardous & regulatory complex materials



● Detection Chemistry

- Chemiluminescence
- Colorimetric
- Fluorescence

● Antibody Production

- Monoclonal and polyclonal antibody production
- Blood typing
- Infectious diseases
- Biomarkers

● Protein/Enzyme Production

- Recombinant
- Plant and animal sourced
- Animal-source free

Support for Your In-house Lateral Flow Assay Development - LFADS

Lateral Flow Assay Development Services

Developing a successful diagnostic lateral flow assay can be challenging, and requires significant expertise in many disciplines:

- Biology & Chemistry
- Engineering
- Process Scale Up
- IVD Manufacturing
- Diagnostic Regulatory Requirements

In response to requests from diagnostics customers, we are delighted to present our new Lateral Flow Assay Development Service.

Optimising Lateral Flow Assay Performance

Our goal is to work with you to optimise your lateral flow test for success. We provide expertise as a raw material developer, and in particular, a leader in lateral flow membranes to accelerate your IVD commercialisation.

Some benefits of working with a lateral flow membrane expert include:

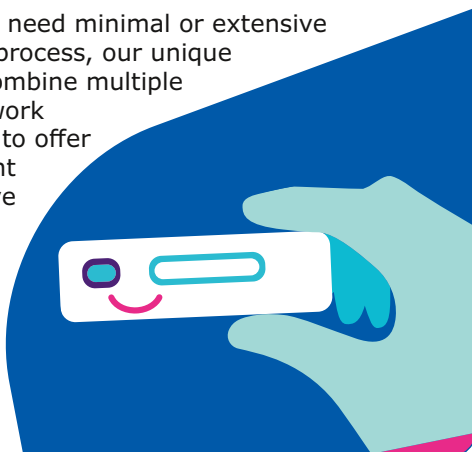
- Utilise vast knowledge of assay raw material market and kit component interactions for sourcing products

- Leverage expert lateral flow assay R&D scientists with dedicated laboratories for troubleshooting
- Avoid common IVD assay development pitfalls and accelerate commercialisation
- Reduce time and supplies in optimisation steps
- Work with a global partner with robust quality systems

Expert support can increase confidence in response to regulatory challenges.

So, whether you need minimal or extensive support in your process, our unique resources can combine multiple disciplines and work closely with you to offer effective, efficient and cost-effective support for your assay development.

[Discover more](#)



Experienced Project Management to Ensure Success

- Single point of contact for operations and project management
- Expertise in:
 - Supply chain
 - Procurement
 - Quality/regulatory
 - R&D
 - Technology transfer
 - Packaging engineering
- Resources to help you navigate industry guidelines and regulations
- Support through your project's life cycle



What do our customers say?

"Having Merck as a supplier helps us to commercialize Elypta's test without significant manufacturing investments and will accelerate time to market," said Karin Mattsson, vice president of Research & Development at Elypta. "Merck's history in IVD product custom manufacturing is well reflected in their current efforts with our kits and we have great confidence in their quality and manufacturing capabilities."

Upcoming Technical meetings for Diagnostic Developers & Manufacturers

We offer annual multi-day meetings and workshops for assay developers and manufacturers covering a variety of technical, commercial, and regulatory topics in conjunction with other industry leaders.

Join us at our face-to-face events in the first half of 2023:

SAVE THE DATE

March 21-22, 2023
Rome, Italy

2023 IVD Conference

Collaboration and Discovery

[Register Today](#)

Keep up to date with all our News on Diagnostics by subscribing to future editions at SigmaAldrich.com/newsondiagnostics

