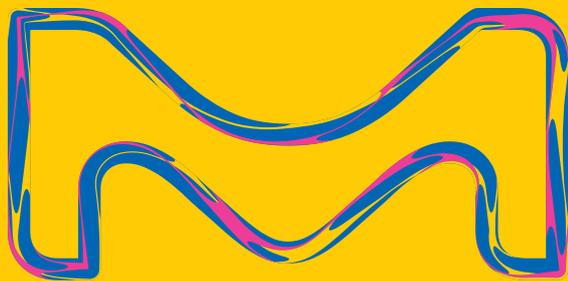


YOUR SCIENCE, OUR EXPERTISE

Contract Manufacturing Solutions

- *In vitro* diagnostics OEM, contract, and custom manufacturing services
- Compliant with quality systems for regulated IVD markets
- Global manufacturing and distribution capabilities



Leverage our Scientific Expertise

Novel product development and manufacturing

Key Technologies

● 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 for 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

Case Study: Co-Development for High-Throughput Automation

Needs	A large clinical diagnostics company needed a partner to co-develop an improved extraction reagent formulation and column for their cell-free molecular kit. They wanted to match their high-throughput automation platform with a larger kit packaging design.
Support	The company worked with our R&D team to co-develop a new extraction tube with improved specificity. They were also able to leverage our portfolio of products and network of supply chain partners for sourcing and development of unique kit components.
Solution	The bulk packaging design reduced their costs by 50% and the streamlined process resulted in a more robust assay. We now manufacture >100,000 kits annually for this client.

Take Advantage of our Manufacturing Expertise

Accelerate your time to market



Our core capabilities include:

- Custom liquid batching and blending
- Custom dry powder manufacturing
- Product development
- Process development and validation
- Tablet manufacturing
- Sterile and low-bioburden filling
- Bulk and vial lyophilization
- Small- and large-scale filtration
- Protein conjugation
- Small- and large-scale bioorganic synthesis
- Kit assembly of manufactured products
- Secure global supply chain and sourcing capabilities
- Cell line creation

Case Study: Outsourcing for Supply Chain Security

Needs	An emerging molecular diagnostics manufacturer was looking for a partner with tableting capabilities who could handle large-scale manufacturing. They were also looking for a partner who could secure their supply chain for critical raw materials.
Support	The client's fast-paced growth required rapid validation. We invested in additional tableting capacity, tanks, and a new fill line to meet the client's growing demands.
Solution	Working together, we were able to complete validation within 3 months. The client leveraged our global supply network to secure their critical raw materials. We are now the primary manufacturer for the client's IVD kits.

Comprehensive Contract Manufacturing Solutions

Increase capacity, quality, and revenue

Extensive contract manufacturing capabilities for private-labeled:

- Reagents
- Buffers and solutions
- Consumables
- Tablets
- Standards
- Multicomponent kits

Commitment to Quality

Our quality systems are designed to meet stringent regulatory requirements, but are flexible enough for us to customize any specific items for your needs.

We offer IVD manufacturing at **21 ISO 13485 certified sites.**

Registrations/Certifications:

- ISO 9001:2015
- ISO 13485:2016
- 21 CFR 82098/79
EC *In Vitro* Diagnostics Directive
- ISO 14001:2015



Staff Story - Cheri Drennan Head of Strategic Implementation

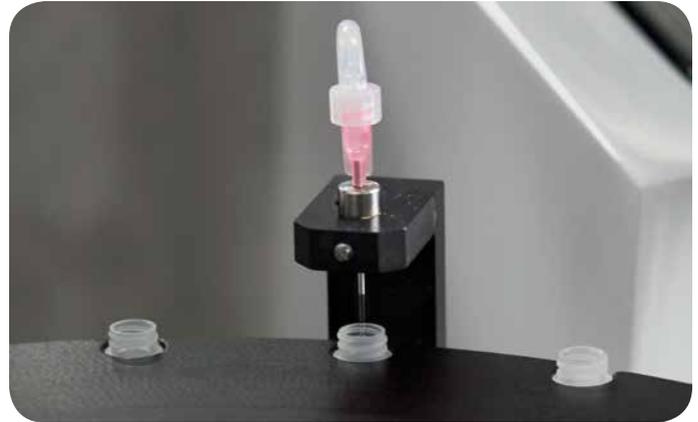
I enjoy partnering with our customers and watching them grow. After 26 years with the company, I have had a variety of roles, from senior scientist to operations management, to head of strategic implementation. It is rewarding to use my experience and knowledge of both our internal operations and the diagnostics market to help customers navigate bringing their products to market and to anticipate their future needs as their businesses grow.

Customized Filling and Packaging Capabilities

Flexibility and options to meet your needs

Key filling capabilities:

- Sterile filtration
- Hazardous materials
- Automated torque and weight checks
- Environmentally-controlled suites
- Molecular biology-grade environments:
 - DNase-free
 - RNase-free
 - Protease-free
 - Phosphatase-free



Powder Fill

- 10 µg to 200 kg+
- Multiple sealing and capping options
- Pouching and tableting

Liquid Fill

- High-throughput automated filling capabilities
- Large batch volume for IVD grade liquid solutions
- 10 µL to 20 L fill volumes
- Large lyophilization capacity
- Environmentally-controlled filling

Formats

- Glass and plastic bottles
- Tubes
- Vials
- Boxes and bags
- Cubitainer® products
- Large-volume totes
- Multiwell plates
- Custom labeling including barcoding

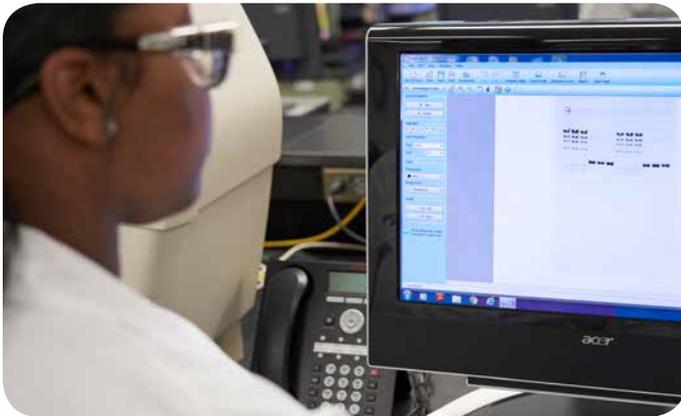


Staff Story - Ray Hapak Senior Project Manager

It is exciting to see the new and unique technologies that our customers are developing. Every new project must be integrated into our operations and resource planning systems and my role is to be our customers' internal champion, translating their requirements into our systems, and helping our operations teams meet our customer needs.

Custom QC Testing

Choose assays relevant to your application



State-of-the-art technology for in process and release testing of IVD raw materials.

Our analysis capabilities:

Molecular

- qPCR, PCR, western blotting, Southern blotting, electrophoresis, nuclease contamination, bacterial growth, cell component isolation kits (DNA, RNA, protein)

Concentration

- Absorbance, titration, biuret, Bradford & BCA, specific gravity

Immunological

- ELISA, western blotting, Ouchterlony double diffusion, cell staining, histology, serology

Functional

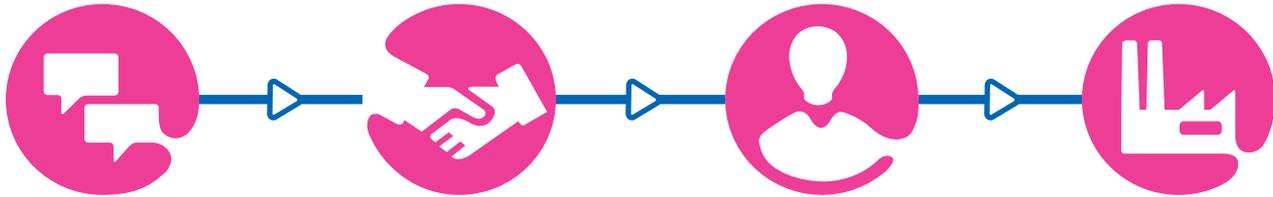
- Plasmid purification, cloning, protein depletion, proximity ligation assays (Duolink®)

Other specialized analyses

- Endotoxins, hematology, enzymatic activity and contamination, cell culture, tablet testing (hardness, friability, and dissolution)
- Test method validation for niche QC needs and ability to partner with external testing labs for esoteric tests
- Functional testing of contract manufactured products on client platform

Your Pathway to Success

Project guidelines and support



Inquiry and Consultation

After receiving your inquiry, you will be contacted by one of our Business Development Specialists

Acceptance

Project specifications are reviewed internally to determine feasibility and costing. A quote for the project is then sent to you.

Creation of Project Team/Implementation

A cross-functional project team is assembled with expertise specific to the project. Small-scale validation batches are produced.

Full-Scale Implementation

We manufacture at scale to your specifications with your custom packaging/labeling for regional or global distribution.

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



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