

# NEWS on diagnostics

2020 Volume 3



Welcome to volume 3 of News on Diagnostics in 2020. This issue covers our contract manufacturing offering for the clinical diagnostics industry.

Our quality systems and regulatory expertise combined with a full range of custom and contract manufacturing 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 organizations worldwide.

## Ensure your Success with Extensive Contract Manufacturing Capabilities for Private Labeled Reagents and Kits

We manufacture single reagents through to finished kits. Our clients have access to our fully traceable supply chain for cost effective sourcing of raw materials. We can maintain your pre-selected raw material suppliers and subcontractors or utilize our global sourcing capabilities on your behalf.

### Our core capabilities include:

- Reagents
- Buffers and Solutions
- Consumables
- Tablets
- Standards
- Multicomponent Kits



Changes in international standards and regulations have created challenges and roadblocks to the commercialization of diagnostic devices. The choice of a contract manufacturing (CM) partner with the expertise to provide guidance and manufacturing capabilities is one strategy diagnostics companies can use to mitigate risk. A well-chosen CM partner can accelerate the commercialization process by anticipating potential roadblocks.

To find out more about best practices and key considerations for vetting a contract manufacturing partner, visit [SigmaAldrich.com/vettingcmopartners](https://www.sigmaaldrich.com/vettingcmopartners)

## 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

## Rely on Quality Systems Compliant with Stringent Regulatory Requirements

We offer IVD manufacturing at 21 ISO 13485-certified sites. Our manufacturing sites are compliant with FDA, International, and ISO regulations. Our registrations and certifications include:

- ISO 9001:2015
- ISO 13485:2016
- 21 CFR 820
- 98/79 EC In Vitro Diagnostics Directive
- ISO 14001:2015



Did you know that working with a robust CMO partner can help support your risk mitigation efforts? To find out more, please visit [Sigmaaldrich.com/riskmitigation](https://Sigmaaldrich.com/riskmitigation)

## Customized Filling and Packaging Capabilities Give the Flexibility and Options to Meet your Needs

### Our filling capabilities include:

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

#### 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

### Case Study: Outsourcing for Supply Chain Security

|                 |   |
|-----------------|---|
| <b>Needs</b>    | 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. |
| <b>Support</b>  | 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.  |
| <b>Solution</b> | 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.                          |

### Custom QC Testing Helps you Choose Assays Relevant to your Application

MilliporeSigma uses state-of-the-art technology for in-process and release testing of IVD raw materials.

### Our analysis capabilities include:

#### Molecular

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

#### Functional

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

#### Immunological

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

#### Concentration

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

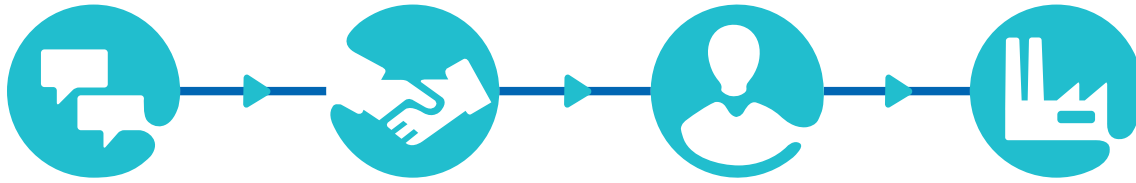


#### Other specialized analyses

- 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



#### What do our customers say?

Having MilliporeSigma 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. "MilliporeSigma'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."

Need more information?

Please visit [SigmaAldrich.com/OEM](https://SigmaAldrich.com/OEM) and download our CMO brochure!

