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Molecular Diagnostics OEM and Commercial Supply Services

Your partners for success

ThermoFisher
SCIENTIFIC

We enable the success of our molecular diagnostics partners in the development and commercialization of integrated solutions using our nucleic-acid–based analysis portfolio of operational and technological capabilities.

Trust us to offer:

- Largest depth and breadth of trusted brands and products
- Leading technologies
- Wide range of IP and manufacturing, and an unsurpassed level of service and support
- Dedicated molecular diagnostics support team



Partnership

How we work with you—one strategic partner



Evaluate workflow needs

- Dedicated licensing and commercial supply team
- In-depth product and capabilities knowledge
- Confidentiality



Select products from our portfolio

- Extensive collection of technologies and tools for genetic analysis
- Many options available to fit your business needs



Customize products as needed

- Comprehensive development and customization capabilities
- Process control
- Pilot lab/prototyping capabilities



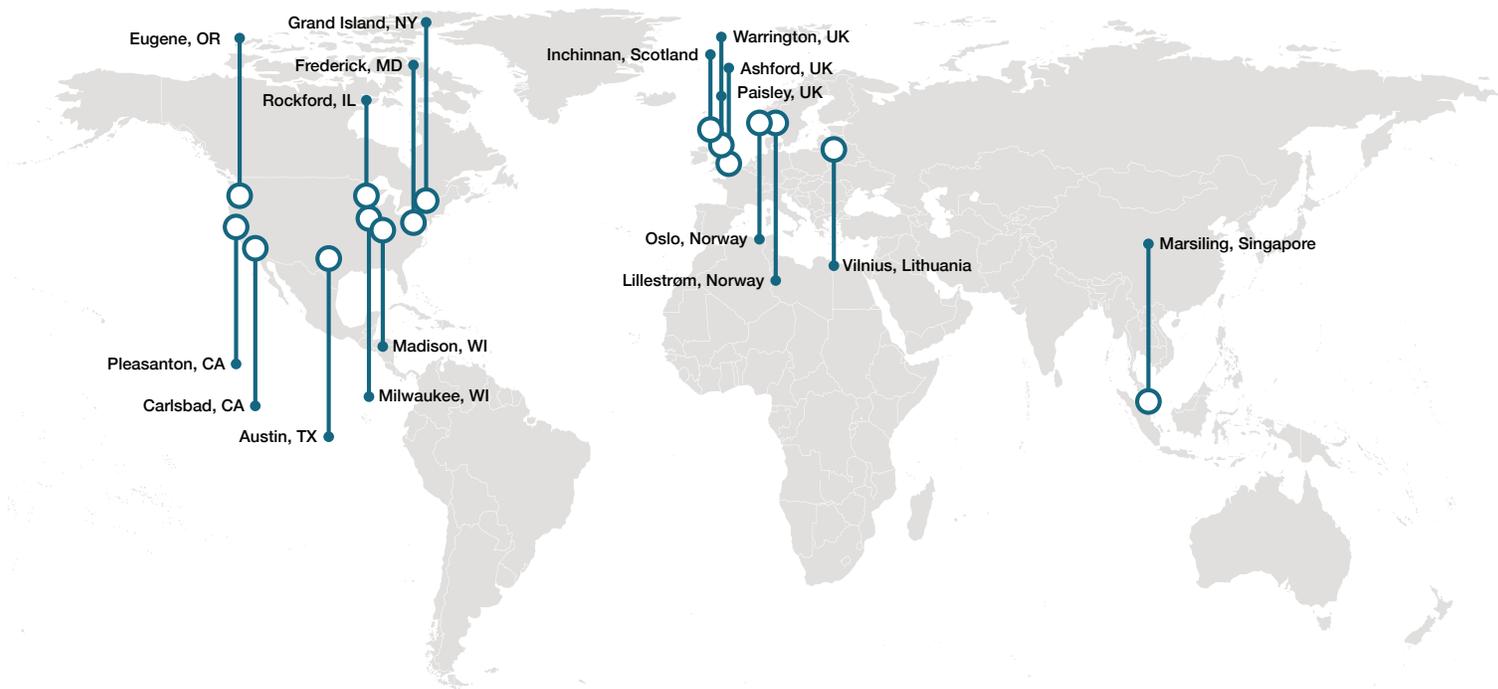
Licensing and supply agreements

- Longstanding expertise in agreements
- Out-licensing
- Change control
- Security of supply



Manufacture products

- Compliance with regulatory standards
- Kitting, packaging, and private labeling



Manufacturing capabilities—the infrastructure to help meet your needs

Making it real: expert manufacturing

Our state-of-the-art manufacturing centers bring your vision into being. True to our commitment to advancing the life sciences, our manufacturing facilities feature:

- **Innovation**—advances in formulation and assembly combined with the power of computerized tracking and controls
- **Maximum flexibility**—configure your product with customized buffer formulation at any scale
- **Reproducibility**—automated liquid handling and stringent quality control
- **Compliance**—certified quality system with ISO 9001, ISO 13485, 14001, and GMP/CFR 820*
- **Global service and distribution**—worldwide manufacturing facilities and global distribution network

Custom development

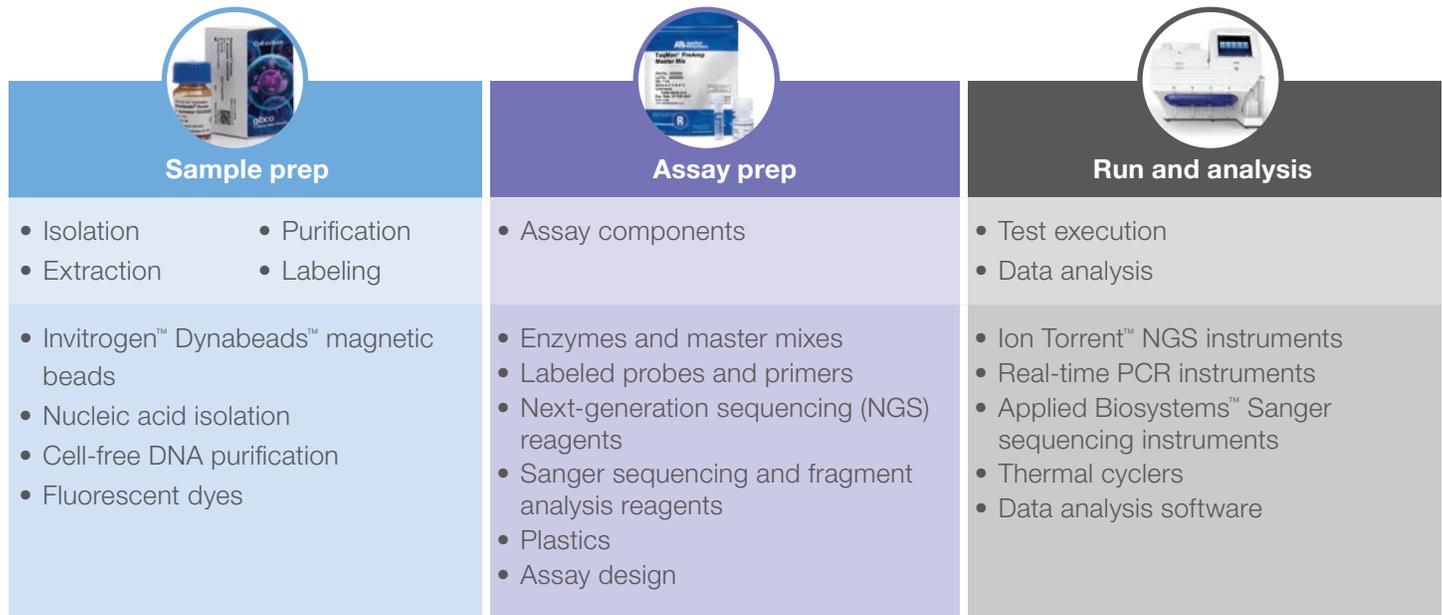
Our dedicated scientists also perform custom development services for OEM partners to meet their unique technical, performance, and process needs.

Partner for the future

Our success helps build yours. With Thermo Fisher Scientific as your provider of customized, quality products, there's no limit to what you can achieve.

* Certification varies from site to site.

End-to-end solutions for molecular diagnostic development



For research use only. Not for use in diagnostic procedures.



“The broad range of genetic analysis products, including Ion Torrent™ next-generation sequencing instruments, is only one of the many reasons we chose Thermo Fisher Scientific as our strategic partner for developing molecular diagnostic tests. Its dedicated team—including field engineers, bioinformaticians, key account managers, CFDA registration experts, and global leaders—has been a great resource in helping us expand our business.”

—Junquan Xu, President, CapitalBio Technology

Nucleic acid isolation products for purifying a wide range of sample types

We support your molecular diagnostic workflow by offering:

- Invitrogen™ Dynabeads™ and Applied Biosystems™ MagMAX™ DNA and RNA extraction products for blood, cell-free DNA, pathogen DNA/RNA, and formalin-fixed, paraffin-embedded (FFPE) samples
- Automation with Thermo Scientific™ KingFisher™ instruments
- Proven track record with a history of supporting diagnostic companies for over 20 years
- Regulatory compliance (ISO 9001 and ISO 14001)
- Contract manufacturing capabilities for consistent, reproducible results
- Customizable components supporting diagnostic assay development: buffers, bead types, packaging, and more



“Securing access to Invitrogen™ Dynabeads™ MyOne™ magnetic beads and reagents for our second-generation colorectal cancer blood test enabled us to reduce the complexity of the kit significantly. The high-quality materials were able to improve reproducibility and robustness of our method.”

—Uwe Staub, PhD, Chief Operating Officer, Epigenomics

Assay development

We support our partners with our high-quality enzymes and master mixes, Applied Biosystems™ TaqMan® Real-Time PCR Assays, Sanger and NGS solutions, and target sequencing oligos. We offer sensitive, specific detection and quantification of nucleic acid targets, together with our powerful assay design informatics algorithms.

Run and analysis

We offer a range of genetic analysis systems specifically designed for regulated laboratory environments and *in vitro* diagnostic applications. Whether you develop molecular tests for infectious disease, oncology, or inherited disease diagnostics, our instruments support your lab's assay development needs along with a workflow to match your diagnostic requirements.

- Applied Biosystems™ real-time PCR systems
- Applied Biosystems™ genetic analyzers
- Ion Torrent™ NGS instruments
- Applied Biosystems™ PCR thermal cyclers
- Data analysis software



“Adding the Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System to the VERSANT™ kPCR Molecular Solution brings a new level of innovation to the market by providing more flexibility and customization to the molecular laboratory workflow. We are excited to strengthen our dedication to molecular laboratory innovations through our partnership with Thermo Fisher Scientific.”

—Fernando Beils, Head of Molecular Diagnostics, Siemens Healthineers

“The quality and performance of Applied Biosystems™ master mixes and custom oligos are key for our diagnostic kit development. The Thermo Fisher team provided us with a one-stop solution for the entire process—from assay test design, assay optimization, and kit validation, to partnering on the development of our commercialization strategy.”

—Patrick Burke, PhD, Executive Vice President, Emerging Products, Myriad Genetics



For more information about molecular diagnostics partnership opportunities, go to thermofisher.com/mdxoem or contact us at mdxoem@thermofisher.com

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