

# **Our service**

# your success

- · In vitro diagnostics OEM, licensing and contract manufacturing
- · Compliant with FDA, International and ISO guidelines
- · Global facilities with wide-ranging capabilities



## Thermo Fisher Scientific

# **Enabling Partner Innovation and Productivity Through Custom Solutions**

Thermo Fisher Scientific Clinical Diagnostics is an industry-leading provider of products and services for the *In vitro* diagnostics (IVD) market. With over 35 years of manufacturing and partnering experience, we are dedicated to OEM and contract manufacturing and are a trusted partner of global *In vitro* diagnostics companies. Thermo Fisher Scientific offers unparalleled scale and process breadth, with over 3,000 products manufactured and 1,800 employees working across global locations. Our focus is to provide quality, delivery and reliability with the ability to offer flexible solutions to our customers.

## **Contract Development and Manufacturing**

Our contract development services enable our partners to increase and optimize their ability to identify biomarkers and design IVDs. We can accelerate time to market by developing assay applications on instruments, including partners' proprietary instruments. Our partners and customers can increase their available manufacturing capacity and shorten lead times by using our large scale liquid formulation, lyophilization, filling of bottles and vials, as well as final label, pack and kitting operations. Customers can expand their product reach by taking advantage of our extensive distribution network and have confidence in product delivery with our logistics services.

## **Commitment to Quality**

Our mission is to create value for our customers, shareholders and employees by continuously improving the quality of our products, services, skills and processes. Being able to rely on our Quality and Regulatory Systems is a cornerstone for our contract manufacturing customers and partners.

- FDA Medical Device/IVD Regulations
- Canadian Medical Device Regulations
- 98/79 EC In vitro Diagnostic Directive
- ISO 13485:2003 Medical Device and Quality Systems Certified
- ISO 9001 Certified
- ISO 14001 Certified





Large Volume Formulation: up to 40,000 liters



Small & Custom Formulation: up to 4,000 liters



2,100 sq ft of shelf space with 11 lyophilizers



**Customized high speed filling lines** 



## **Global Manufacturing Footprint**

Our development and manufacturing centers of excellence are located in the United States, Europe and Asia. All current sites are compliant with FDA and International regulations. Many opportunities are available for global relationships with regional and local manufacturers.







## Fremont, California

46500 Kato Road Fremont, CA 94538 Phone: +1 800-232-3342

Email: sales.diagnostics.fmt @thermofisher.com

## Middletown, Virginia

8365 Valley Pike Middletown, VA 22645 Phone: +1 800-528-0494

Email: sales.diagnostics.mtn @thermofisher.com

## Hennigsdorf, Germany (includes Nimes, France)

Neuendorfstraße 25

16761 Hennigsdorf, Germany Phone: +49 (0)3302 883 753

Email: info.nebud.brahms @thermofisher.com

## Vantaa, Finland

Ratastie 2, 01620 Vantaa, Finland

Phone: +358 10 329 200

Email: sales.cdx.fi @thermofisher.com

## Suzhou, China

297 Taishan Road, New District Suzhou, P.R. China 215129 Phone: +1 800-528-0494

Email: sales.diagnostics.mtn @thermofisher.com

thermoscientific.com/dx-contract-services

© 2015 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries.

