

Your preferred partner for IVD assay development

- Validated products recognized for superior reproducibility
- Flexible world-class manufacturing facilities at relevant regulatory levels
- Extensive proprietary knowledge enables customized product development

A track record to be proud of

Leading diagnostic companies choose Dynabeads® and have done so for over 15 years. A comprehensive range of products is available, across different sizes and surface chemistries. Dynabeads® products are provided on an OEM basis, as well as directly to end-users and to centralized services laboratories. More than 25,000 automated IVD instruments worldwide employ these uniform and mono-sized magnetic beads. And the number is increasing.

As the preferred partner for biomagnetic separations, we work with a wide range of customers and partners to develop optimized Dynabeads® that meet their specific application and regulatory requirements. Our competence reflects the knowledge and intellectual property (IP) rights built up through many years in research and development, production and quality assurance. Dynabeads® provide the quality and reproducibility your products—and customers—demand.

Highly controlled processes

We firmly believe that quality cannot be tested into a product—it must be included during development, built in during manufacture and provided in follow-up support. Quality is planned into each product by unambiguous raw material specifications,

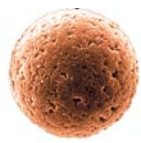
highly controlled and reproducible manufacturing processes and meticulous QC procedures.

With modern and flexible production facilities, we are able to manufacture batches ranging in size from 1 g up to 2 kg. Products are manufactured to meet the relevant regulatory requirements, backed with documentation and validation. Production processes are continuously developed, improved, scaled up, controlled and validated. Customer-specific QC methods and specifications are available, when required.

Dynabeads® are thoroughly characterized. They show a unique level of reproducibility both within and between batches. Patented manufacturing processes ensure careful control of bead parameters and product properties, securing their performance. Expertise and first class manufacturing make Invitrogen and Dynal® the safest choice for your assay development.

Increase your manufacturing efficiency

Leading IVD companies benefit from the highly controlled and reproducible Dynabeads® production processes, allowing reduced incoming QC testing, cut in process QC costs and increased manufacturing efficiency. Close to zero off-grade batches and a flexible production scale secure long-term product supplies, and make Dynabeads® a good business choice.



Dynabeads® OEM Capabilities

The monodispersity and superparamagnetism of the Dynabeads® ensure optimal behavior in automated systems. Minimal batch-to-batch variation allows for simpler, standardized, and automatable production processes.

QA and regulatory compliance

We have won the confidence with our customers by offering flexible world-class manufacturing at relevant regulatory levels. We audit our suppliers and are routinely audited by our customers, as well as by the FDA and the Norwegian Notified Body (Det Norske Veritas Certification AS).

Our quality system complies with ISO 9001:2000 as well as ISO 13485:2003 (medical devices, quality management systems, requirements for regulatory purposes). The quality system is based on customer requirements and describes quality assurance in design, development, production, and servicing. It follows the requirements included in Quality System Regulations for Medical Devices (21 CFR part 820, US cGMP), when necessary.

More than just a bead supplier

Dynabeads® are recognized as the proven gold standard for magnetic separations. We put much emphasis on IP and hold a strong portfolio of international patents and patent applications covering both the production and use of monosized polymer magnetic particles. Our IP portfolio and competencies provide exceptionally strong support for products, applications, and services. Extensive proprietary knowledge enables customized product development.

The Dynal® brand is associated with unique products and innovative work. The high level of competence within R&D, process development, and manufacturing is a very valuable asset for our customers. We grant access to in-house expertise in bead manufacture, surface chemistries, and ligand immobilization. We respond to your changing needs and meet your present and future assay development, manufacturing, and regulatory challenges.

Dynabeads® make good business sense. Learn more about Dynabeads® IVD assay development at www.invitrogen.com/ivd.

If you would like to discuss a potential collaboration or an OEM agreement, please contact us at email: dynal@invitrogen.com.

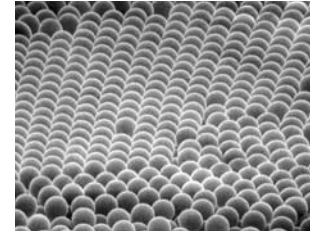


Figure 1—All Dynabeads® are equal. Extensive proprietary knowledge and careful control of bead parameters facilitates customized product development.



Figure 2—Quality cannot be tested into a product. It must be included during development, built in during manufacture, and provided in follow-up support.



Figure 3—World-class manufacturing capabilities. The production facilities are flexible and will meet your regulatory requirements.