

Immunodiagnosics

Transition to a high-performance magnetic bead-based immunoassay

invitrogen

Partner with us to upgrade to magnetic beads—improve and speed up your immunodiagnostic assays

Finding the best combination of tools and technology to develop a scalable high-performance immunodiagnostic assay is a challenge. Our goal is to make your transition from colorimetric ELISAs to high-throughput chemiluminescence immunoassays easier. Thermo Fisher Scientific integrates Invitrogen™ Dynabeads™ magnetic beads and chemiluminescence detection technologies into efficient and sensitive platforms for the development and optimization of effective, high-quality immunoassays. Thermo Fisher has collaborated with many of the world's leading immunodiagnostics companies for decades. By partnering with us, you will have access to our extensive technology offerings and support to rapidly and cost-effectively develop your immunodiagnostic assay and reach your market faster.

With us, you can achieve:

- **Optimal performance**—on a sensitive, random-access platform that combines magnetic bead immobilization and chemiluminescence detection
- **An easier transition**—our goal is to enable a smooth transition from your colorimetric ELISA to a bead-based chemiluminescence assay
- **Faster time-to-market**—get a head start with our trusted automation partners and our experience in immunodiagnostic assay development
- **Cost-effective development and automation**—with a streamlined development process facilitated by our experience working with automation partners, e.g., Immunodiagnostic Systems (IDS), our customization services, and extensive portfolio of products

[Watch our video](#) to see how plate-based ELISA compares to Dynabeads magnetic bead-based ELISA, saving hands-on time and manual errors with our automation-enabled solution.

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Dynabeads magnetic beads are used in over 25,000 IVD instruments worldwide

Customizable conjugation with Dynabeads magnetic beads

Dynabeads team—over 30 years of partnering with leading *in vitro* diagnostics manufacturers

Comprehensive assay development capability

- Complete workflows
- Alkaline phosphatase substrates
- Antibodies and antibody conjugates

Thermo Scientific™ KingFisher™ automation system is optimized for use with Dynabeads magnetic beads

Collaboration with automation partners such as IDS

Making assay transfer easier

Transitioning to a new platform doesn't have to be difficult

Our collaboration begins by understanding your needs and the challenges you might encounter, which will enable us to tailor our service and support offerings for each stage of your development process. Thermo Fisher can work with you from start to finish and provide scientific consulting services like bead screening. We can also help you conjugate your biomolecule to any of our standard Dynabeads magnetic beads or create custom beads for your specific needs. We offer development and manufacturing consulting services, and we can support your commercialization process when you are ready. With our technical support and a

reliable supply chain, you can enjoy peace of mind throughout the journey to market. When developing a magnetic bead-based assay, automate the assay using our KingFisher instruments, or collaborate with one of our trusted automation partners to enable, for example, random access to samples and higher assay sensitivity. As you develop your assay, you will have access to consumables and instrument service and support. With access to our reagents and customization capabilities along with your technology platform's instrumentation, support, and ancillaries, you can smoothly transfer your assay.

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Automation partners



A success story

Volition Nu.Q immunoassay development and automation on the IDS-i10 platform

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Volition is a multinational diagnostics company that developed the Nucleosomics™ immunoassay platform to profile the epigenetic features of circulating extracellular nucleosomes for early-stage cancer detection. Volition Nu.Q™ immunoassays run on the Nucleosomics platform can identify individuals who are at risk for colorectal cancer, lung cancer, and a range of blood cancers. The performance of Nu.Q assays improved significantly when Volition transitioned them to the IDS-i10™ platform of Immunodiagnostic Systems (a PerkinElmer company) and coupled its biomolecules to Invitrogen™ Dynabeads™ MyOne™ Tosylactivated beads, and the company was able to reach its launch targets.

Nu.Q immunoassays were originally developed to be run in standard 96-well plates. While the plate format worked well, the company's nucleosome profiling approach required a step change in development throughput. By partnering with Thermo Fisher and IDS, Volition was able to reduce its limits of detection (LODs) and limits of quantitation (LOQs) by nearly an order of magnitude. They also saw a 5-fold improvement in precision and less inter-day variability.

The plate-based assays required 5 hours for one person to run, with a maximum throughput of ~120 samples per day. The bead-based assays can be run in 45 minutes, so 60–80 tests can be performed in one hour. The dynamic range of the bead-based assays is also wider, so fewer dilutions are necessary when biomarker abundance is high.

Table 1. Improvements in Nu.Q immunoassay performance after transitioning to a bead-based format.

Specification	ELISA	Assay on IDS-i10 platform with Dynabeads MyOne beads	Benefit
LOD	9.1 ng/mL	1.27 ng/mL	7-fold improvement
LOQ	22.07 ng/mL	3.15 ng/mL	7-fold improvement
Range	22.7–650 ng/mL	5–1,500 ng/mL	Wider dynamic range
Precision (QC samples)	7.1–11.8%	0.9–2.3%	5-fold improvement
Inter-day and -operator precision	8.5–19.3%	4.8–10.4%	1.9-fold improvement
Assay time	5 hours	45 minutes	>6-fold improvement
Throughput	120 samples per person per day	60–80 tests per hour	Less hands-on time

“Volition was able to scale up quickly and reach its target of developing and analytically validating four new Nu.Q assays per quarter, all while adhering to the guidelines of the Clinical and Laboratory Standards Institute (CLSI). Transitioning from our plate-based RUO format to Thermo Fisher beads coupled with the open-access IDS-i10 platform has been transformational in terms of the speed with which we can develop and validate new assays in our discovery pipeline. The combination provides a seamless link from Nu.Q biomarker discovery to clinical test validation through regulatory approval and market launch for our products.”



Dr. Mark Eccleston,
scientific founder
and CTO of Volition



Dynabeads and custom solutions

Developing a reproducible chemiluminescence assay that is sensitive, specific, and precise can be a complex process. Many things must be executed correctly if you want to develop the best assay on the market, so you need more than just a supplier—you need a partner who can deliver scientific innovation and support from development through commercialization. This is exactly what the Dynabeads team has been doing for more than 30 years. We apply our deep knowledge, leading manufacturing capabilities, and legal and regulatory experience to support and enable our partners from early development through validation, scale-up, and commercialization. Our best-in-class reagents and technologies provide the high quality and lot-to-lot consistency you need to develop a high-performance immunoassay.

Dynabeads magnetic beads

Dynabeads magnetic beads provide superior uniformity in size, shape, and surface area to help ensure consistent performance and rapid solid-liquid phase reaction kinetics. Leading *in vitro* diagnostics manufacturers have chosen Dynabeads magnetic beads for over 30 years. Our Dynabeads portfolio includes a range of particle sizes and surface chemistries, and we can customize beads for your specific application.

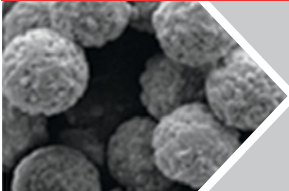
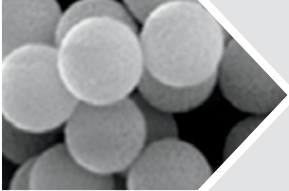
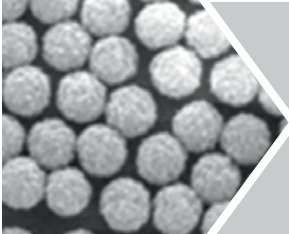
All Dynabeads products are validated for excellent reproducibility within and between batches. Bead parameters and product quality are carefully controlled in our manufacturing processes to help ensure consistently excellent performance.

Custom Dynabeads solutions

Let us facilitate your transition to a Dynabeads magnetic bead-based platform by directly coupling your biomolecule to the optimal bead for your assay. The production scale at our world-class manufacturing facilities is flexible, and our commercial agreements will help you avoid quality issues and supply chain disruptions that could get in the way of your success.

KingFisher systems

KingFisher systems offer versatile laboratory benchtop automation. Workflows remove manual steps and reduce overall processing time, even when compared with other instruments. Our data show that sample processing results from KingFisher systems are consistent across runs and different users, which is crucial for sensitive downstream applications such as immunodiagnostic assays. KingFisher instruments are optimized for Dynabeads reagents, which is central to consistent binding and reliable, reproducible results.

	Magnetic beads platform	Characteristics	Surface chemistry options
	Invitrogen™ Dynabeads™ M-280 beads (hydrophobic) 2.8 µm	High surface-to-volume ratio High antibody loading Wide application range	Tosylactivated (no charge) Streptavidin
	Invitrogen™ Dynabeads™ M-270 beads (hydrophilic) 2.8 µm	High surface-to-volume ratio Fast coupling, no need for blocking Low background	Carboxylic acid (negative charge) Epoxy (no charge) Streptavidin
	Invitrogen™ Dynabeads™ MyOne™ beads (hydrophilic or hydrophobic) 1.1 µm	Highest surface-to-volume ratio Fastest kinetics Slow sedimentation	Tosylactivated Carboxylic acid Epoxy Silane Streptavidin

KingFisher instrument specifications

KingFisher instruments are the most versatile sample preparation instruments in the lab, and are elegantly designed to support multiple applications.

- **Variable throughputs**—process 6–96 samples per run depending on the instrument model
- **Interchangeable formats**—choose 24- and 96-well formats so you can process a wide range of input volumes
- **Protocol customization**—easily edit, modify, or create new protocols (touchscreen-enabled only on the Thermo Scientific™ KingFisher™ Apex instrument)
- **Optimized reagents**—compatible with various magnetic bead–based reagents
- **Barcoded plastics**—for increased user confidence and smooth processing on the KingFisher Apex instrument

Test the KingFisher platform in your lab

One of our specialists can provide an on-site or virtual demonstration of how to process your samples using a KingFisher instrument. We select the instrument, consumables, and reagents that best suit your research needs. The specialist will show you how to set up the instrument, process samples, modify protocols, and perform other tasks specific to your needs. Find out more at thermofisher.com/kingfisherdemo

Find the KingFisher model that meets your needs



KingFisher instrument	Duo Prime system	Flex system	Apex system	Presto system
Instrument size	Compact benchtop	Benchtop	Benchtop	Benchtop—integrates with liquid handler
Throughput	Low to medium	High	High	Ultrahigh
Processing volumes	<ul style="list-style-type: none"> • 30–1,000 µL: 12-pin magnet head • 200–5,000 µL: 6-pin magnet head 	<ul style="list-style-type: none"> • PCR plate (20–100 µL),* skirted • 20–200 µL (96-well plate) • 50–1,000 µL (96 deep-well plate) • 200–5,000 µL (24 deep-well plate) 	<ul style="list-style-type: none"> • 15–1,000 µL (96-well plate) • 15–150 µL (KingFisher 96 microplate, 200 µL) • 10–80 µL (96-well plate) • 30–5,000 µL (24 deep-well plate) • 30–200 µL (96 storage tubes) • 200–1,000 µL (24 storage tubes) 	<ul style="list-style-type: none"> • 50–1,000 µL (96-well plate) • 200–5,000 µL (24 deep-well plate) • 50–150 µL (KingFisher 96 microplate, 200 µL)
Samples per run	6 or 12	24 or 96	24 or 96	24 or 96
Customizable protocols	Yes	Yes	Yes, with touchscreen or PC software	Yes
Heating/cooling	<ul style="list-style-type: none"> • 10–75°C (plate row block A) • 4–75°C (elution strip block) 	From 5°C above ambient temperature to 115°C	<ul style="list-style-type: none"> • From 4°C above ambient temperature to 100°C • Cools down to 4°C 	From 5°C above ambient temperature to 115°C
Ultraviolet lamp	8 W for up to 16 hr	No	2 UV lamps, 23 hr 59 min maximum	No
Additional details	For Research Use Only	For Laboratory Use	For Laboratory Use	For Laboratory Use

* Or similar skirted PCR plate.

Assay development and automation on the IDS-i10 platform

Assay developers can easily optimize their protocols using the IDS-i10 developer module and tailor them for individual assays. The platform allows every step of a protocol to be modified in multiple ways, which makes protocol development easy and flexible. The IDS-i10 platform minimizes hands-on time, so you can focus on optimizing your immunoassay. Samples, reagents, solid waste, and ancillaries can be loaded or unloaded without pausing the run. With its onboard refrigeration and automatic startup and system maintenance features, the IDS-i10 platform is truly a walkaway system.

IDS random access instrumentation is manufactured with best-in-class components in GMP manufacturing facilities. Users of the IDS-i10 system have access to assay development service and training support. FDA 510(k) clearance and full traceability of samples, reagents, and consumables on the IDS-i10 platform can also facilitate laboratory accreditation. As an OEM with 70 years of automation experience, IDS is truly a partner for OEM automation of your assay.

IDS will install your IDS-i10 system and provide training to build your immunoassay. When necessary, on-site instrument service and support from the IDS service team can help you avoid costly and time-consuming delays.

Assay developers and end users love:

- Total protocol flexibility
- Developer module designed for optimizing assays
- Individual assay-specific protocols
- Possibility for thousands of protocols
- Minimal hands-on time
- Continuous loading and unloading of samples
- Automatic startup, self-check, and standby defined by the user
- Automatic self-maintenance
- True walkaway system
- Future-proof engineering
- Track docking to sample conveyors
- Full traceability and compatibility with laboratory accreditation
- Excellent reliability (MTBF >200 days)



Making the transition to a high-performance magnetic bead-based immunoassay

Are you considering transitioning your immunoassays to a bead-based format, and would you like an experienced partner to do so with?

Do not hesitate to contact us for an exploratory conversation.

Contact information:

Thermo Fisher Scientific

oeodynamal@thermofisher.com

Are you looking for an instrument partner and instrument to commercialize your assays on? Please contact us to learn more about how we can help you all the way from development to launch.

Contact information:

IDS

info@idsplc.com

 Learn more at thermofisher.com/immunoassaydynabeads

invitrogen