

## Helio Diagnostics:

### A European CDMO dedicated to In Vitro Diagnostics

Helio Diagnostics is backed by a team with 25+ years of experience in the development and manufacturing of complex diagnostic devices.

**Marseille, France – September 22, 2025** – Helio Diagnostics, a European leader in end-to-end Contract Development and Manufacturing (CDMO) services for In Vitro Diagnostics (IVD), was founded by seasoned entrepreneurs. Under the leadership of CEO Stéphane Debono, the company is supported by a Board of Directors bringing together Corinne Danan, Philippe Dhamelincourt, Vincent Fert, and Fabienne Hermitte.

*“Our goal is to become a reference European CDMO in IVD outsourcing, making innovation operational”* said **Stéphane Debono, CEO**. *“The diagnostic industry is expanding rapidly, and clients need partners who combine technical depth with operational agility. With our experience and pure focus on IVD, Helio Diagnostics is ideally positioned to become a trusted partner to the world’s leading diagnostic companies.”*

### Trusted by Industry Leaders

Helio Diagnostics has already established long-term partnerships with global diagnostic companies:

*“Helio Diagnostics provides reliable manufacturing and technical support for our Ipsogen RUO and IVD products – a partner we trust for long-term collaboration. Their team has ensured seamless technology transfer and lifecycle management for some of our IVD-R product registrations. With their ongoing technical support, customer focus, agility and flexibility, they are a partner of choice.”* - **Thierry Bernard, CEO at QIAGEN**.

*“Veracyte has selected Helio Diagnostics to maintain continuity of supply for our Prosigna IVD nCounter test. Having worked with this team before, we are confident that Helio Diagnostics is a partner we can count on to serve our customers outside the US.”* – **Marc Stapley, Veracyte’s CEO**.

### A Strategic Market Opportunity

The \$13 billion global IVD outsourcing market is growing at 7.5% annually but remains fragmented, with few specialized end-to-end CDMOs.

Helio Diagnostics was created to fill this gap: a dedicated European partner focused solely on In Vitro Diagnostics. With a seasoned team and seamless “plug-and-play” integration, Helio Diagnostics delivers flexible, customized solutions already trusted by leading diagnostic companies.

**From concept to commercialization, Helio Diagnostics covers the full IVD lifecycle with a 360° perspective:**

- Feasibility & development - assay design, development studies and pilot production
- Performance Verification, Analytical and Clinical Validation
- Industrialization and Tech Transfer - scale-up, process verification and validation
- Quality Assurance & Regulatory Affairs - ISO 13485 and 21 CFR Part 820 compliance, CE - marking, FDA and global submissions
- Manufacturing & Logistics - kit production, cold chain management and worldwide shipping
- Lifecycle Management - post launch monitoring, real-time stability studies and continuous improvement

Helio Diagnostics combines flexibility, integration, and operational excellence to support diagnostic innovators from concept to market across multiple fields: oncology, infectious diseases, and more. Our team leverages decades of combined expertise to help partners overcome technical, regulatory, and operational challenges with agility, accelerating time to market while delivering reliable, compliant solutions at scale.

**At Helio Diagnostics, our mission is to be the trusted European partner for diagnostics companies looking to accelerate innovation, scale efficiently and succeed globally.**

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## **About Helio Diagnostics**

Helio Diagnostics is a European CDMO dedicated to In Vitro Diagnostics (IVD) — helping companies bring tests from concept to market with speed, compliance, and reliability.

With 25+ years of proven manufacturing expertise in Marseille, Helio Diagnostics' team combines technical depth, regulatory know-how, and operational excellence to support diagnostic innovators worldwide with:

- Development & Validation
- Regulatory support
- Scalable manufacturing
- Global logistics
- Lifecycle management

The mission: make innovation operational with customized and flexible solutions.

Helio Diagnostics already serves a global client base and maintains trusted partnerships with leading diagnostic companies worldwide.

## **Contacts**

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