

CASE STUDY

Take your assay anywhere

**Company**

Midsized global company

Background

The client developed PCR-based multiplex assays for research in infectious and inherited diseases. These assays are run on an instrument platform that utilizes a disposable cartridge containing a lyophilized PCR assay. In early phase assay development, the client evaluated *Taq* DNA polymerases and reverse transcriptases (RTs) from multiple enzyme suppliers and determined that *Taq* DNA polymerase and Invitrogen™ SuperScript™ III RT from Thermo Fisher Scientific provided the performance that met their assay requirements.

Challenges

While Thermo Fisher Scientific provided the needed performance in glycerol-based PCR enzymes, it would require an integrated development and manufacturing team to provide the same characteristics in a custom lyophilization-compatible (lyo-ready) formulation.

Evaluations

Capabilities

- Dedicated R&D and manufacturing codevelopment team with the client involving R&D, QC, manufacturing scientists, and business development manager to work closely from development and manufacturing to scaling and verification
- Expertise in development and manufacturing of enzymes, such as industry-leading Invitrogen™ SuperScript™ RTs
- Integrative quality systems covering supply chain, manufacturing, and quality control processes in a ISO 9001–certified facility

Partnership

Over 25 years in the OEM and commercial supply business with understanding of the implications of product development for commercialization such as logistics of scale, and format.

Results

- Dedicated custom project management team was established, led by a project manager with R&D, operation, and business lead from both Thermo Fisher and the client. For product development and launch, Thermo Fisher was a holistic partner in all phases of development, verification, scale-up, and launch.
- Understanding the client's commercialization plans and concerns—the business development manager worked with the client to develop a flexible contract that helped the client reframe their financial model and move forward with a commercialization plan.
- Comprehensive development and manufacturing capabilities in Thermo Fisher Scientific for custom product formulation and configuration—a lyo-ready enzyme formulation was developed without glycerol for lyophilized assays (e.g., *Taq* DNA polymerase and SuperScript III RT). In addition to meeting specific requirement for the client's platform, the lyo-ready enzymes retained the same optimal performance as the standard formulation enzymes.

Thermo Fisher Scientific R&D

Development of a method to remove glycerol from SuperScript III RT and *Taq* DNA polymerase

Thermo Fisher Scientific R&D and manufacturing

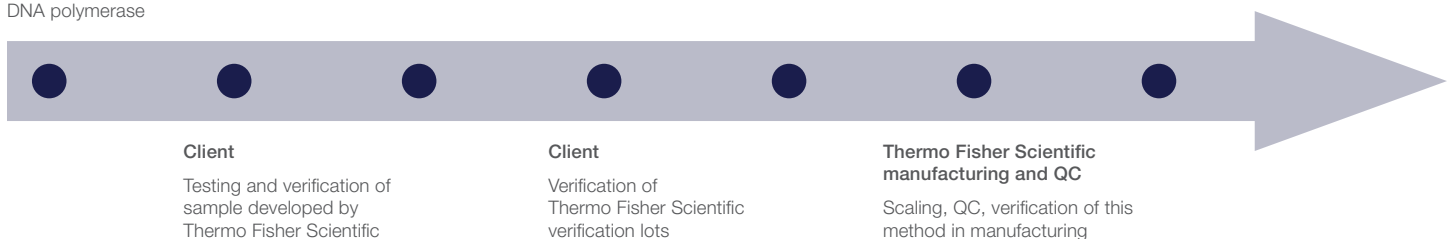
Transfer this method to manufacturing of verification batches

Thermo Fisher Scientific R&D and manufacturing

Transfer this method to manufacturing of production-scale batches

Client

Verification of Thermo Fisher Scientific production-scale batches



Summary

Partnering with our client to codevelop and manufacture a custom product formulation, the OEM team at Thermo Fisher Scientific delivered a lyo-ready enzyme solution that allowed our client to bring their assay to market. In addition, the partnership helped our client review and consider all aspects of the products they chose to include in their assay, not just the technical aspects. These included rights, logistics, etc. Our commitment to the client helped them avoid additional pitfalls and meet their needs for commercialization.



About Thermo Fisher Scientific OEM and Commercial Supply

The breadth of our product portfolio affords our partners a range of options in selecting tailored technologies to help shorten their development timelines and maximize return on investment. And our dedicated commercial-supply cross-functional team understands the unique nature of OEM requirements, to make the partnership process a smooth one.

Our best-in-class manufacturing processes, certified cleanroom facilities, integrated quality management system, and extensive R&D experience enable us to produce the high-quality products, and develop innovative workflow solutions for partners in molecular development, life science research, and applied markets.

A solid worldwide infrastructure helps ensure on-time delivery, long-term sustainability, and superior service and support. Our team works with you every step of the way.

Find out more at thermofisher.com/oemmolecular

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