

CASE STUDY

Flexibility makes a good enzyme package

**Company**

Midsized global company

Background

The client was developing a PCR assay to screen for hundreds of pathogens for infectious disease research. They had been evaluating *Taq* DNA polymerases from several suppliers. Unfortunately, all of these enzymes contained DNA contamination from host cells used for production of the recombinant enzymes. The client came to Thermo Fisher Scientific and asked if we could manufacture *Taq* DNA polymerase with no- or low-nucleic acid contamination at a specific price point. The client chose us because we had:

- The flexibility to produce and supply multiple small sample batches for the client's evaluation
- The capability in R&D and operations to develop and manufacture a product that met the client's needs

- The ability to holistically partner with the client in all phases of development, scale-up, launch, and postlaunch support (R&D, manufacturing, business teams)

With our successful partnership in supplying nucleic acid-free *Taq* DNA polymerase, the client asked if we could also provide another enzyme, Thermo Scientific™ Maxima™ Reverse Transcriptase (RT), with low-DNA contamination. Utilizing the technical know-how from the previous custom manufacturing of *Taq* DNA polymerase, Thermo Fisher Scientific was able to deliver Maxima RT with low nucleic acid contamination.

Challenges

The client's assays were particularly sensitive to any contaminating DNA present in the assay mixture. Minute quantities of contaminating DNA can lead to false-positive or false-negative results in highly sensitive molecular assays. Many commercially available PCR enzymes contain DNA contamination, estimated at 10–1,000 genome copies per enzyme unit. Therefore, the client asked if Thermo Fisher Scientific could manufacture PCR enzymes with low DNA contamination while retaining the same product performance.

Evaluations

Capabilities

- Establishment of a dedicated Thermo Fisher Scientific custom project team that included representatives from R&D, quality control, manufacturing, and business development. The project team worked closely with the client in all phases of development, scale-up, launch, and postlaunch support.
- Over 40 years of expertise in the development and manufacturing of enzymes, including next-generation enzymes, which were developed through molecular *in vitro* evolution.
- Integrative quality systems covering supply chain, manufacturing, and quality-control processes in a ISO 13485–certified facility.

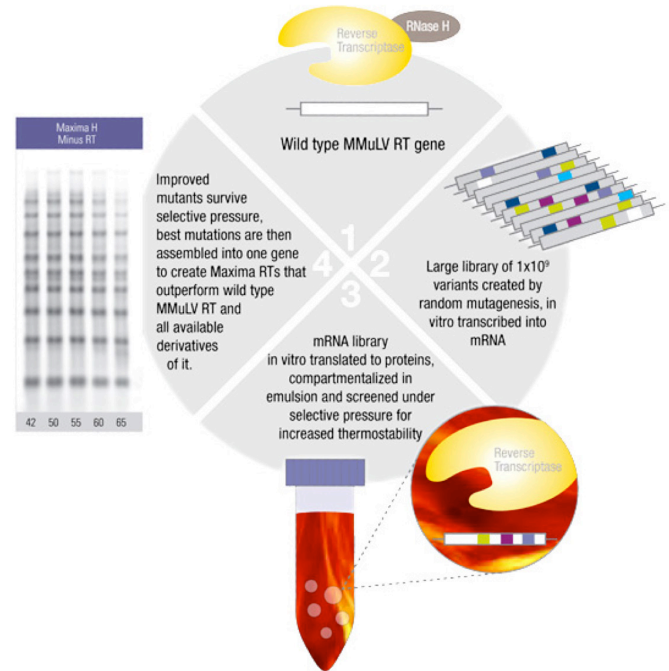
Partnership

An open, two-way dialogue leading Thermo Fisher Scientific to fully understand the client's technical and business requirements. This allowed Thermo Fisher Scientific to help navigate the cost constraints and logistical challenges to meet the client's needs for commercialization.

Results

- The client chose to work with Thermo Fisher Scientific because we had the technical expertise, manufacturing capability, and flexibility to deliver a *Taq* DNA polymerase and an RT with low nucleic acid contamination.
- Maxima RT was found to have the best performance to address the client's assay requirement. This enzyme was developed using our proprietary technology for molecular *in vitro* evolution, which enabled the introduction and selection of multiple favorable mutations into the traditional Moloney murine leukemia virus (MMLV) reverse transcriptase. Without sacrificing the performance of

Maxima RT, the R&D and manufacturing scientists utilized the previous custom manufacturing process for *Taq* DNA polymerase to deliver Maxima RT with low DNA contamination.



R&D and manufacturing utilized this custom manufacturing process to deliver low contamination Maxima RT.

- With an understanding of the client's commercialization plans and concerns, the business development manager at Thermo Fisher Scientific worked with the client to develop flexible contract terms that will enable the client to expand their menu and assay content for many years to come.
- Thermo Fisher Scientific manufacturing offers a unique flexibility to provide small batch production samples for the client's functional testing and validation.

Summary

The Thermo Fisher Scientific OEM team developed an integrative partnership with our client, providing flexibility in R&D to develop low-DNA contaminant PCR and RT enzymes that met specific assay requirements, flexibility in operation for custom manufacturing and QC, and flexibility in business with contract terms that allow our client to move forward with their commercialization plans.



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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