

Case Study

How to develop the perfect business model — a case study of a diagnostic company

Customer Company Profile

Our client described in this case specializes in a wide range of commercial genetic testing services. Their diagnostic laboratory is well equipped with novel diagnostic facilities using modern molecular biology and genetic engineering techniques. Importantly, the complete testing process, from sample intake, through genetic material isolation, to RT-qPCR and analysis, is conducted on-site, following the guidelines regarding biological material handling and proper lab work practices.

Customer priorities

- Isolation reagents of the highest quality and purity, meeting the strict standards of internal QC.
- Compatibility of all workflow elements for an all-in-one SARS-CoV-2 testing solution.
- Optimization of supply chains to enable fast and effective product development.
- Batch reagent delivery, facilitating large-scale production.

Background

In the first stages of the coronavirus outbreak in Europe, due to their expertise in RT-qPCR, the client decided to focus on developing commercial diagnostic tests aiming to detect the presence of SARS-CoV-2 in affected patients. With extensive background in genetics and well-equipped facilities, our customer had almost every element necessary to become a regional leader in this emerging field. However, a steady supply of the highest quality reagents was needed for all testing stages, from RNA extraction to RT-qPCR-based virus detection.

Challenges

The client searched for a steady supplier of high-quality reagents tailored for a still-emerging application in detecting a novel pathogen. The short delivery time was also crucial, as rapid product development would give our customers a significant edge in the race for market leadership. However, the production process still needed to be characterized with maximum reliability and repeatability, meeting the strict guidelines of in vitro diagnostics-certified products.



Partnership

We are committed to our motto 'Enzymes as You Need', tailoring the product to fit every client's request. Our flexibility and extensive experience in R&D allow us to offer personalized solutions of the highest quality. A signed qualitative contract assures mutual understanding, declares our dedication to meet the project deadlines, and guarantees the quality and consistency of all product characteristics. As we are an EU-based company, it is guaranteed that the availability of our services, delivery time, and customs should never be an obstacle in achieving the client's business goals.

Results

The client has trusted us to become their leading reagent supplier for the final components of the viral RNA extraction kit and RT-qPCR reagents. Firstly, we have designed a streamlined kit to isolate and purify genetic material from test samples with the highest efficiency. Secondly, the reagents were portioned into requested bulk quantities to facilitate a high production throughput. Additionally, as time was of utmost importance, we kept implementing a significant scale-up of reagent fabrication, achieving a 10-fold manufacturing volume increase in under six months. Based on our kits, enzymes, and proteins, our customer developed and introduced their unique RT-qPCR SARS-CoV-2 (certified CE IVD) diagnostic tests to the market as one of the first manufacturers in the region.

Summary

During our partnership with this client, we provided a fully personalized service that facilitated the introduction of their product to the market and fulfillment of all the set business goals. We ensured that the customer's emerging requirements were met through:

- Continuous reagent optimization during the development process.
- Delivery of exceptional quality products, eliminating concerns about the strict certification process for in vitro diagnostics.
- Providing expertise, transparency, flexibility in cooperation, and the capabilities of our state-of-the-art manufacturing facilities.
- A strict the development process without missing a single deadline, allowing our client to be one of the first companies to introduce locally produced SARS-CoV-2 testing solutions to the regional market.

Our products

The reagents sourced by the client included RNase Inhibitor, Reverse Transcriptase, and the complete ExtractMe and AmplifyMe kits. The latter was specifically optimized for multiplex PCR, assuring the best possible performance in detecting multiple genes at a time. We made sure to deliver our reagents in batches that were portioned according to the client's request. All the components manufactured by BLIRT show high cross-compatibility, which helped our client to fully optimize the final market-ready testing kit.

About BLIRT — Biolab Innovative Research Technologies

BLIRT is a primary European manufacturer of recombinant enzymes for the Life Science industry. Our motto 'Enzymes as You Need' reflects our business philosophy and dedication to providing services of a remarkable quality to our business partners. We are focused on providing components for the innovative products of our customers, with a particular emphasis on precise portioning services, product form adjustment, and flexible cooperation models.

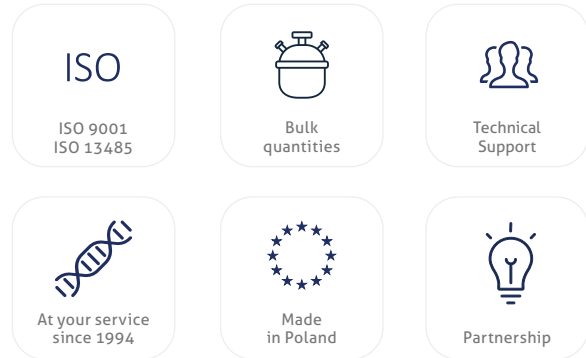
Our experienced R&D team offers continuous technical support to meet the most complex customer requirements, including product adaptation and process adjustment.

Quality assurance

The quality management system implemented at BLIRT is crucial to ensure reproducibility and reliability of results. It is based on three major elements – strict separation of various production facilities, carefully designed

and monitored processes, and an exceptionally experienced team. Our dedication to excellence in quality is reflected by full ISO 9001 and ISO 13485 certification.

Why is that important for you?



We provide information

Transparent communication with our partners, full traceability of the documentation, and monitoring the product life cycle.

We deliver product

Stable supply chain, minimized risk by continuous verification and quality assurance at every manufacturing stage.

We guarantee quality

Stringent QA validation methods to ensure consistency in enzyme/protein/kit manufacturing.

Testimonials

"We have contacted BLIRT S.A. with high expectations, knowing their reputation of the market of life science services. Our product needed to be developed fast, adhere to strict standards, and show the highest quality and specificity. Without further ado, they did not disappoint. The continuous optimization of the sourced reagents by their R&D team, high transparency of the production process, and the ability to quickly scale up the manufacturing process to meet our deadlines allowed us to be one of the first to introduce a fully functional all-in-one SARS-CoV-2 testing kit to the regional market. I fully recommend cooperation with BLIRT to all life science innovators looking for reliable business partners for tailored product development solutions."

CEO of the genetic testing company