



Oligonucleotides for Molecular Diagnostics

Experienced and Quality Oriented

Microsynth is a well-established oligonucleotide manufacturer for commercial diagnostic applications. We offer manufacturing that is compliant with ISO 13485 and ISO 9001.

Customization and Easy Upscaling

Microsynth supports your development with the custom synthesis of oligos for concept testing and diagnostic pilot testing, through to final manufacturing and batch release.

Professional Project Management

We assign you with a dedicated expert contact person to provide consultation on all aspects of manufacturing and regulatory compliance.

Overview

Transitioning oligonucleotides from research to molecular diagnostics applications — where reagent quality influences diagnostic results — involves significantly more than merely trying to figure out how to scale up production.

With over 30 years of experience in oligonucleotide synthesis, we at Microsynth have established our company as a trusted and reliable business partner for providing high-quality customized products. Our state-of-the-art production facilities, superior

quality reagents, and our highly flexible, yet consistent production processes, make us the ideal partner for molecular diagnostic test manufacturers.

Key Service Features and Benefits

Cost-effective and customized client solution

- Customized manufacturing processes (synthesis scale, purification, formulation, and QC) as well as documentation across all phases of development

Scalability

- All phases of product development are covered; custom-synthesized oligos for research, oligos for pilot diagnostic testing or even oligos for molecular diagnostic assays that are manufactured under controlled processes
- Final yields up to several 1000 nmol

Professional project management

- We assign you with a dedicated expert contact person to provide consultation on all aspects of manufacturing and regulatory compliance
- We provide regular status updates

Full process traceability and risk mitigation

- Comprehensive batch records
- Continuous risk management process
- Tech transfer is possible at any product development phase

Consistent lot-to-lot reproducibility

- Stringent product release criteria
- The oligonucleotide production facilities of Microsynth are EN ISO 9001:2015 and EN ISO 13485:2016 certified.

Getting Started With Microsynth

Our modular integrated synthesis and work process allows us to accommodate your project at any stage of your IVD program. Please contact one of

our project managers to discuss your personal program and needs. Our dedicated experts will then create a customized project proposal and timing

schedule for you that we are confident will meet all your expectations.

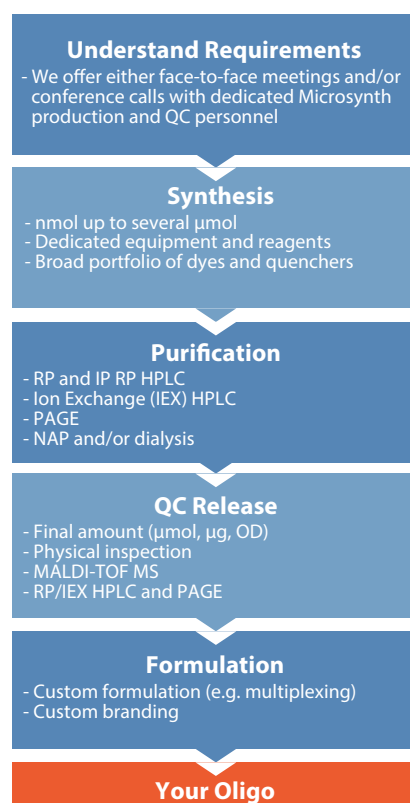


Figure 1. The typical process for the production of molecular diagnostic oligos.