

# Oligonucleotides for Molecular Diagnostics

Cost-effective and Customized Client Solutions **Easy Upscaling from R&D to Commercialization Choose from a Large Selection of Backbones and Modifications** 

#### **Overview**

Transitioning oligonucleotides from research to molecular diagnostics applications — where reagent quality has an influence on diagnostic results involves a lot more than figuring out how to scale up production.

With over 25 years of experience in oligonucleotide synthesis, Microsynth has established itself as a trusted and reliable business partner for providing high-quality customized products. Our state-of-the-art production facil-

ilities, superior quality reagents and our very flexible, yet consistent production processes, make us an ideal partner for molecular diagnostic test manufacturers.

#### **Cost-effective and customized client solution**

• Customized manufacturing processes (synthesis scale, purification, formulation, 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 manufactured under controlled processes
- Bulk production up to 10 g possible

#### **Professional project management**

- Dedicated expert contact person for consultation on all aspects of manufacturing and regulatory compliance
- Regular status updates

#### Full process traceability and risk mitigation

- Comprehensive batch records
- Continuous risk management process
- Tech transfer 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.

#### **Need More Information?**

Call us at +41 71 722 83 33 or email us at oligo.support@microsynth.ch

#### **Understand Requirements**

face-to-face meetings and/or conference calls with dedicated Microsynth production and QC personnel

# Synthesis |

- ug to multi grams dedicated equipment and reagents broad portfolio of backbones and modifications

## **Purification**

- Reverse Phase (RP) HPLC Ion Exchange (IE) HPLC Dual HPLC

- PAGE NAP and/or dialysis

# **QC** Release

- Final amount (μmol, μg, OD)
- Physical inspection MALDI-TOF MS
- RP/IP HPLC and PAGE External Partner: Stability Testing

### **Formulation**

- Custom formulation (e.g. multiplexing) - Custom branding

#### **Your Oligo**

Figure 1. Typical process for the production of molecular diagnostic oligos.