

# CLINICAL LAB OLIGONUCLEOTIDES



cGMP MANUFACTURING  
FOR EUROPEAN DIAGNOSTIC LABORATORIES

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## The increasing need for development of in-house PCR tests

The increase in the diagnostic possibilities of genetic disorders and emerging infectious diseases (like Avian flu, SARS and the current pandemic H1N1 flu outbreak) have enhanced the need for development of routine PCR testing by European service laboratories. The need for such tests requires in-house development and manufacturing of assays, rather than using commercial kits.

## The quality dilemma: balancing quality and cost for sourcing oligos

Despite the critical importance of oligo quality for diagnostic assay performance most laboratories will source «research-grade» reagents (produced under ISO 9001) rather than «diagnostic-grade» GMP reagents (produced under the medical device ISO 13485 Quality System) to save costs. From a quality perspective this is far from optimal, according to the medical lab quality standard ISO 15189 sufficient control measures over critical reagents and their suppliers must be implemented to ensure reliable and consistent performance (§4.6.2 and §4.6.4).

## The solution: Clinical Lab Oligonucleotides (CLOs)

Eurogentec, a leading supplier of GMP diagnostic-grade oligos to diagnostic kit manufacturers, now offers **Clinical Lab Oligos** for routine labs performing in-house PCR. CLOs allow labs to upgrade the quality of oligos to the highest diagnostic level at a reasonable price. This will significantly add to a further quality improvement of in-house PCR diagnostics.

## The benefits of the CLOs are:

- **Highly reduced contamination risks** through production in a GMP clean room facility.
- **Highest consistent quality** through GMP production in an ISO13485-certified facility. This is in line with the quality standard for medical labs ISO 15189 .
- **Attractive pricing and additional cost saving**, as the high quality will greatly reduce your need for performing incoming QC.
- **Fill & finish (mixing, aliquoting, dispensing)** customized to your need with the possibility for robotic dispensing of mastermixes in tubes/ microtiter plates.
- **Standardization**, possibility for reference labs to have access to the **same batch of oligos** and to order oligo sets off the shelf (6 months shelf life). This standardization will enhance within- and between-laboratory precision (repeatability and reproducibility) of routine PCR assays. Moreover, as they are produced in large quantities, the costs will also be significantly reduced.

## GMP manufacturing of Clinical Lab Oligos

➤ **Clinical Lab Oligonucleotides** are intended for in-house PCR assays that are either in clinical validation or in routine diagnostic use. These oligos are manufactured according to Eurogentec's Diagnostic GMP manufacturing process, which is compliant to the medical device quality standard ISO 13485:2003, the European IVD directive 98/79 EEC and FDA's Quality System Regulations. Production is performed in a dedicated GMP clean room facility (class 100.000/ISO 8), using fully optimized and validated Quality Control methods and equipment. Basic aspects of the manufacturing process are monitored and documented resulting in a batch record, which is archived for 5 years traceability. After review of the batch record, QC-authorized personnel release the product; labs are supplied with a Certificate of Analysis with all relevant QC data attached.

Clinical Lab Oligonucleotide production complies to the quality standard for medical labs (ISO 15189 §4.6.2 and §4.6.4) requiring control measures over critical reagents and suppliers.

➤ **Research Oligonucleotides** are most cost effective option for research applications and early phases of diagnostic assay development. This grade is less appropriate for clinical diagnostic assays in validation or routine use, because the high throughput research production environment cannot assure the highest consistent quality throughout the entire manufacturing process. Production is performed in an ISO 9001-certified non-clean room facility. Oligos are provided with standard Technical Data Sheet.

