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Biotechnology — Nucleic acid synthesis —

Part 1: Requirements for the production and quality control of synthesized oligonucleotides

Biotechnologie – Synthèse des acides nucléiques —

Partie 1: Exigences relatives à la production et au contrôle qualité des oligonucléotides synthétisés

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Foreword

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This document was prepared by Technical Committee ISO/TC 276, *Biotechnology*.

A list of all parts in the ISO 20688 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Single stranded, linear bio-polymers made up of nucleotides which are called "synthetic oligonucleotides" or 'oligos' are indispensable components for biotechnology. For example, they are used as polymerase chain reaction (PCR) amplification primers, microarray, real time PCR or next generation sequencing (NGS) capture probes, and as input starting materials for the creation of entire target genes.

Control of quality in production is important in the synthesis of oligonucleotides. The quantification of the size range, concentration and contaminants is necessary to ensure that quality requirements are met for end-use applications. Considering that oligonucleotides are used in biologically active applications, their quality, particularly sequence and conformation, will affect fitness or function, for example molecular recognition of cognate binding site, chemical behaviour. The specific requirements for each end-use application can differ.

This document defines common quality attributes of synthetic oligonucleotides and addresses their quantification and assessment for end-use.

It is intended to help improve quality management and demonstrate product quality.

International, national or regional regulations or requirements can also apply to specific topics covered in this document. For example, when synthesized oligonucleotides are used as investigational drugs or pharmaceutical agents, regional regulations and/or good manufacturing practices (GMP) may need to be considered.