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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 43629.1-2023

**Biotechnology - Nucleic acid synthesis - Part 1: Requirements
for the production and quality control of synthesized
oligonucleotides**

生物技术 核酸合成 第1部分：合成寡核苷酸的生产和质量控制要求
(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents" Drafting:

This document is Part 1 of GB/T 43629 "Biotechnology Nucleic Acid Synthesis": GB/T 43629 has released the following parts:

---Part 1: Production and quality control requirements for synthetic oligonucleotides:

This document has made the following minimal editorial changes:

---In combination with the specific conditions of our country's standards, a page of bets has been added:

This document is equivalent to ISO 20688-1:2020 "Biotechnology Nucleic Acid Synthesis Part 1: Production and Quality of Synthetic Oligonucleotides" Control requirements":

Please note that some content in this document may be subject to patents: The publisher of this document assumes no responsibility for identifying patents:

Introduction

Single-stranded, linear biological compounds composed of nucleotides are called "synthetic oligonucleotides" or "oligonucleotides" and are indispensable in biotechnology:

missing ingredient: For example, they can be used as polymerase chain reaction (PCR) amplification primers, microarrays, real-time PCR, or next-generation sequencing (NGS) capture in the probe technology, it can also be used to synthesize starting materials for the insertion of target genes:

GB/T 43629 is intended to consist of the following parts:

---Part 1: Production and quality control requirements for synthetic oligonucleotides:

Suitable for synthetic oligos up to 250 bases in length glycosides:

---Part 2: General definitions and requirements for the production and quality control of

synthetic gene fragments, genes and genomes: Suitable for low length Synthetic gene fragments, genes and genomes based on 10Mbp base pairs, including non-cloned fragments (linear) and cloned bases in plasmids Because (cyclic):

During oligonucleotide synthesis, quality control during production is very important: To ensure compliance with the quality requirements of the final application, it is necessary to Size ranges, concentrations and contaminants need to be quantified: Considering the application of oligonucleotides in biological activities, their quality (especially sequence and conformation) will affect its adaptability or function, such as molecular recognition of homologous binding sites, chemical behavior, etc: Specific for each terminal application Requirements may vary:

Biotechnology Nucleic Acid Synthesis Part 1:

Production and quality control requirements for synthetic oligonucleotides

1 Scope

This document specifies the minimum requirements for the production and quality control of synthetic oligonucleotides (generally up to 250 bases):

This document also describes general quality metrics for synthetic oligonucleotides and common methods for evaluating quality metrics:

2 Normative reference documents

This document has no normative references:

3 Terms and definitions

The following terms and definitions apply to this document:

A reference material/reference sample certificate with characteristic values, associated uncertainties and metrological traceability statements is provided using valid procedures:

A reference material/standard sample for one or more characteristic values:

[Source: ISO Guide30:2015,2:1:2, modified] 3.2 performance has the ability to meet the specific needs of biological reagents:

Note 1: When synthetic oligonucleotides are used as PCR primers, the synthetic oligonucleotides have primer capabilities:

Note 2: When synthetic oligonucleotides are used as probes for DNA microarrays, real-time PCR or NGS, the synthetic oligonucleotides have the ability to interact with the target nucleic acid:

The ability to hybridize specifically:

Note 3: Confirm the ability of the oligonucleotide by evaluating its function in its respective use:

puritypurity

The ratio between the expected sequence and/or length of a synthetic oligonucleotide and the total amount of oligonucleotides:

NOTE: The purity of a synthetic oligonucleotide is the ratio of the absorption peak area corresponding to the expected sequence and/or length of the synthetic oligonucleotide to the total peak area of the oligonucleotide:

Rate: Calculate the absorbance at 260 nm (OD₂₆₀) by high performance liquid chromatography (HPLC) or capillary electrophoresis (CE): Purity is determined by HPLC or CE or mass spectrometer results are calculated by the area normalization method:

Standard material/standard sample referencematerial;RM A substance that possesses one or more specific properties that are sufficiently uniform and stable that their values are suitable for the intended use in the measurement process:

[Source: ISO Guide30:2015,2:1:1, modified] 3.5 Chemically synthesized deoxyribonucleic acid (DNA) or ribonucleic acid (RNA):