SIST

SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 19807-2:2023

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Nanotehnologije - Magnetni nanomateriali - 2. del: Specifikacija lastnosti in merilnih metod za nanostrukturirane magnetne kroglice za ekstrakcijo nukleinskih kislin (ISO/TS 19807-2:2021)

Nanotechnologies - Magnetic nanomaterials - Part 2: Specification of characteristics and measurement methods for nanostructured magnetic beads for nucleic acid extraction (ISO/TS 19807-2:2021)

Nanotechnologies - Nanomatériaux magnétiques - Partie 2: Spécification des caractéristiques et des méthodes de mesure pour les billes magnétiques nanostructurées pour l’extraction d’acide nucléïque (ISO/TS 19807-2:2021)

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English Version

Nanotechnologies - Magnetic nanomaterials - Part 2: Specification of characteristics and measurement methods for nanostructured magnetic beads for nucleic acid extraction (ISO/TS 19807-2:2021)

Nanotechnologies - Nanomatériaux magnétiques - Partie 2: Spécification des caractéristiques et des méthodes de mesure pour les billes magnétiques nanostructurées pour l'extraction d'acide nucléïque (ISO/TS 19807-2:2021)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

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Endorsement notice

The text of ISO/TS 19807-2:2021 has been approved by CEN as CEN ISO/TS 19807-2:2023 without any modification.

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Nanotechnologies — Magnetic nanomaterials —

Part 2: Specification of characteristics and measurement methods for nanostructured magnetic beads for nucleic acid extraction

Nanotechnologies — Nanomatériaux magnétiques —

Partie 2: Spécification des caractéristiques et des méthodes de mesure pour les billes magnétiques nanostructurées pour l'extraction d'acide nucléïque

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Foreword

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Introduction

Magnetic beads are composed of a large number of magnetic nanoparticles immobilized within a nonmagnetic matrix with a size range between tens of nanometres and hundreds of micrometres (see Annex A). The immobilization matrix is typically based on silica or organic polymers. The beads are commonly supplied while dispersed in a liquid suspension, for example, ethanol, isopropanol, sodium azide solutions, pure water. Magnetic beads in liquid suspension have become one of the most widely used nanomaterials in the biological and chemical fields, due to their unique magnetic properties and interactions with applied magnetic fields.

When the size of a magnetic object is small enough, it will form a single magnetic domain, behaving as a single large macrospin. At yet smaller sizes (for iron oxide, typically less than 30nm[1]), the thermal energy of the object can be sufficient to result in frequent reorientations of the magnetization direction of the object. If the timescale of these reorientations is shorter than the timescale of the measurement, the term ‘superparamagnetism’ is used to describe this behaviour and the magnetic nano-objects are said to be superparamagnetic. In large non-interacting ensembles of such particles, the thermally induced switching events will result in the average magnetization of the ensembles being zero in the absence of an applied magnetic field. In the presence of an applied large field, the ensemble of magnetic nano-objects is observed to acquire a large net magnetization, as the magnetic field overcomes the thermal fluctuations and aligns the macrospins of the individual magnetic nano-objects within the ensemble. Beads, if incorporating a large fraction of magnetic nano-objects which exhibit this behaviour, are often referred to as “superparamagnetic beads”. However, as the beads may not themselves be superparamagnetic, they are referred to as “magnetic beads” herein.

Magnetic beads have been applied in many fields, especially in biosensing applications[2] such as *in vitro* diagnostics, targeted drug delivery[3]-[5], magnetic resonance imaging[6], bioseparation[7], and genetic engineering[8], among others. For example, nucleic acids, which carry genetic information, can be extracted or isolated from blood, saliva, faeces, urine, leaves, viral lysates, using suitably functionalized magnetic beads.

The nucleic acids (DNA) and ribonucleic acid (RNA) carry the key information that organisms use to build or maintain their biostructures. Correctly identifying DNA offers immensely valuable information on health. In recent years, in the human blood stream, scientists have not only found circulating cell free DNA (cfDNA), but also circulating tumour DNA (ctDNA). Now ctDNA extraction is one of the most widely used liquid-biopsy methods to determine cancer or track cancer development. However, the content of ctDNA is only 1 % or less of the total cfDNA amount. The concentration of cfDNA is very low, generally 5 ng/ml blood to 30 ng/ml blood. Therefore, the development of reliable methods for extracting the ctDNA is critical. The proper description of physicochemical characteristics of magnetic beads for DNA extraction is both valuable for developers of extraction kits and for users applying them for DNA analysis.

Nucleic acid binding to magnetic beads relies on electrostatic interactions, hydrophobic interactions, hydrogen bonding or specific binding mechanisms to the bead surface. Once DNA or RNA from cell or tissue lysate is released into the solution, then nucleic acids can bind to surface-modified magnetic beads to form a “nucleic acid-magnetic bead complex”.[9]-[19]

Then, the complex can be separated under a proper combination of magnetic field and magnetic field gradient. The eluate can wash away the residual impurities. Finally, the nucleic acids to be extracted can be obtained from the beads after desalination and purification.[9]-[19]

The different forms of magnetic beads and dispersing media for the extraction of nucleic acid will have different physicochemical characteristics such as specific surface area, bead concentration etc. All these characteristics will affect their performance to extract nucleic acid to varying extents. [9]-[19]

In common with other nanostructured materials, the manufacturing and material specification of composite magnetic beads are complex. Small variations in the synthesis conditions during bead manufacturing and functionalization can lead into dramatic shifts in the properties and binding capacities of the manufactured beads. This requires these products to have high manufacturing consistency. Currently, different manufacturers provide different characteristics and most of them