TECHNICAL SPECIFICATION

ISO/TS 23367-1

First edition
2022-12

Nanotechnologies — Performance characteristics of nanosensors for chemical and biomolecule detection —

Part 1: Detection performance

Nanotechnologies — Caractéristiques de performance des nanocapteurs pour la détection de molécules chimiques et de biomolécules —
Partie 1: Performances de détection

Reference number
ISO/TS 23367-1:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 229 *Nanotechnologies*.

A list of all parts in the ISO 23367 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

Nanostructured materials possess fascinating properties such as high reactivity, excellent electrical conductivity, quantum-scaled confinement, great degree of biocompatibility, versatile optical transmission, outstanding electromagnetic properties and substantial surface area-to-volume ratio. Physical and chemical behaviour of nanomaterials are tunable by morphological variation as well as surface modification. It is these unique properties and functionalities that enable nanomaterials to be a novel solution for the development of advanced high-performance sensing devices.

Applications of advanced nanomaterials in the detection of chemicals or biomolecules have been widely studied to cater to variety of demands from innovative healthcare practice to industrial process improvement to potent environmental surveillance. By introducing nanotechnology in sample preparations, biomolecule reactions and chemical sensing procedures, the performance of traditional sensor technologies has been enhanced, brand-new nanosensors have been commercialized, and related markets have achieved remarkable growth.

There are several standards that specify the performance characteristics and the performance evaluation of a specific sensing or metrological device/equipment, especially in in vitro diagnosis, food safety management and environmental monitoring. Existing standards describe the performance of conventional sensors, however, there is not any standard document which generally addresses the enhanced sensing performance of a nanosensor. Moreover, the enhancement of sensing performance by nanotechnologies is not yet reflected in the existing relevant standards for conventional sensor technologies. As a result, there is a growing need for standardization to accurately describe the performance characteristics of nanosensors for chemical and biomolecule detection. This document standardizes performance characteristics of nanosensors which are utilized for performance evaluation in medical diagnosis, personal healthcare, environment monitoring, food quality and safety monitoring and biohazard defence.

Nanotechnologies — Performance characteristics of nanosensors for chemical and biomolecule detection —

Part 1: Detection performance

1 Scope

This document describes the performance characteristics necessary to evaluate the detection performance of nanosensors for chemical and biomolecule detection. This document does not cover the analytical performance characteristics or the performance evaluation procedure of a specific sensor.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO 16604:2004, *Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X 174 bacteriophage*

ISO 17511:2020, *In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples*

ISO 18113-1:2022, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions, and general requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99:2007, ISO 16604:2004, ISO 17511:2020, ISO 18113-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
analyte
component represented in the name of a measurable quantity

EXAMPLE In the type of quantity "mass of protein in 24-hour urine", "protein" is the analyte. In "amount of substance of glucose in plasma", "glucose" is the analyte. In both cases the long phrase represents the *measurand* (3.9).

[SOURCE: ISO 17511:2020, 3.1]

3.2
analytical performance
<nanosensor> ability of an assay using a nanosensor to measure or detect a particular analyte in a reference sample

3.3
assay
set of operations to determine the presence of or concentration of a particular component

[SOURCE: ISO 16604:2004, 3.2, modified — "analysis of a mixture" has been changed to "set of operations" and Note 1 to entry has been deleted.]

3.4
cut-off value
quantity value used as a limit to identify samples that indicate the presence or the absence of a specific disease, condition, or measurand

Note 1 to entry: The cut-off value defines which measurement results are reported as positive and which are reported as negative.

Note 2 to entry: Measurement results near the cut-off value can be inconclusive due to measurement uncertainty.

Note 3 to entry: The selection of the cut-off value determines the clinical specificity and clinical sensitivity of the examination.

[SOURCE: ISO 18113-1:2022, 3.2.15, modified — "decision limit" has been changed "limit" and Notes 1,2 and 3 to entry have been revised.]

3.5
detection performance
<nanosensor> ability of an assay using a nanosensor to determine the presence of a particular analyte above the cut-off value in a test sample

Note 1 to entry: A test sample is defined as a sample used to validate the performance of the nanosensor.

3.6
detection sensitivity
<nanosensor> ability of an assay using a nanosensor to recognize the presence of an analyte in a test sample

3.7
detection specificity
<nanosensor> ability of an assay using a nanosensor to recognize the absence of an analyte in a test sample

3.8
detection signal ratio
<nanosensor> ability of an assay using a nanosensor to clearly differentiate a positive response from a negative response

3.9
measurand
quantity intended to be measured

[SOURCE: ISO/IEC Guide 99:2007, 2.3, modified — Notes 1, 2, 3 and 4 to entry, and Examples 1 and 2 have been deleted.]

3.10
nanosensor
nano-enabled or nano-enhanced apparatus used to detect or identify events and changes in its environment, and transmit features of data to other electronics to convert them to a measurable output

3.11
performance characteristic
<nanosensor> parameter used to define the performance of a nanosensor

EXAMPLE Sensitivity, specificity and signal ratio.

Note 1 to entry: Information about more than one performance characteristic is usually required to evaluate the suitability of a nanosensor for its intended use.

3.12
performance evaluation
<nanosensor> investigation of a device or apparatus for the purpose of establishing or verifying its performance claims

4 Detection performance characteristics

4.1 General

Detection performance is the ability of an assay to discriminate between two subclasses of subjects, and detection performance evaluation of the assay using a nanosensor is intended mainly to detect the presence of a target chemical or biomolecule above a cut-off value. Examples of assays include the tests for infectious diseases in in vitro diagnosis,[1] food poisoning in food quality and safety monitoring,[2] defective product screening in quality control[3] and detection of biohazards in environmental monitoring.[4] In such cases, the assay is designed to distinguish between positive and negative responses, i.e. between results above or below a pre-determined cut-off value.

Typical detection performance characteristics for conventional sensors are detection sensitivity and detection specificity. However, there are limitations on existing detection performance characteristics to assess the enhanced performance of nanosensors as described in Annex A and Annex B. Therefore, detection performance characteristics for nanosensors need to be defined well enough to assess the enhancement of performance by nanotechnology as well as the reliability of the assay using nanosensors.

Clause 4 describes detection performance characteristics of nanosensor for chemical and biomolecule detection that shall be essentially evaluated using test samples.

4.2 Detection sensitivity

Detection sensitivity is the probability of the assay scoring positive in test samples coming from subjects known to have the analyte. Detection sensitivity is expressed as the ratio of true positive samples over the total number of samples which should give positive results, i.e. true positive samples plus false negative samples. This performance characteristic may be expressed as percentage, after multiplication by 100.

$$D_{\text{sens}} = \frac{N_{\text{TP}}}{N_{\text{TP}} + N_{\text{FN}}}$$

where

D_{sens} is the detection sensitivity;

N_{TP} is the number of true positives;

N_{FN} is the number of false negatives.

4.3 Detection specificity

Detection specificity is the probability of the assay scoring negative in test samples coming from subjects known to be free of the analyte. Detection specificity is expressed as the ratio of the true negative samples over the total number of samples which should give negative results, i.e. true negative plus false positive samples. This performance characteristic may be expressed as percentage, after multiplication by 100.

$$D_{\text{spec}} = \frac{N_{\text{TN}}}{N_{\text{TN}} + N_{\text{FP}}}$$

where

D_{spec} is the detection sensitivity;

N_{TN} is the number of true negatives;

N_{FP} is the number of false positives.

4.4 Detection signal ratio

Detection signal ratio is the ability of an assay to clearly differentiate a positive response from a negative response in test samples. Detection signal ratio is expressed as the ratio of the averaged signal intensity of true positive samples over the averaged signal intensity of the true negative samples.

$$R_{D\text{signal}} = \frac{I_{\text{averaged,TP}}}{I_{\text{averaged,TN}}}$$

where

$R_{D\text{signal}}$ is the detection signal ratio;

$I_{\text{average,TP}}$ is the averaged signal intensity of true positive samples;

$I_{\text{average,TN}}$ is the averaged signal intensity of the true negative samples.