SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 16099:2026

01-julij-2026

Kakovost vode - Verižna reakcija s polimerazo (PCR) za ugotavljanje prisotnosti in števila mikroorganizmov in virusov - Splošne zahteve, zagotavljanje kakovosti in validacija (ISO/TS 16099:2025)

Water quality - Polymerase chain reaction (PCR) for the detection and quantification of microorganisms and viruses - General requirements, quality assurance and validation (ISO/TS 16099:2025)

Wasserbeschaffenheit - Polymerase-Kettenreaktion (PCR) zum Nachweis und zur Quantifizierung von Mikroorganismen und Viren - Allgemeine Anforderungen, Qualitätssicherung und Validierung (ISO/TS 16099:2025)

Qualité de l'eau - Réaction de polymérisation en chaîne (PCR) pour la détection et la quantification des microorganismes et des virus - Exigences générales, assurance de la qualité et validation (ISO/TS 16099:2025)

Ta slovenski standard je istoveten z: **CEN ISO/TS 16099:2026**

ICS:

13.060.70	Preiskava bioloških lastnosti vode	Examination of biological properties of water

SIST-TS CEN ISO/TS 16099:2026 **en,fr,de**

TECHNICAL SPECIFICATION

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CEN ISO/TS 16099

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ICS 13.060.70

English Version

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This Technical Specification (CEN/TS) was approved by CEN on 3 May 2026 for provisional application.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

The text of ISO/TS 16099:2025 has been prepared by Technical Committee ISO/TC 147 "Water quality" of the International Organization for Standardization (ISO) and has been taken over as CEN ISO/TS 16099:2026 by Technical Committee CEN/TC 230 "Water analysis" the secretariat of which is held by DIN.

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Endorsement notice

The text of ISO/TS 16099:2025 has been approved by CEN as CEN ISO/TS 16099:2026 without any modification.

Technical Specification

ISO/TS 16099

First edition
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Water quality — Polymerase chain reaction (PCR) for the detection and quantification of microorganisms and viruses — General requirements, quality assurance and validation

Qualité de l'eau — Réaction de polymérisation en chaîne (PCR) pour la détection et la quantification des microorganismes et des virus — Exigences générales, assurance de la qualité et validation

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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 document 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).

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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 147, *Water quality*, Subcommittee SC 4, *Microbiological methods.*

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

PCR-based methods are developed for the detection and/or quantification of, for example, pathogenic bacteria, for rapid and reliable outcomes as an alternative to culture-based methods. For example, for the screening on the presence of *Legionella* or faecal-related microorganisms in water, see References [26], [29], [43], [49] and [56] for further information.

Performing nucleic acid quantification assays to a high standard of analytical quality can be challenging. For example, it is well known that impure or degraded nucleic acid extracts can affect the accuracy of quantification. Similarly, a poorly designed quantitative polymerase chain reaction (qPCR) assay with poor amplification efficiency and poor primer specificity will impact the quantification accuracy of nucleic acid targets.

In addition, aspects such as the water matrix and standard curves can have a significant influence on the accuracy of quantitative measurements of nucleic acid targets. Therefore, it is important to improve the reliability of data by setting general requirements for PCR-based methods.

Water quality — Polymerase chain reaction (PCR) for the detection and quantification of microorganisms and viruses — General requirements, quality assurance and validation

1 Scope

This document specifies the general requirements for the in vitro amplification of nucleic acid sequences (DNA or RNA). This includes polymerase chain reaction (PCR)-based methods like quantitative PCR, qualitative PCR, reverse transcription-PCR and digital PCR.

The minimum requirements laid down in this document are intended to ensure that comparable and reproducible results are obtained in different organizations. It covers quality assurance aspects to be considered when working with PCR-based methods in a laboratory as well as validation and verification.

In addition to laboratory PCR-based methods, this document is also applicable to on-site PCR-based methods.

This document is applicable to PCR-based methods used for the analysis of microorganisms and viruses in different water matrices, including but not limited to:

— drinking water;

— groundwater;

— pool water;

— process water;

— surface water;

— wastewater.

This document is applicable to the detection and quantification of nucleic acids (DNA or RNA) of microorganisms by PCR-based methods in water such as bacteria, yeasts, fungi but also parasites such as *Cryptosporidium, Giardia,* amoebas and multicellular organisms. In addition, this document is applicable to the detection and quantification of nucleic acids from viruses in water by PCR-based methods.

NOTE In the context of this document, viruses are considered to be microorganisms. Clauses in this document can also specifically apply to viruses and not to other types of microorganisms. In these clauses, viruses are mentioned separately.

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 19458, *Water quality — Sampling for microbiological analysis*

ISO 20836, *Microbiology of the food chain — Polymerase chain reaction (PCR) for the detection of microorganisms — Thermal performance testing of thermal cyclers*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.