
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
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TECHNICAL SPECIFICATION
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CEN ISO/TS 16099

May 2026

ICS 13.060.70

English Version

**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)**

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)

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

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Contents	Page
European foreword.....	3

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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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Technical Specification

ISO/TS 16099

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*

**First edition
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Contents

	Page
Foreword	vi
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Principle	11
4.1 General.....	11
4.2 Test material.....	11
4.3 Sampling, transport and storage.....	12
4.4 Preparation of the sample.....	12
4.4.1 General.....	12
4.4.2 Preparation and concentration of samples.....	12
4.4.3 Treatment of samples containing heavy metal particles.....	13
5 Nucleic acid extraction	14
5.1 General.....	14
5.2 Nucleic acid removal or inactivation from damaged microorganism(s).....	14
5.3 Nucleic acid quantity and quality.....	15
5.4 Stability of nucleic acid extracts.....	15
6 PCR-based methods	16
6.1 General.....	16
6.2 Qualitative PCR-based methods.....	17
6.3 Quantitative PCR-based methods.....	17
6.4 Digital PCR.....	17
7 Laboratory setup	18
7.1 General.....	18
7.2 Layout of laboratory areas and workflow.....	18
7.3 Working environment.....	19
7.3.1 General.....	19
7.3.2 Reagents preparation area.....	20
7.3.3 Sample preparation area.....	20
7.3.4 PCR area.....	21
7.4 Cleaning of laboratory.....	21
7.5 Environmental monitoring for PCR.....	21
8 Equipment	21
8.1 General.....	21
8.2 Biological safety cabinet.....	22
8.3 Centrifuge.....	22
8.4 Digital PCR system.....	22
8.5 Filtration setup.....	23
8.6 Freezer and ultra-low temperature freezer.....	23
8.7 Heating block module.....	23
8.8 PCR workstation.....	23
8.9 Pipettes.....	24
8.10 Pipetting robots (optional).....	24
8.11 Refrigerators.....	24
8.12 Thermal cycler.....	24
8.13 Spectrophotometry or fluorometry instrument.....	25
8.14 On-site PCR systems.....	25
9 Reagents and consumables	25
9.1 General.....	25
9.2 Primers and probes.....	26

ISO/TS 16099:2025(en)

9.2.1	General	26
9.2.2	Quality control	26
9.2.3	Storage	26
9.3	Lyophilized PCR reagents	26
9.4	Ammonium oxalate solution	27
9.5	Pipetting tips	27
9.6	Membrane filters	27
9.7	PCR plates and tubes	27
9.8	Calibration standard	27
9.9	Master mix	28
9.9.1	General	28
9.9.2	Commercially available master mixes	28
9.9.3	Master mix prepared by user	28
9.10	Chemicals and consumables for nucleic acid extraction kits	29
9.10.1	General	29
9.10.2	Commercially available extraction kits	29
9.10.3	Nucleic acid extraction chemicals prepared by user	29
9.11	On-site PCR	29
10	Procedure	30
10.1	Controls	30
10.1.1	General	30
10.1.2	Negative process control	30
10.1.3	Positive process control	31
10.1.4	Internal process control	31
10.1.5	Amplification control	31
10.1.6	Positive PCR control	32
10.1.7	Negative PCR control	32
10.1.8	Required controls for dPCR	32
10.2	Data analysis of results	33
10.2.1	Data analysis for real-time PCR	33
10.2.2	Data analysis for dPCR	33
10.3	Evaluation of results	34
10.3.1	General	34
10.3.2	Evaluation of positive controls using control charts	35
10.3.3	Standard curve evaluation	35
10.3.4	Absolute quantification (real-time PCR and dPCR)	36
10.3.5	Relative quantification	36
10.4	Test report	37
11	Validation and verification of PCR-based methods	37
11.1	General	37
11.2	Pre-validation	38
11.3	Validation	39
11.3.1	General	39
11.3.2	Method comparison studies	39
11.3.3	Validation without method comparison	40
11.4	Sample preparation	40
11.5	Water matrices	41
11.6	Performance characteristics for validation	41
11.7	Validation of the PCR step	43
11.7.1	General	43
11.7.2	Multiplex PCR-related methods	43
11.7.3	Calibration of standard curve	43
11.7.4	Measurement range	44
11.7.5	Inclusivity and exclusivity	44
11.8	Validation of qualitative PCR-based methods	45
11.8.1	General	45
11.8.2	Sensitivity	45
11.8.3	(Relative) trueness	45

ISO/TS 16099:2025(en)

11.8.4	(Relative) limit of detection.....	46
11.9	Validation of quantitative PCR-based methods.....	46
11.9.1	General.....	46
11.9.2	(Relative) trueness.....	46
11.9.3	(Relative) limit of quantification.....	47
11.9.4	(Relative) limit of detection.....	47
11.9.5	Linearity.....	47
11.9.6	Specificity and sensitivity.....	48
11.9.7	Precision.....	48
11.9.8	Robustness.....	48
11.10	Controls and validation.....	49
11.11	Interlaboratory study.....	49
11.12	Verification of PCR-based methods.....	49
Annex A	(informative) Example of an interpretation of qualitative PCR results for <i>Escherichia coli</i>	51
Annex B	(informative) Example of an interpretation of quantitative PCR results for <i>Legionella pneumophila</i> with an internal control	53
Annex C	(informative) Example of an interpretation of dPCR results for SARS-CoV-2	57
Annex D	(informative) Verification of the calibration function of the quantitative PCR phase	60
Bibliography	68

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ISO/TS 16099:2025(en)

Foreword

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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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This document was prepared by Technical Committee ISO/TC 147, *Water quality*, Subcommittee SC 4, *Microbiological methods*.

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ISO/TS 16099:2025(en)

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.

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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

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.