
Mikrobiologija v prehranski verigi - Odkrivanje in kvantifikacija mikroorganizmov s polimerazno verižno reakcijo (PCR) - Izvedbena merila (ISO/DIS 22118:2026)

Microbiology of the food chain - Polymerase chain reaction (PCR) for the detection and quantification of microorganisms - Performance characteristics (ISO/DIS 22118:2026)

Mikrobiologie der Lebensmittelkette - Polymerase-Kettenreaktion (PCR) zum Nachweis und zur quantitativen Bestimmung von Mikroorganismen - Leistungsmerkmale (ISO/DIS 22118:2026)

Microbiologie de la chaîne alimentaire - Réaction de polymérisation en chaîne (PCR) pour la détection et la quantification des micro-organismes - Caractéristiques de performance (ISO/DIS 22118:2026)

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Food microbiology

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Microbiology of the food chain — Polymerase chain reaction (PCR) for the detection and quantification of microorganisms — Performance characteristics

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ISO/DIS 22118:2026(en)**Foreword**

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This document was prepared by Technical Committee ISO/TC 34, Food products, Subcommittee SC 9, Microbiology, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 463, Microbiology of the food chain, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 22118:2011), which has been technically revised. The main changes are as follows:

- adapted the whole document for PCR-based assay specifications to have a clear distinction between this document and method validation according to ISO 17468 [1] and ISO 16140 (all parts) [2];
- updated Terms and Definitions with references to new documents;
- removed clauses about trueness, false-positives, false negatives and the outdated annex;
- added more guidance and examples for generating the performance characteristics;
- editorially revised.

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Introduction

Molecular detection and quantification methods have been developed during the last few decades, and are now available for many food associated non-pathogenic (including probiotics) and pathogenic microorganisms.

Although until now most molecular based methods have been based on the polymerase chain reaction (PCR) and real-time PCR, other molecular detection and quantification principles should be kept under consideration.

To compare molecular based assays with conventional methods or with other principles, it is necessary to generate minimum requirements for performance characteristics of the assays to be developed. Validation for the complete analytical procedures are specified in ISO 17468 [\[1\]](#) and the ISO 16140 (all parts) [\[2\]](#).

This International Standard is part of a series of documents under the general title *Microbiology of the food chain — Polymerase chain reaction (PCR) for the detection and quantification of microorganisms* together with:

- ISO 20836 [\[3\]](#), *Microbiology of the food chain — Polymerase chain reaction (PCR) for the detection of microorganisms — Thermal performance testing of thermal cyclers*
- ISO 22174 [\[4\]](#), *Microbiology of the food chain — Polymerase chain reaction (PCR) for the detection and quantification of microorganisms — General requirements and definitions*

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