



# SLOVENSKI STANDARD

## oSIST prEN 18000-3:2025

01-junij-2025

---

**Diagnostične analize zdravja živali - Nadzor diagnostičnih reagentov in vitro - 3.  
del: Reagenti za metode PCR**

Animal health diagnostic analyses - Control of in vitro diagnostic reagents - Part 3:  
Reagents for PCR techniques

Tiergesundheitsdiagnostische Analysen - Kontrolle von in-vitro-diagnostischen  
Reagenzien - Teil 3: Reagenzien für PCR Verfahren

Analyses de diagnostic en santé animale - Contrôle des réactifs de diagnostic in vitro -  
Partie 3 : Réactifs pour les techniques PCR

**Ta slovenski standard je istoveten z:** prEN 18000-3

<https://standards.itelko.si/standardi/istovetenje/18000-3>

<https://standards.itelko.si/standardi/18000-3>

**ICS:**

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
11.220	Veterinarstvo	Veterinary medicine

**oSIST prEN 18000-3:2025**

**en,fr,de**



**EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM**

**DRAFT  
prEN 18000-3**

April 2025

ICS 11.220

English Version

**Animal health diagnostic analyses - Control of in vitro  
diagnostic reagents - Part 3: Reagents for PCR techniques**

Analyses de diagnostic en santé animale - Contrôle des réactifs de diagnostic in vitro - Partie 3 : Réactifs pour les techniques PCR

Tiergesundheitsdiagnostische Analysen - Kontrolle von in-vitro-diagnostischen Reagenzien - Teil 3: Reagenzien für PCR Verfahren

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 469.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

<https://standards.iteh.ai/catalog/standards/sist/27e197a9-c38e-4160-9928-e1c45e6104c5/osist-pren-18000-3-2025>

**Warning :** This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

# prEN 18000-3 (E)

## Contents

Page

<b>European foreword .....</b>	<b>3</b>
<b>Introduction .....</b>	<b>4</b>
<b>1 Scope .....</b>	<b>5</b>
<b>2 Normative references .....</b>	<b>5</b>
<b>3 Terms and definitions .....</b>	<b>5</b>
<b>4 General control steps .....</b>	<b>10</b>
<b>5 Prerequisites of the PCR reagent control for the control organisation .....</b>	<b>10</b>
5.1 General .....	10
5.2 Reference material .....	10
5.3 Definition of the purpose of the PCR reagents and of the PCR method when applicable .....	11
5.4 Additional useful information .....	11
<b>6 Initial conformity control .....</b>	<b>11</b>
6.1 General .....	11
6.2 Characterization of the reagents by the applicant and documentary review by the control organization .....	11
6.2.1 General .....	11
6.2.2 Definition of the interpretation method and threshold(s) .....	14
6.2.3 Analytical specificity of the PCR reagent .....	14
6.2.4 Analytical sensitivity of the PCR reagent ( $LOD_{PCR}$ and $MDL_{PCR}$ ) .....	15
6.2.5 Operating range of the quantitative PCR reagent (linearity, amplification efficiency and limit of quantification) when applicable .....	15
6.2.6 Within-laboratory reproducibility of the PCR reagent .....	16
6.2.7 Analytical sensitivity of the PCR method ( $MDL_{METHOD}$ ) when applicable .....	16
6.2.8 Accuracy of the quantitative PCR method (operating range and limits of quantification) when applicable .....	16
6.2.9 Within-laboratory reproducibility of the PCR method when applicable .....	17
6.2.10 Interlaboratory reproducibility of the PCR method when applicable .....	17
6.2.11 Diagnostic sensitivity and diagnostic specificity .....	17
6.2.12 Validation of the conditions of use - Robustness .....	17
6.2.13 Verification of the stability .....	17
6.3 Initial control of the reagents by the control organisation .....	18
6.3.1 General .....	18
6.3.2 Analytical specificity of the PCR reagent .....	18
6.3.3 Analytical sensitivity of the PCR reagent ( $MDL_{PCR}$ ) .....	19
6.3.4 Operating range of the quantitative real-time PCR reagent (linearity, amplification efficiency and limit of quantification) .....	19
6.3.5 Analytical sensitivity of the PCR method ( $MDL_{METHOD}$ ), when applicable .....	19
6.3.6 Diagnostic sensitivity and specificity of the PCR method when applicable .....	19
6.3.7 Accuracy of the quantitative PCR method (validity range and limit of quantification), when applicable .....	19
<b>7 Batch-to-batch control .....</b>	<b>19</b>
7.1 Control at the start of the batch shelf-life .....	19
7.2 Control during the batch shelf-life .....	20
7.3 Derogations from systematic batch-to-batch control .....	20
<b>8 Special cases .....</b>	<b>20</b>
8.1 Multiple protocols .....	20
8.2 Multiple matrices .....	20
8.3 Pooling of samples .....	20
<b>Bibliography .....</b>	<b>22</b>