



SLOVENSKI STANDARD

oSIST prEN 18000-2:2023

01-december-2023

Diagnostične analize zdravja živali - Nadzor diagnostičnih reagentov in vitro - 2. del: Reagenti za imunološke tehnike

Animal health diagnostic analyses - Control of in-vitro diagnostic reagents - Part 2:
Reagents for immunological techniques

Tiergesundheitsdiagnostische Analysen - Kontrolle von in-vitro-diagnostischen
Reagenzien - Teil 2: Reagenzien für immunologische Verfahren

Analyses de diagnostic en santé animale - Contrôle des réactifs de diagnostic in vitro -
Partie 2 : Réactifs pour les techniques immunologiques

Ta slovenski standard je istoveten z: prEN 18000-2

<https://standards.sistech.si/catalog/standards/sist/18000-2/2023>

ICS:

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

oSIST prEN 18000-2:2023

en,fr,de

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
prEN 18000-2

September 2023

ICS

English Version

Animal health diagnostic analyses - Control of in-vitro diagnostic reagents - Part 2: Reagents for immunological techniques

Analyses de diagnostic en santé animale - Contrôle des réactifs de diagnostic in vitro - Partie 2 : Réactifs pour les techniques immunologiques

Tiergesundheitsdiagnostische Analysen - Kontrolle von in-vitro-diagnostischen Reagenzien - Teil 2: Reagenzien für immunologische 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.

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (prEN 18000-2:2023) has been prepared by Technical Committee CEN/TC 469 “Animal health diagnostic analyses”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

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prEN 18000-2:2023 (E)**Introduction**

The objective of the EN 18000 series is to facilitate the mutual recognition of the work of the animal health *in vitro* diagnostic reagent control organizations at European level (or even more widely) and thus to eventually allow the use of strategic reagents controlled by a single control organization for a given disease.

The EN 18000 series aims to describe the optimal requirements for *in vitro* diagnostic reagents in animal health. It is divided into three parts. The first part concerns terms and definitions and the submission of a reagent dossier to a control organization for control and approval. The second and third parts concern the specific aspects of the control of an immunological diagnostic reagent and of a polymerase-chain reaction diagnostic reagent for the detection or quantification of pathogen-specific nucleic acids (PCR), respectively.

Like any standard, it is intended to be voluntary and, if its use is prescribed by a competent authority or any other animal health stakeholder, it will be up to them to determine for which diseases this standard be applied by the control bodies they have designated for this purpose.

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