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**

ICS:

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

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EUROPEAN STANDARD

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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.

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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
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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.

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.