



DPC: 25/30507115 DC

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Date: 03 April 2025

Origin: European

Latest date for receipt of comments: 27 May 2025

Project No. 2025/00018

Responsible committee: AW/469

Interested committees:

Title: Draft BS EN 18000-3 BS Animal health diagnostic analyses - Control of in vitro diagnostic reagents. Part 3: Reagents for PCR techniques.

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- iii) requires additional national guidance or information

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Responsible Committee Secretary:

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

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.

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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.

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.



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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (prEN 18000-3:2025) has been prepared by Technical Committee CEN/TC "Animal health diagnostic analyses", the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

Introduction

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

The EN 18000 series establishes the requirements for the *control* of *in vitro diagnostic reagents* in animal health. This series 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 part concerns the specific aspects of the *control* by such organizations of an immunological *diagnostic reagent*.

The third part concerns the specific aspects of the *control* by such organizations of a *polymerase-chain reaction (PCR) diagnostic reagent* for the *detection* or quantification of pathogen-specific *nucleic acid*. It involves *control organizations (CO)* and *applicants* (including their subcontractors, when relevant).

Like any *standard*, this document 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 and to which extent this document will be applied by the control bodies they have designated for this purpose.

1 Scope

This document specifies the *control* and approval of *in vitro diagnostic reagents* used in animal health for the *detection*, and/or absolute quantification of pathogen-specific *nucleic acid* (DNA or RNA) by *PCR* (e.g. *endpoint PCR*, *real-time PCR*, *reverse transcription-PCR*).

This document is applicable to *diagnostic reagents* as a priority for infectious diseases (due to bacteria, viruses, fungi, or parasites, including genetic markers associated with pathogenicity, such as antimicrobial resistance or toxin production) and associated animal species for which harmonization of practices in this area is needed, i.e. those for which the national, regional or international regulatory framework provides for the control of trade in animals and/or animal products and/or the definition of a health status (absence of infection) of areas, establishments or individuals. Anyhow, all *reagents* designated by the competent authorities fall under the scope of this document. Nevertheless, the authorities or any other animal health stakeholder can choose to derogate in specific and very limited situations such as emerging, exotic or rare diseases.

This document is not applicable to all existing *diagnostic reagents*, in particular those for which certain parameters described in this document cannot be validly evaluated in accordance with international requirements, due, e.g. to the absence of a specific reference standard and/or accessible and duly validated *reference materials*.

The *PCR* diagnosis usually involves the use of a *nucleic acid extraction* and/or *purification reagent*, and a *PCR reagent*. The *PCR method* (when applicable) involves the successive use of these distinct *reagents*. *PCR reagent control* can be performed if the *applicant* provides evidence of the validity of the *PCR reagent* for use in the animal health diagnostic analysis, by proving its diagnostic performances with *nucleic acid* extracts obtained from the different matrices described in the instruction for use. The *control* of a complete *PCR method* by the *applicant* and the *control organization* is performed only if the *PCR reagent* cannot be dissociated from an *nucleic acid extraction* and/or *purification* systems. This document does not cover the control of the *nucleic acid extraction* and/or *purification reagents*, only.

This document does not cover the step in which the *user* verifies a *reagent* (*analysis method adoption*).

NOTE Prion diseases are not included in the scope of this third part of the EN 18000 series. Unlike other infectious diseases, prion diseases are not diagnosed using *PCR* assays because prions lack a *nucleic acid* component and consist solely of an abnormally folded conformer of the normal host protein.

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.

prEN 18000-1:2025, *Animal health diagnostic analyses - Control of in vitro diagnostic reagents - Part 1: Application file for the initial and the batch-to-batch control*

prEN ISO 22174:2024, *Microbiology of the food chain - Polymerase chain reaction (PCR) for the detection and quantification of microorganisms - General requirements and definitions (ISO/DIS 22174:2022)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in prEN 18000-1:2025 and the following apply.

NOTE These terms are written in italics throughout the EN 18000 series.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <http://www.iso.org/obp>

— IEC Electropedia: available at <http://www.electropedia.org/>

3.1

absolute quantification by real-time PCR

procedure involving *PCR* amplification to determine the concentration of a target *nucleic acid* in a *sample* by comparison with a standard curve, derived from standards containing a defined amount of target

[SOURCE: prEN ISO 22174:2024]

3.2

accepted reference value

value that serves as an agreed-upon reference for comparison, and which is derived as:

- a) theoretical or established value, based on scientific principles;
- b) an assigned or certified value, based on experimental work of some national or international organization;
- c) a consensus or certified value, based on collaborative experimental work under the auspices of a scientific or engineering group;
- d) when a), b) and c) are not available, the expectation of the (measurable) quantity, i.e. the mean of a specified population of measurement

[SOURCE: [1]]

3.3

accuracy

closeness of agreement between the *test result* and the *accepted reference value*

Note 1 to entry: The term *accuracy*, when applied to a set of *test results*, involves a combination of random components and a common systematic error or *bias* component.

[SOURCE: [1]]

3.4

background fluorescence

intrinsic level of fluorescence resulting from the *reagents*, consumables and instruments used

[SOURCE: [2]]

3.5

bias

difference between the expectation of the *test results* and an *accepted reference value*

Note 1 to entry: *Bias* is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the *bias*. A larger systematic difference from the *accepted reference value* is reflected by a larger *bias* value.

[SOURCE: [1]]

3.6

deoxyribonucleic acid

DNA

polymer of deoxyribonucleotides occurring in a double-stranded (*dsDNA*) or single-stranded (*ssDNA*) form

[SOURCE: [2]]