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Interested committees:

Title: Draft BS EN 18000-2 Animal health diagnostic analyses - Control of in-vitro diagnostic reagents. Part 2: Reagents for immunological 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 Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.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 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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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Page

European foreword	3
Introduction	4
1 Scope.....	5
2 Normative references.....	5
3 Terms and definitions.....	5
4 General control steps	6
5 Prerequisites of the reagent control for the control organization	6
5.1 General.....	6
5.2 Reference materials.....	6
5.3 Definition of the objectives of the reagents.....	6
5.4 Additional useful information.....	7
6 Initial conformity control	7
6.1 General.....	7
6.2 Characterization of the reagents by the applicant and control by the control organization	7
6.3 Initial control of the reagents by the control organization	11
7 Batch-to-batch control	12
7.1 Control at the start of the batch.....	12
7.2 Control during the batch validity period.....	13
8 Special cases	13
8.1 Multiple protocols	13
8.2 Multiple matrices.....	13
8.3 Pooling of samples.....	13
8.4 Derogations to systematic batch-to-batch control	13
Bibliography	14

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.