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English version

**Water quality - Guidance on validation of microbiological  
methods (ISO/TR 13843:2000)**

Qualité de l'eau - Lignes directrices pour la validation des  
méthodes microbiologiques (ISO/TR 13843:2000)

Wasserbeschaffenheit - Richtlinie zur Validierung  
mikrobiologischer Verfahren (ISO/TR 13843:2000)

This European Prestandard (ENV) was approved by CEN on 7 April 2001 as a prospective standard for provisional application.

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

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### **Foreword**

The text of the Technical Report from Technical Committee ISO/TC 147 "Water quality" of the International Organization for Standardization (ISO) has been taken over as a European Prestandard by Technical Committee CEN/TC 230 "Water analysis", the secretariat of which is held by DIN.

This European Prestandard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2001, and conflicting national standards shall be withdrawn at the latest by November 2001.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

### **Endorsement notice**

The text of the Technical Report ISO/TR 13843:2000 has been approved by CEN as a European Prestandard without any modifications.

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# Water quality — Guidance on validation of microbiological methods

## 1 Scope

This Technical Report deals with validation of microbiological methods, with particular emphasis on selective quantitative methods in which the quantitative estimate is based on counting of particles either directly, with the aid of a microscope, or indirectly, on the basis of growth (multiplication) into colonies or turbidity.

The principles and procedures within this scope are commonly known as the presence/absence (P/A), most probable number (MPN), colony count and direct (microscopic) count.

This Technical Report does not apply to the validation of the so-called rapid or modern methods which mostly depend on measuring products or changes due to microbial activity but do not address the detection of individual particles.

## 2 Terms and definitions

For the purposes of this Technical Report, the following terms and definitions apply.

### 2.1

#### **accuracy of measurement**

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

NOTE 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.

[ISO 3534-1:1993, 3.11]

### 2.2

#### **analyte**

#### **measurand**

particular quantity subjected to measurement

NOTE 1 See reference [5].

NOTE 2 In microbiology the analyte is ideally defined as a list of taxonomically defined species. In many cases, in practice the analyte can only be defined by group designations less accurate than taxonomic definitions.

### 2.3

#### **analytical portion**

#### **test portion**

volume of particle suspension inoculated into a detector unit

NOTE Examples of a detector unit are agar plate, membrane filter, test tube, microscopic grid square.

### 2.4

#### **application range**

range of particle concentrations routinely subjected to measurement by a method