ISO 13843:2017-06 (E)

Water quality - Requirements for establishing performance characteristics of quantitative microbiological methods

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Basic concepts 6
4.1 General 6
4.2 Characterization 7
4.3 Verification 8
4.4 Method comparison 8
4.5 Samples 9

5 Specifications:someguidelinevalues 9

6 Designs for determining performance characteristics of a method 10
6.1 General considerations 10
6.2 Determination of sensitivity, specificity, efficiency, selectivity, false positive rate and false negative rate 10
6.2.1 Type of samples to be used 10
6.2.2 Number of samples 11
6.2.3 Procedure 11
6.2.4 Categorical performance characteristics 11
6.2.5 Worked example 12
6.3 Determination of the upper limit and consideration of the lower limit of detection 14
6.3.1 Working range 14
6.3.2 Upper limit related to linearity 14
6.3.3 Type and number of samples to be used 14
6.3.4 Worked example 15
6.3.5 The lower limit of detection 16
6.4 Assessment of precision: Determination of repeatability and reproducibility 16
6.4.1 General 16
6.4.2 Repeatability 17
6.4.3 Intralaboratory reproducibility 18
6.5 Robustness 20
6.5.1 General 20
6.5.2 Experimental designs for effects due to time and temperature 20
6.6 Relative recovery 21
6.6.1 General 21
6.6.2 Determination of relative recovery 21
6.7 Uncertainty of counting 22
6.7.1 General 22
6.7.2 Experimental design for assessing the uncertainty of counting colonies 22
6.7.3 Example of individual (or personal) uncertainty of counting colonies 22
6.7.4 Example of intralaboratory uncertainty of counting colonies 23
6.7.5 Example of intralaboratory uncertainty of reading MPN 23

7 Designsforsinglelaboratoryverificationofamethod 24
7.1 General considerations 24
7.2 Calculation of sensitivity, specificity, efficiency, selectivity, false positive rate and false negative rate 24
7.2.1 Type of sample to be used 24
7.2.2 Number of samples 25
7.2.3 Procedure for confirmation 25
7.2.4 Categorical performance characteristics 25
7.3 Determination of repeatability 26

7.4 Uncertainty of counting 26
7.5 Procedure for single laboratory verification 26

Annex A (informative) Mathematical models of variation 30

Annex B (normative) Assessment of the lower limits 40

Annex C (normative) Assessment of the upper limit 43

Annex D (normative) Determination of the operational variability in repeatability and intralaboratory reproducibility conditions 44

Annex E (normative) Uncertainty of counting 48

Annex F (normative) Determination of the operational variability (interlaboratory reproducibility) in a collaborative performance study 50

Annex G (informative) Glossary of principal symbols 58

Bibliography 60