

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	Terms and definitions	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: some guideline values	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	Designs for single laboratory verification of a method	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