

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 |