

ISO 16140-2:2016-06 (E)

Microbiology of the food chain - Method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General principles for the validation of alternative methods	1
5 Qualitative methods -- Technical protocol for validation	2
5.1 Method comparison study	2
5.1.1 General considerations	2
5.1.2 Paired or unpaired study	2
5.1.3 Sensitivity study	2
5.1.4 Relative level of detection study	7
5.1.5 Inclusivity and exclusivity study	9
5.2 Interlaboratory study	10
5.2.1 General considerations	10
5.2.2 Measurement protocol	10
5.2.3 Calculations and summary of data	12
5.2.4 Interpretation of data	15
6 Quantitative methods -- Technical protocol for validation	16
6.1 Method comparison study	16
6.1.1 General considerations	16
6.1.2 Relative trueness study	16
6.1.3 Accuracy profile study	20
6.1.4 Limit of quantification study	24
6.1.5 Inclusivity and exclusivity study	24
6.2 Interlaboratory study	26
6.2.1 General considerations	26
6.2.2 Measurement protocol	26
6.2.3 Calculations, summary, and interpretation of data	27
Annex A (informative) Classification of sample types and suggested target combinations for validation studies	30
Annex B (normative) Order of preference for use of naturally and artificially contaminated samples in validation studies	46
Annex C (informative) General protocols for contamination by mixture and artificial contamination of foods	47
Annex D (informative) Models for RLOD calculations using data from the method comparison study	50
Annex E (normative) Points to be considered when selecting strains for testing inclusivity and exclusivity	52

Annex F (informative) Considerations for calculations of the relative level of detection (RLOD) between laboratories as obtained in an interlaboratory study	54
Annex G (informative) Principle of the accuracy profile for validation of quantitative models	57
Annex H (informative) Application of the accuracy profile in the method comparison study	59
Annex I (informative) Example of the application of the accuracy profile for an interlaboratory study	62
Bibliography	66