

DIN EN ISO 16140-5:2020-12 (E)

Microbiology of the food chain - Method validation - Part 5: Protocol for factorial interlaboratory validation for non-proprietary methods (ISO 16140-5:2020)

Contents	Page
European foreword	3
Foreword	4
Introduction	5
1 Scope	9
2 Normative references	9
3 Terms and definitions	10
4 General principles for the factorial interlaboratory validation of non-proprietary methods	11
4.1 General	11
4.2 Validation against a reference method	11
4.3 Validation without a reference method	11
5 Qualitative methods -- Technical protocol for factorial interlaboratory validation	11
5.1 In-house validation study	11
5.2 Interlaboratory validation study against a reference method	12
5.2.1 General considerations	12
5.2.2 Measurement protocol	12
5.2.3 Selection of the factors to be studied	13
5.2.4 Experimental design	14
5.3 Calculations and summary of data	14
5.4 Interpretation of data	16
5.4.1 Paired study	16
5.4.2 Unpaired study	17
5.4.3 Analysis of factorial effects with respect to RLOD	17
6 Quantitative methods -- Technical protocol for factorial interlaboratory validation	18
6.1 In-house validation study	18
6.2 Interlaboratory validation study against a reference method	18
6.2.1 General considerations	18
6.2.2 Measurement protocol	18
6.2.3 Experimental design	19
6.3 Calculations, summary, and interpretation of data	20
6.3.1 Summary of test results	20
6.3.2 Precision data	21
6.3.3 Accuracy profile	22
6.4 Interlaboratory validation study without a reference method	22
Annex A (informative) List of factors and factor levels for factorial validation	23
Annex B (informative) Example of a factorial interlaboratory study for a quantitative method	25
Annex C (informative) Example of a factorial interlaboratory study for a qualitative method	36
Bibliography	42