

# 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 )

---

<b>Contents</b>		<b>Page</b>
European foreword .....		3
Foreword .....		4
Introduction .....		5
<b>1</b>	<b>Scope .....</b>	<b>9</b>
<b>2</b>	<b>Normative references .....</b>	<b>9</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>10</b>
<b>4</b>	<b>General principles for the factorial interlaboratory validation of non-proprietary methods</b>	<b>11</b>
4.1	General .....	11
4.2	Validation against a reference method .....	11
4.3	Validation without a reference method .....	11
<b>5</b>	<b>Qualitative methods -- Technical protocol for factorial interlaboratory validation .....</b>	<b>11</b>
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
<b>6</b>	<b>Quantitative methods -- Technical protocol for factorial interlaboratory validation .....</b>	<b>18</b>
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