

ISO 16140-6:2019-11 (E)

Microbiology of the food chain - Method validation - Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General principles for the validation of confirmation and typing methods	3
5 Strains	4
6 Method comparison study	4
6.1 General	4
6.2 Selection of test strains	4
6.3 Inclusivity study	4
6.3.1 Testing of target strains	4
6.3.2 Family level (non-Salmonella)	5
6.3.3 Genus level (non-Salmonella)	5
6.3.4 Species level (non-Salmonella)	5
6.3.5 Microbial (sub)type level (non-Salmonella)	5
6.3.6 Salmonella genus or species level	5
6.3.7 Salmonella serovar level	6
6.4 Exclusivity study	6
6.4.1 Testing of non-target strains	6
6.4.2 Family level (non-Salmonella)	6
6.4.3 Genus level (non-Salmonella)	6
6.4.4 Species level (non-Salmonella)	6
6.4.5 Microbial (sub)type level (non-Salmonella)	6
6.4.6 Salmonella genus or species level	7
6.4.7 Salmonella serovar level	7
6.5 Expression and interpretation of results	7
6.6 Evaluation	9
7 Interlaboratory study	10
7.1 General	10
7.2 Data sets to be obtained	10
7.3 Protocol	11
7.4 Expression of results	12
7.5 Interpretation and evaluation	12
Annex A (normative) Points to be considered when selecting strains for testing inclusivity and exclusivity	14
Annex B (informative) Example of the validation of an alternative confirmation method to the species level (<i>Listeria monocytogenes</i>)	16

Annex C (informative) Example of the validation of an alternative typing method to the Salmonella serovar level (15 different serovars claimed)	19
Annex D (normative) Overview of the various options for validation under this document and the acceptability limits	23
Bibliography	25