

ISO 16140-3:2021 (E)

Microbiology of the food chain — Method validation — Part 3: Protocol for the verification of reference methods and validated alternative methods in a single laboratory

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	General principles of verification of qualitative (detection) methods and quantification methods
4.1	General
4.2	Implementation verification
4.3	(Food) item verification
4.4	Requirements for implementation verification and (food) item verification
4.5	Performance characteristics
5	Qualitative methods — Technical protocol for verification
5.1	Estimated LOD50 (eLOD50) determination
5.2	Experimental design
5.3	Selection of (food) items
5.4	Artificial contamination
5.4.1	Selection of strains
5.4.2	Inoculation of the test portions
5.5	Evaluation of results
5.5.1	Determination of eLOD50 using protocol 1
5.5.2	Determination of eLOD50 using protocol 2
5.5.3	Use of protocol 3
5.6	Acceptability limits
5.7	Root cause analysis
6	Quantitative methods — Technical protocol for verification
6.1	Intralaboratory reproducibility standard deviation determination
6.1.1	General
6.1.2	Experimental design
6.1.3	Selection of the (food) item
6.1.4	Natural contamination
6.1.5	Artificial contamination
6.1.5.1	Selection of the strain
6.1.5.2	Inoculation of the test portion
6.1.6	Evaluation of results
6.1.7	Acceptability limit
6.1.8	Root cause analysis
6.2	Estimated bias (eBias) determination
6.2.1	General
6.2.2	Experimental design
6.2.3	Selection of (food) items
6.2.4	Artificial contamination
6.2.4.1	Selection of strains
6.2.4.2	Inoculation of the test portions
6.2.5	Evaluation of results

- 6.2.6 Acceptability limit
- 6.2.7 Root cause analysis
- 7 Validated alternative confirmation and typing methods — Technical protocol for verification
 - 7.1 General
 - 7.2 Implementation verification
 - 7.3 Experimental design
 - 7.3.1 General
 - 7.3.2 Strain selection
 - 7.4 Evaluation of results
 - 7.5 Acceptability limit
 - 7.6 Root cause analysis
- 8 Summary of acceptability limits for the verification of validated methods
- Annex A (informative) Classification of (food) categories and suggested target combinations for verification studies
- Annex B (informative) Guidance on how to choose challenging (food) item(s) for (food) item verification
 - B.1 General
 - B.2 Matrix effects to consider
 - B.2.1 Microbial characteristics
 - B.2.2 Physical and chemical characteristics
 - B.2.3 Food process induced characteristics
 - B.3 Selection of (food) items for verification
- Annex C (informative) Qualitative method verification — Example
 - C.1 Method to be verified
 - C.2 Preparation for verification
 - C.3 Verification
- Annex D (informative) Quantitative method verification — Example
 - D.1 Determination of intralaboratory reproducibility standard deviation — Example
 - D.2 Determination of eBias — Example
 - D.2.1 Preparation for verification
 - D.2.2 Verification
- Annex E (informative) Validated alternative confirmation or typing method verification — Examples
 - E.1 Alternative confirmation method verification — Example
 - E.2 Alternative typing method verification — Example
- Annex F (normative) Protocol for the verification of non-validated reference methods in a single laboratory
 - F.1 General
 - F.2 (Food) item verification
 - F.3 Requirements for (food) item verification
 - F.4 Performance characteristics
 - F.5 Qualitative methods — Technical protocol for verification of a non-validated reference method
 - F.5.1 Estimated LOD50 (eLOD50) determination
 - F.5.2 Experimental design
 - F.5.3 Selection of (food) items
 - F.5.4 Artificial contamination
 - F.5.4.1 Selection of strains
 - F.5.4.2 Inoculation of the test portions
 - F.5.5 Evaluation of results
 - F.5.6 Acceptability limits
 - F.5.7 Root cause analysis
 - F.6 Quantitative methods — Technical protocol for verification of a non-validated reference method
 - F.6.1 Intralaboratory reproducibility standard deviation determination
 - F.6.2 Estimated bias (eBias) determination
 - F.7 Summary of acceptability limits