

DIN EN ISO 23418:2022-09 (E)

Microbiology of the food chain - Whole genome sequencing for typing and genomic characterization of bacteria - General requirements and guidance (ISO 23418:2022)

Contents	Page
European foreword	4
Foreword	5
Introduction	6
1 Scope	7
2 Normative references	7
3 Terms and definitions	7
4 Principle	12
4.1 General	12
4.2 Laboratory operation: sample preparation and sequencing	12
4.3 Bioinformatics analysis	13
4.3.1 General	13
4.3.2 SNP analyses	13
4.3.3 MLST analyses	13
4.3.4 Kmer distance analysis	13
4.4 Metadata formats and sequence repository deposition	13
4.5 Validation and verification of WGS workflow	14
5 General laboratory guidance	14
5.1 Bacterial isolation and DNA extraction	14
5.2 Laboratory environment	14
5.3 Standard operating procedures and nonconforming work	14
5.4 Laboratory information management system	14
5.5 Laboratory competence	14
6 Laboratory operations	15
6.1 Sample preparation and storage	15
6.2 Bacterial isolates	15
6.3 DNA isolation	15
6.4 Library preparation and sequencing	15
6.4.1 Library preparation	15
6.4.2 DNA sequencing	16
6.4.3 Use of controls	16
6.4.4 Assessing raw read data quality	16
6.4.5 Sample and data storage and retention	16
7 Bioinformatic data analysis	17
7.1 Requirements for software and bioinformatic pipelines used for data analysis	17
7.2 Logging and documentation	17
7.3 Quality assessments	17
7.4 SNP analyses	18
7.5 MLST analyses (cgMLST and wgMLST)	18
7.6 Target gene detection	19
7.7 Phylogenetic tree or dendrogram generation	19
7.8 Metrics and log files	19
7.9 Interpreting and reporting the results of bioinformatics analyses	19
7.9.1 Interpreting results from bioinformatics pipelines	19
7.9.2 Reporting genomic analysis results	20

8	Metadata.....	20
8.1	General.....	20
8.2	Metadata interoperability and future-proofing.....	20
8.2.1	General.....	20
8.2.2	Ontologies.....	20
8.2.3	ISO WGS Slim.....	20
8.3	Formatting metadata using this document.....	21
8.4	Metadata associated with sample collection.....	21
8.5	Metadata associated with the isolate.....	22
8.6	Metadata associated with the sequence.....	23
9	Sequence repositories.....	25
10	Validation and verification.....	26
10.1	Validation.....	26
10.1.1	General.....	26
10.1.2	Validation of laboratory operations.....	27
10.1.3	Validation of the bioinformatics pipeline.....	27
10.1.4	Validation of the end-to-end workflow.....	28
10.2	Verification.....	28
10.2.1	General.....	28
10.2.2	Verification of laboratory operations.....	28
10.2.3	Verification of the bioinformatics pipeline.....	28
Annex A (informative) Development of quality metrics and use of controls.....	30	
Annex B (informative) Laboratory contact information fields.....	35	
Annex C (informative) Geographic location of sample collection fields.....	37	
Annex D (informative) Isolate passage history fields.....	38	
Annex E (informative) Antibiogram results and methods fields.....	39	
Annex F (informative) Virulence factor detection and methods fields.....	41	
Annex G (informative) Sequence quality control metrics.....	42	
Annex H (informative) Metadata specification.....	43	
Annex I (informative) Instructions for ontology slim integration by software developers.....	46	
Bibliography.....	50	