

ISO 20688-2:2024-03 (E)

Biotechnology - Nucleic acid synthesis - Part 2: Requirements for the production and quality control of synthesized gene fragments, genes, and genomes

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Requirements for quality management	3
4.1	General requirements	3
4.2	Control of documents	4
4.3	Quality management system	5
4.4	Biorisk management and safety control	5
5	Requirements for resource management	5
5.1	Facilities and environmental condition	5
5.2	Equipment and instruments	5
5.3	Raw materials	6
5.4	Personnel	6
6	Biosafety and biosecurity requirements	6
6.1	General	6
6.2	DNA sequence screening mechanism	6
7	Requirements for quality control in production	7
7.1	General	7
7.2	Quality control in synthetic gene fragments production	7
7.2.1	General	7
7.2.2	Sequence design	7
7.2.3	Assembly	8
7.2.4	Purification	8
7.2.5	Product preservation	8
7.3	Quality control in synthetic gene production	8
7.3.1	General	8
7.3.2	Colony screening	8
7.3.3	DNA preparation from the host cell	8
7.3.4	Sequence verification	9
7.3.5	Product preservation	9
7.4	Quality control in synthetic genome production	9
7.4.1	General	9
7.4.2	Assembly	9
7.4.3	Sequence verification	9
8	Requirements for product quality	10
8.1	Synthetic gene fragments	10
8.1.1	General	10
8.1.2	Yield	10
8.1.3	Purity	10
8.1.4	Size	10
8.1.5	Gene cloning accuracy	10
8.2	Synthetic genes	10
8.2.1	General	10
8.2.2	Yield	10

8.2.3	Purity.....	11
8.2.4	Sequence.....	11
8.2.5	Integrity.....	11
8.2.6	Residual impurities analysis.....	11
8.2.7	Supercoiled plasmid.....	12
8.2.8	Bioburden.....	12
8.2.9	Specific quality indicators for synthetic DNA libraries.....	12
8.3	Synthetic genome.....	12
8.3.1	General.....	12
8.3.2	Sequence.....	12
9	Delivered/synthesized material specifications.....	13
9.1	Main information.....	13
9.2	Other information.....	13
	Annex A (informative) Example equipment and device list and their control requirements.....	14
	Annex B (informative) Exemplary quality measurement methods.....	16
	Annex C (informative) Electrophoretogram.....	18
	Annex D (informative) Sanger sequencing.....	22
	Annex E (informative) Massively parallel sequencing.....	23
	Annex F (informative) Additional quality control options for synthetic gene fragments.....	26
	Annex G (informative) Example ranking of the risk posed by DNA products.....	28
	Bibliography.....	29