



## E. coli Cell Bank Characterization Services

E. coli cell bank release testing is essential for biopharmaceutical production of plasmids and therapeutic proteins. Regulatory agencies require thorough characterization of the identity, purity, and genetic stability of the E. coli cell banks used in GMP manufacturing. This ensures the cell bank is contaminant-free, genetically stable, and possesses the necessary characteristics for reliable and safe bioprocesses.

Our E. coli cell bank testing services include:

### E. coli Pre-bank Testing

Critical Quality Attributes	Assay	Description
<b>Purity</b>	Lytic Phage Detection	Microbiological assay to test for presence of lytic phage in cell bank
	Lysogenic Phage Detection	Microbiological assay to test for presence of lysogenic phage in cell bank
	Phage ID Confirmation	Confirmation of phage identity by NGS
<b>Identity</b>	Plasmid Sequencing	Confirmation of full or partial sequence of the plasmid by Sanger sequencing or NGS

### E. coli Cell Bank Testing (CGMP)

Critical Quality Attributes	Assay	Description
<b>Identity</b>	Plasmid Sequence Confirmation	Confirmation of full or partial sequence of the plasmid by Sanger sequencing or NGS
	Strain ID	Various biochemical tests to confirm the strain's genotype based on phenotypic characteristics
	Species ID	Confirmation of bacterial species using bioMerieux API20E test

## E. coli Cell Bank Testing (CGMP) (cont.)

Critical Quality Attributes	Assay	Description
Identity	Gram Staining	Confirmation of Gram Stain phenotype of bacterial cell bank
	Colony Morphology Testing	Confirm morphology of colonies after expansion of cells on agar plates
Purity	Purity Testing	Test for aerobic and anaerobic bacteria and aerobic fungi in cell bank
	Lytic Phage Detection	Microbiological assay to test for presence of lytic phage in cell bank
	Lysogenic Phage Detection	Microbiological assay to test for presence of lysogenic phage in cell bank
Stability	Marker Retention	Determine percentage of cells capable of maintaining selectable marker/plasmid
	Plasmid Copy Number	Quantify copies of plasmid per cell in MCB, WCB, and EOPC by QPCR or ddPCR
	Plasmid Gene of Interest Sequence Confirmation	Confirmation of full or partial sequence of the plasmid in MCB, WCB, and EOPC by Sanger sequencing
	Viability Testing	Determine percentage of viable cells in cell bank (cfu/ml)
	mRNA Sequencing	Sequencing of the target gene of protein expression in MCB, WCB, and EOPC by Sanger sequencing

## Other E. coli Cell Bank Testing

Critical Quality Attributes	Assay	Description
Other	Antibiotic Sensitivity Testing	Confirmation of antibiotic resistance in E. coli cell bank
	16S rRNA Sequencing	Identification of Bacterial species by 16S/ITS Sequencing by Sanger
	E. coli Genome Confirmation	Confirmation of full or partial E coli genome by NGS
	Residual plasmid clearance testing	Testing for line clearance of residual plasmid using TaqMan assays targeting Kanamycin or other plasmid sequences in between plasmid batch production by QPCR