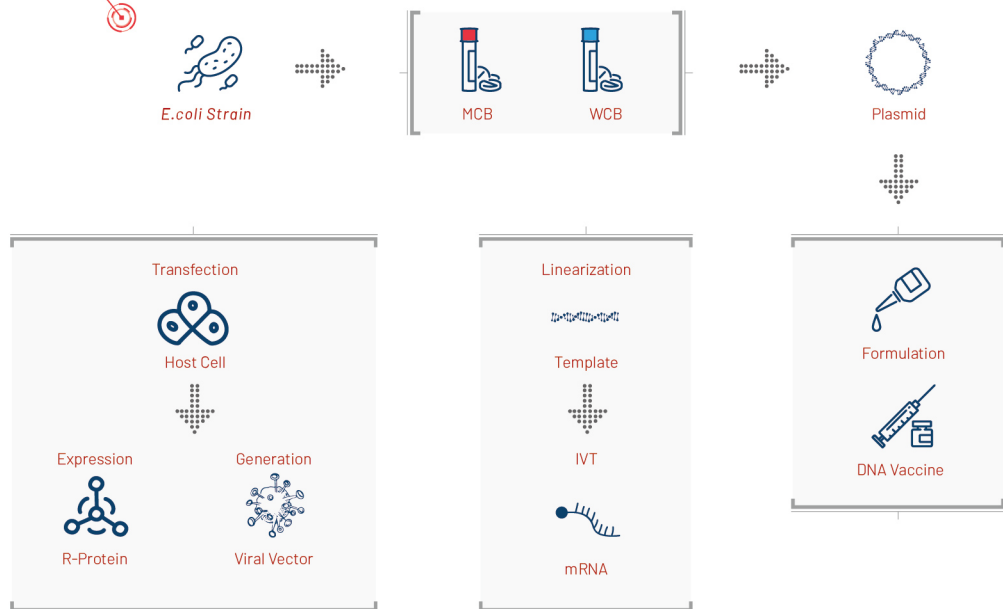


High Quality Testing Service Meeting Global Regulatory Compliance

Escherichia coli Microbial Bank Characterization & Plasmid Testing

Modalities

E. coli and its plasmids play an important role in biopharmaceuticals, which are used in the research, development and production of different biological modalities to meet the requirement of large-scale clinical applications.

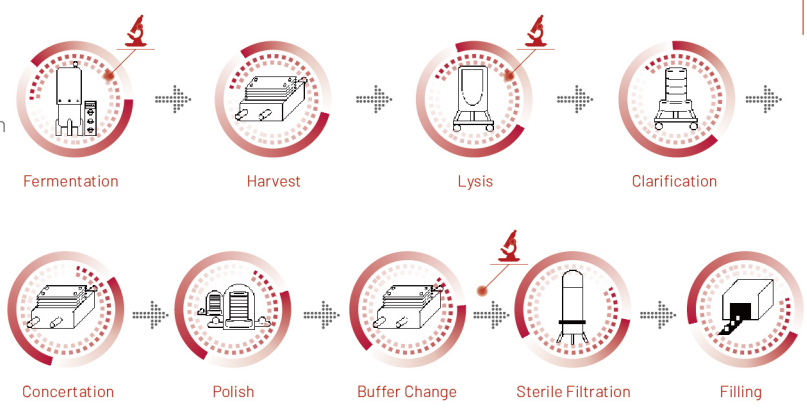


BRC Bio offers quality testing for *E. coli* and plasmid products, meeting the requirement of gene therapy, gene-modified cell therapy, vaccine, nuclear acid drug etc.

Process Challenge

- ▶ Purity of Microbial Bank
- ▶ Plasmid Retention Rate in Host Strain
- ▶ Antibiotic Residual Testing
- ▶ Lysis Efficiency of Bacteria
- ▶ Endotoxin Residual
- ▶ Plasmid Construction
- ▶ Genetic Stability of *E. coli*
- ▶ Bacteriophage Contamination
- ▶

Biosafety Consideration of Plasmid Process



Regulatory Requirement

- ▶ EP 5.14
- ▶ FDA 2016 Guidance
- ▶ General Section for Human Used Gene Therapy Products

Biosafety Testing for *E.coli* and Its Plasmid Products

	MCB	WCB	EOPC	Plasmid Product	USP, ChP, EP
Viability	🔬	🔬	🔬		✅
Identity	🔬	🔬	🔬		✅
Purity	🔬	🔬			✅
Biochemical/Physical	🔬	🔬	🔬		✅
Genotype	🔬		🔬		✅
Bacteriophage Detection	🔬				✅
Plasmid Identity	🔬			🔬	✅
Plasmid Stability			🔬	🔬	✅
Sterility/Mycoplasma				🔬	✅
Impurity				🔬	✅

Our Advantages

- ▶ Rapid Development
- ▶ Comprehensive Quality
- ▶ Professional Practice
- ▶ Localized Service

