

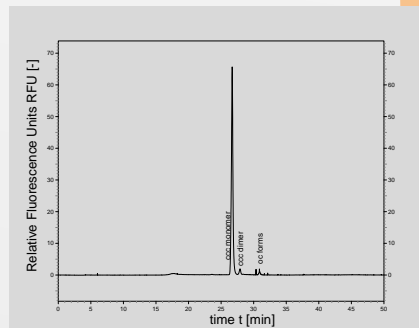
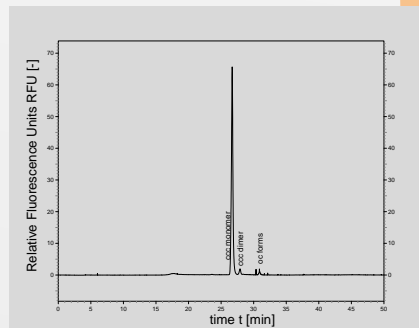
# High Quality Grade

## Plasmid DNA

Highly purified, intensively tested and animal-free for:

- pre-clinical applications
- highly efficient (co-)transfections
- virus production - e.g. AAV, LV, ...
- reference standards

The basis of  
your successful  
biomanufacturing

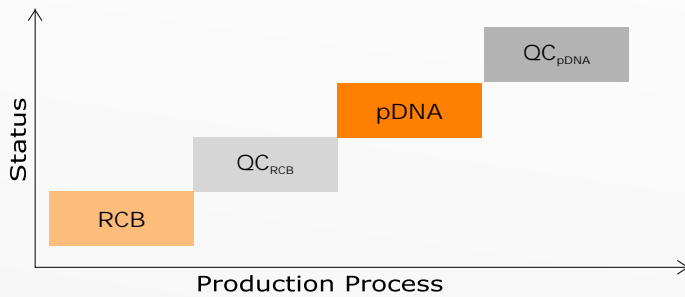


Our innovative production process is mainly characterized by:

- Animal-free production from cellbank to finished product
- Cultivation without antibiotics
- Completely enzyme-free process
- Specific removal of bacterial chromosomal DNA and all non-supercoiled plasmid forms
- Highly purified product
- Comprehensive documented QC

Depending on your individual requirements all QC tests can be performed under different quality levels such as R&D, ISO, GLP, GMP and following respective regulations, e.g. DAB, EP, USP.

# High Quality Grade Plasmid DNA



Tailor-made *High Quality* production according to your individual requirements

## Cell Bank production (RCB):

- Cell Bank production in combination with the PlasmidFactory DNA manufacturing service
- Pilot cultivation
- RCB storage

## Quality Controls for RCB (QC<sub>RCB</sub>):

### RCB tests

Plasmid  
Plasmid identity  
Plasmid yield  
Plasmid stability (segregative)  
*E. coli* host  
Host identity (K12)  
  
Purity  
Microbial purity  
Bacteriophage  
Filling  
Test of containers  
Test of volume

### Analytical method

Restriction enzyme mapping with various enzymes\*  
Sequencing (double strand)  
Plasmid DNA purification with subsequent spectrophotometric determination (260 nm)\*  
Colony plating  
  
API-20E  
16s rRNA  
RADP fingerprinting  
Riboprinting  
  
Presence of bacterial and fungal contaminants (Plating on selective media)  
Plaque test on indicator host  
  
Visual inspection of vials\*  
Inspection conforming to United States Pharmacopeia (USP)

## Plasmid DNA production (pDNA):

- In certified *ccc Grade classic* quality
- In guaranteed amount
- Filling of aliquots, formulated in a buffer of your choice
- Shipped on dry ice

## Quality Controls for plasmid DNA (QC<sub>pDNA</sub>):

### Plasmid DNA tests

DNA concentration  
DNA homogeneity (ccc content)  
  
Identity  
Plasmid identity  
  
Purity  
Appearance  
DNA  
RNA  
Endotoxin (LPS)  
Bacterial chromosomal DNA  
  
Protein  
Host cell derived protein  
Microorganism

### Analytical method

Spectrophotometric determination (260 nm)\*  
Densitometry after agarose gel electrophoresis (AGE)\*  
Capillary gel electrophoresis (CGE)\*  
  
Restriction enzyme mapping with various enzymes\*  
Sequencing (double strand)  
  
Visual inspection\*  
UV-Scan (220-320 nm)\*  
Visual inspection after AGE\*  
*Limulus Amebocyte* Lysate assay (LAL)\*  
Visual inspection after AGE\*  
Quantitative PCR  
Bicinchoninic acid (BCA) assay  
Host cell protein assay  
Presence of bacterial and fungal contaminants (bioburden: TAMC, TYMC)

\* included within plasmid DNA production

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