

### Plasmid Manufacturing Services

KromaTiD's Plasmid Manufacturing Service offers plasmid DNA in a range of purity levels and amounts with fast turnaround and competitive pricing.

Our team has the capability to provide you the best Plasmid Manufacturing Service at any stage of development, research through IND filing and clinical phases to manufacture of commercial plasmids.

### Key Benefits

- Three levels of purity: Research, Transfection and Low Endotoxin Grades
- Three production modes: research, pre-GMP and cGMP
- Compatible with your materials; simply provide pDNA as frozen glycerol stock or stabs for cultures
- Choose the amount of DNA you need, from 100µg to 5g scales
- Fast turnaround and highly competitive pricing
- Standard documentation and QC provided
- Additional tests provided on request

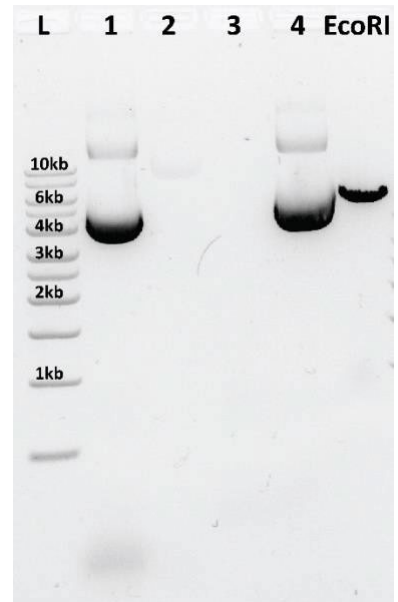
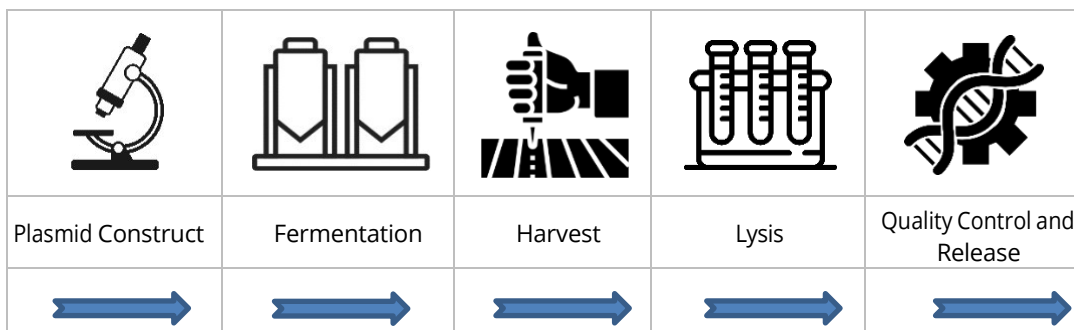


Figure 1. Analytical check of plasmid purification, pAAV-GFP. L: ladder, 1: cleared lysate, 2: lysate flow-through, 3: wash flow-through, 4: eluate, EcoRI: enzymatic digestion.

### Our Process



### Purity Levels

| Plasmid DNA Manufacturing Services | Scale       | Application   | Production   |
|------------------------------------|-------------|---|--|
| Research Grade                     | 100ug-2.5mg | <i>In vitro</i> R&D or preclinical studies  | R&D Grade for cloning or vector construction                       |
| Transfection Grade                 | 100ug-1g    | <i>In vitro</i> R&D or preclinical studies  | Transfection Grade for less sensitive cells                        |
| Low Endotoxin Grade                | 100ug-1g    | <i>In vitro</i> R&D or preclinical studies  | Low Endotoxin Grade for sensitive cells                            |
| High Quality Pre-GMP               | ≥50mg       | Toxicology, GMP vector production for Phase I- II clinical trials, and as template for GMP mRNA | Dedicated, Segregated Non-cGMP Lab (~6 weeks to supply)            |
| cGMP                               | ≥50mg       | Phase I, II, III and commercial viral vector manufacturing, DNA vaccines                        | Certifiable Suite for GMP Manufacturing (inquire for availability) |

## Plasmid Manufacturing Production Mode Comparison

| Plasmid Manufacturing Service Options  | Research | Pre-GMP | cGMP |
|--|----------|---------|------|
| Cloning and Synthesis  | ✓        | ✓       | ✓    |
| Scale-up and manufacturing of existing plasmid constructs  | ✓        | ✓       | ✓    |
| Multiple production scales (shake flask through fermenters)  | ✓        | ✓       | ✓    |
| Proven manufacturing and purification processes for high yield and recovery                        | ✓        | ✓       | ✓    |
| Standardized manufacturing platforms   |          | ✓       | ✓    |
| Establishment of E. coli master and working cell banks   |          | ✓       | ✓    |
| Upstream process development (optimization of transformation and culture conditions, strain, etc.) |          | ✓       | ✓    |
| Downstream process development (optimization of purification and formulation conditions)           |          | ✓       | ✓    |
| Full traceability of materials   |          | ✓       | ✓    |
| Full room changeover prior to each production  |          | ✓       | ✓    |
| Production in segregated and dedicated space   |          | ✓       | ✓    |
| Process and change control   |          | ✓       | ✓    |
| Aseptic fill and finish and vialing  |          | ✓       | ✓    |
| Document support for IND filing  |          | ✓       | ✓    |
| Master Batch Records   |          | ✓       | ✓    |
| Stability studies  |          | ✓       | ✓    |
| Product release tests  |          | ✓       | ✓    |
| Manufacturing in cGMP suite with upgraded air handling   |          |         | ✓    |
| Complete QC monitoring throughout production process   |          |         | ✓    |
| QA Oversight for production  |          |         | ✓    |

### Pricing and Turn Around Times

| Cat.No. | Product Description                   | TAT       | List Price |
|---------|---------------------------------------|-----------|------------|
| KPM-001 | Research-Grade up to 100ug yield      | 5-10 days | \$437.50   |
| KPM-002 | Research-Grade up to 200ug yield      | 5-10 days | \$443.10   |
| KPM-003 | Research-Grade up to 500ug yield      | 5-10 days | \$448.35   |
| KPM-004 | Research-Grade up to 1mg yield        | 5-10 days | \$458.85   |
| KPM-005 | Research-Grade up to 2.5mg yield      | 5-10 days | \$511.70   |
| KPM-006 | Research-Grade >2.5mg yield           | Inquire   | Inquire    |
| KPM-007 | Transfection-Grade up to 100ug yield  | 5-10 days | \$439.43   |
| KPM-008 | Transfection-Grade up to 200ug yield  | 5-10 days | \$457.10   |
| KPM-009 | Transfection-Grade up to 500ug yield  | 5-10 days | \$461.48   |
| KPM-010 | Transfection-Grade up to 1mg yield    | 5-10 days | \$669.10   |
| KPM-011 | Transfection-Grade up to 2.5mg yield  | 5-10 days | \$802.55   |
| KPM-012 | Transfection-Grade >2.5mg yield       | Inquire   | Inquire    |
| KPM-013 | Low Endotoxin-Grade up to 100ug yield | 5-10 days | \$449.50   |
| KPM-014 | Low Endotoxin-Grade up to 200ug yield | 5-10 days | \$467.25   |
| KPM-015 | Low Endotoxin-Grade up to 500ug yield | 5-10 days | \$474.25   |
| KPM-016 | Low Endotoxin-Grade up to 1mg yield   | 5-10 days | \$735.00   |
| KPM-017 | Low Endotoxin-Grade up to 2.5mg yield | 5-10 days | \$861.00   |
| KPM-018 | Low Endotoxin-Grade >2.5mg yield      | Inquire   | Inquire    |
| KPM-019 | Pre-GMP Grade up to 50mg yield        | -6weeks   | Inquire    |
| KPM-020 | cGMP Grade 100mg to 5g yield          | Inquire   | Inquire    |
| KPM-021 | DNA Synthesis per DNA basepair        | 4-8 weeks | Inquire    |
| KPM-022 | Sanger Sequencing Verification        | 5 days    | Inquire    |
| KPM-023 | NGS Sequencing Verification           | 5 days    | \$170.00   |

## Quality Control

| QC Items           | Specification                      | Measurement Method                          |
|--------------------|------------------------------------|---|
| A260/280           | 1.8-2.0                            | Nanodrop UV Absorption                      |
| Appearance         | Clear                              | Visual Inspection                           |
| Concentration      | On request, standard is 0.25 mg/ml | UV Absorption                               |
| Supercoil content  | > 80%                              | Agarose Gel                                 |
| Residue RNA        | Not Visible                        | Agarose Gel                                 |
| Genomic DNA        | Not Visible                        | Agarose Gel                                 |
| Restriction Digest | Matches Reference                  | Enzymatic Digestion and Gel Electrophoresis |
| Endotoxin Assay    | LAL Assay                          | < 0.1 EU/ug plasmid DNA                     |
| BioBurden Assay    | No Growth                          | Agar plate for 48 hours                     |