



## VGXI's Analytics Program

### VGXI – Your Trusted Partner for Plasmid DNA Analysis

For the first time ever, our comprehensive analytics package is available as a standalone service to fast-track your development. With over two decades of plasmid manufacturing expertise, our experienced Quality Team provides reliable and high-quality data to ensure you get high quality plasmid materials with the consistency and regulatory compliance needed across each stage of development and commercialization.

- > Comprehensive Analytical Solutions
- > Optimized Analytical Methods
- > Rapid Turnaround Time
- > Reliable Data
- > Customizable Services

From microbial cell bank testing to plasmid DNA product testing – we are your dedicated partners at every step. Each test we provide is either fully validated or executed in accordance with USP guidelines to ensure data accuracy and consistency to fully support your product development and regulatory submissions.

As a client-focused CDMO, we work closely with our clients to design custom analytical assays based on the product, phase of development, and regulatory requirements to meet a diverse array of program requirements. Contact us at [plasmids@vgxi.com](mailto:plasmids@vgxi.com) or visit our website at [vgxi.com](http://vgxi.com) to learn more about our customizable analytical services.

## CELL BANK TESTING AVAILABLE

| Assay                                       | Method  |
|---|---|
| Host Identification                         | API-20E Tests   |
| Identification of <i>E. coli</i> K12 strain | Plating for Identification of <i>E. coli</i> K-12 Strain        |
| Culture Purity                              | Bacterial and Fungal Contaminants                               |
| Bacteriophage Detection                     | Plating for the Presence of Bacteriophage                       |
| Cell Viability                              | Plating for Cell Viability                                      |
| Plasmid Identification                      | Sanger Sequencing   |
| Plasmid Retention                           | CFU isolation on multiple antibiotic and antibiotic-free plates |

## DRUG SUBSTANCE/PRODUCT TESTING AVAILABLE

| Assay  | Method                                     |
|--|--|
| Nucleic Acid Concentration                                 | cUSP <851>                                 |
| Purity   | A260/280                                   |
| Identity   | Restriction Digest, AGE                    |
| Analysis of Total Forms (% Supercoil, Circular, and other) | HIC-HPLC, AE-HPLC, CGE (>10kb)             |
| Host-Cell RNA  | HPLC                                       |
| Host-Cell Protein  | Micro-BCA                                  |
| Host-Cell DNA  | RT-qPCR                                    |
| Endotoxin  | Bacterial Endotoxins cUSP <85>             |
| pH   | cUSP <791>                                 |
| Osmolality   | cUSP <785>                                 |
| Appearance   | cUSP <790>                                 |
| Transcriptional Activity                                   | RT-PCR                                     |
| Residual Kanamycin   | LC-MS                                      |
| Bioburden (drug substance) or Sterility (drug product)     | Bioburden USP 61 & 62 Sterility, cUSP <71> |
| Mycoplasma   | RT-qPCR                                    |
| Particulate Matter in Injections                           | cUSP <788>                                 |
| Container Closure Integrity Testing (CCIT)                 | Vacuum decay                               |
| Extractable Volume   | cUSP <1> and cUSP <697>                    |

## About VGXI

Backed by two decades of production and regulatory expertise, VGXI is the ideal CDMO partner to support every step of your product pipeline from early development to market launch. Our dedicated team and state-of-the-art facilities ensure that your experience with VGXI exceeds expectations with unrivaled scale, reliability, and excellence. VGXI doesn't just meet today's demands, we're future-proofing demand for tomorrow's innovations and setting new industry benchmarks with the world's largest plasmid DNA manufacturing capacity. For more information on VGXI products and services, contact us at [info@vgxii.com](mailto:info@vgxii.com) or visit our website, [vgxii.com](http://vgxii.com).



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