

# Raw Materials Testing for Cell & Gene Therapy Manufacturing

Eurofins BioPharma Product Testing is well versed in evaluating critical quality attributes (CQAs) of a diverse range of ancillary and raw materials, including monographed and non-monographed materials, used in cell and gene therapy products. Using established GMP methods, platform techniques, and customized methods, Eurofins provides robust, flexible, and high throughput lot release testing for the fast-paced manufacturing of today's therapies.

Our dedicated Biologics Raw Materials testing team has vast experience in cell and gene therapy manufacturing from early clinical, through process validation, product optimization, and marketed release. With 30 years of biopharmaceutical experience, our teams of scientists have current and relevant expertise in marketed and clinical chimeric antigen (CAR-T) and T-cell receptor (TCR) therapies, as well as manufacturing support for a broad array of viral and plasmid vector modalities. This allows us to immediately leverage impactful knowledge in materials used in apheresis, fractionation, cell selection, activation, gene transfer, expansion, and cryopreservation of cell therapy products as well as transfection, vector production, and purification of gene products.

## Why Choose Eurofins BioPharma Product Testing?

We provide a comprehensive raw materials testing package to support all testing needs.

We can develop and validate unique methods to test biologic materials as well as support platform methods for many of the techniques offered.

We have the ability to test non-monographed



materials to satisfy agency scrutiny.

Our secure, 24/7 online data portal, LabAccess.com, provides timely access to your test results.

## Biologic Raw Material Testing Capabilities

### Chemically Defined Growth Media

- Identification and content by amino acid analysis
- Platform pH and osmolality and appearance
- Vitamin and sugar content
- Growth promotion and functional assays
- Microbiological services

### Process Buffers, Cryopreservation Solutions, and Chemical Transfection Agents

- Ion identification (wet chemistry, IC and ICP-MS)
- Platform pH, conductivity, osmolality, FT-IR, specific gravity
- Platform protease, RNase, and DNase,



Phosphatase, Nicking Activity detection

- Platform content procedures – titrations, HPLC, GC
- Cell Viability / Cytotoxicity assays

### ***Cytokines, Growth Factors, Enzymes, etc.***

- Enzyme activity assays and kinetics
- Identification and content by ELISA, Dot Blot, Western Blot or other electrophoretic methods
- Total protein by UV
- Purity, oligomers and aggregation (SDS-PAGE, SEC, GPC)
- Microbiological services
- Cell based potency and functional assays
- Platform pH and Osmolality
- Residual Host Cell DNA, residual Host Cell Protein

#### **Comprehensive GMP Testing Services**

Method Development & Validation • Release Testing • Raw Materials Testing  
Cell Banking Services • Virology Services • Facility & Process Validation  
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology  
Stability Testing & Storage • Primary & Secondary Package Testing

#### **Contact Us**

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