



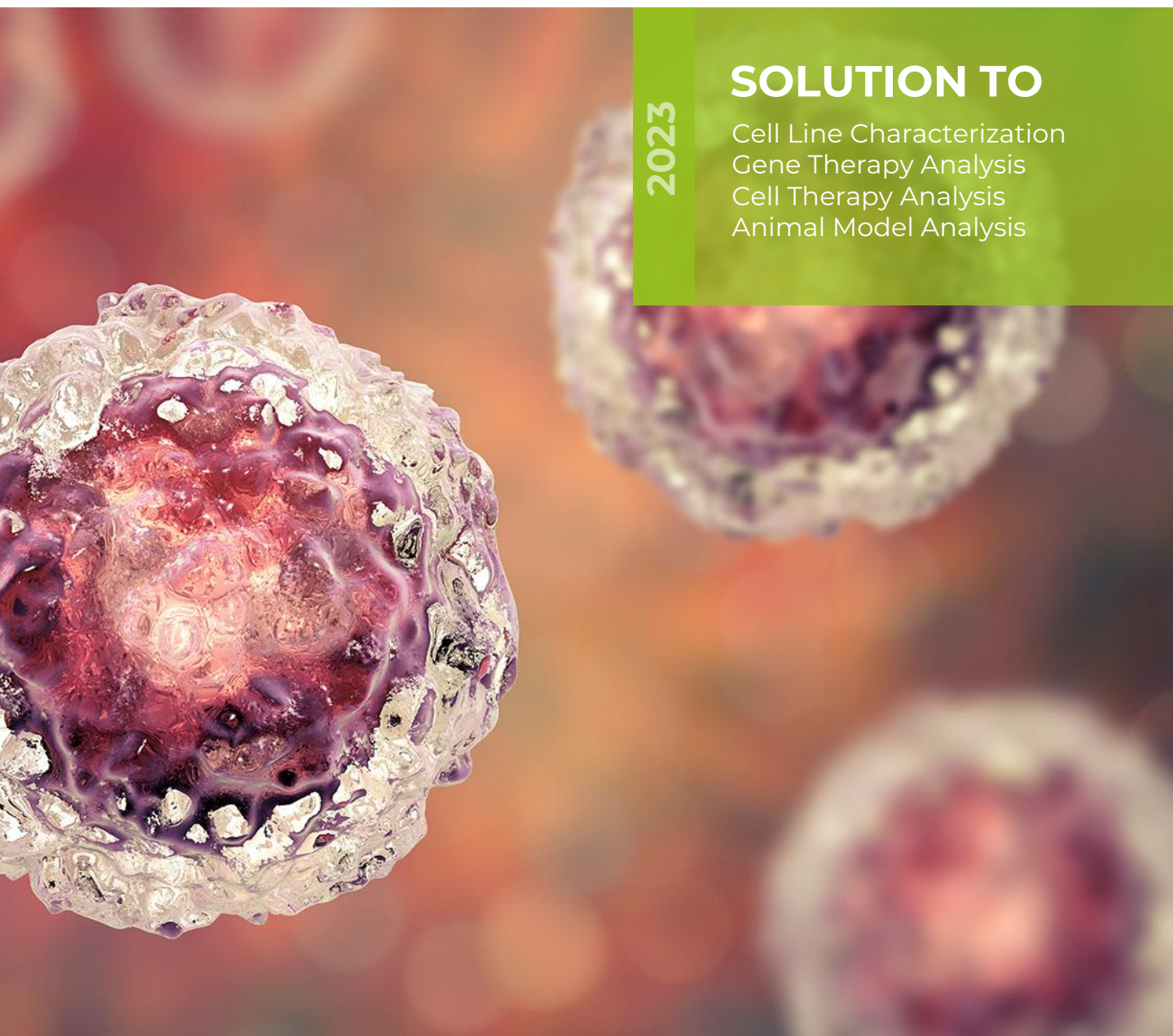
Creative Bioarray



2023

SOLUTION TO

Cell Line Characterization
Gene Therapy Analysis
Cell Therapy Analysis
Animal Model Analysis





About Creative Bioarray

Creative Bioarray is an innovative biotechnology company whose mission focuses on developing unique technologies that provide global scientists with high quality products and satisfactory services to facilitate the investigation of life science researches.

Creative Bioarray ChromoGenetics is a technology-driven spatial biology biotechnology platform and a leading provider of genetic quality control solutions. We are revolutionizing biomarker analysis to improve drug development and diagnostics using the power of RNA and DNA with a consultative approach. Our services and technology improve the data and interpretation from traditional methods, eliminating variability,

and bringing new insights to analysis results. We provide expert scientific consultation for every client. With our widely published and recognized genetic analyses, we support all leading pharma companies and research institutes in the characterization and QC of their **biopharmaceutical cell line development, cell and gene therapy products, and genetically engineered animal models.**

As a reliable partner to accelerate your project, we have the capabilities to utilize strategies that provide the results to meet your needs. And we have supported dozens of cell and gene therapy companies for research studies enabling pre-IND submission.

Delivering innovative solutions to guarantee the genetic quality of future therapies

Cell Line Characterization

Cell Bank characterization is an essential step in ensuring the safety of biopharmaceutical products with the aim of confirming the identity, purity, and genetic stability of cell lines.

Cell and Gene Therapy Analysis

Cell and Gene therapy development requires a comprehensive understanding of the unique aspects of these products in relation to its *in vivo* safety profiles.

Animal Model Analysis

Discovery of a drug or component, equipment, their toxicological studies, dose, side effects are *in vivo* studied for future use in humans considering its ethical issues.



Cell Line Characterization

Being regarded as a starting point in production, cell line characterization improves control and consistency in the manufacturing of the products. Its importance is well recognized for better quality assurance and the uniform supply from clinical trials to commercial use.

Creative Bioarray has extensive experience in characterization of cGMP cell banks used in production of biologic drugs. We offer a broad range of cell line characterization services allow you to efficiently streamline your cGMP-compliant manufacturing processes and accelerate toward successful commercialization. Our reporting fulfils **FDA and EMA regulatory requirements for pharmaceuticals for human use (ICH guidelines Q5B and Q5D, CTD Quality module, section 3.2.S.2.3).**

Mammalian Cell Line Characterization- Recommended Testing Plan

Testing		MCB	WCB	EPC/CAL
Microbial Contamination	Sterility	+	+	+
	Mycoplasma	+	+	+
Cell Line Stability/Identity	DNA Fingerprinting/Barcoding	+	+	+
	Karyology	+		+
Genetic Stability	DNA Sequencing	+		+
	Gene Copy Number	+		+
	Restriction Endonuclease Analysis	+		+
	In vitro Adventitious Viruses	+	+	+
	In vivo Adventitious Viruses	+		+
	Virus Detection by PCR (e.g., Human, Simian, Bovine, Murine, and Porcine)	+		+
	Mouse, Hamster, and Rat Antibody Production Assays (MAP, RAP, and HAP)	+		+
	Transmission Electron Microscopy	+		+



Cell Line Characterization Services Available From Creative Bioarray:

Cell Bank Characterization

- Cell Line Clonality Assessment
 - Cell Line Genetic Stability (MCB, WCB, EOP) Testing
 - Cell Line Transgene Integrations & Copy Number QC (Locus Amplification & Sequencing)
 - Cell Line Transgene Integrations QC (FISH)
 - Cell Chromosomal Aberration Analysis
 - Cell Chromosomal Comparative Genomic Hybridization (aCGH)
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- CHO Cell Bank Characterization
 - HEK293 Cell Bank Characterization
 - BHK-21 Cell Bank Characterization
 - Vero Cell Bank Characterization
 - MDBK Cell Bank Characterization
 - MDCK Cell Bank Characterization
 - ST Cell Bank Characterization
 - EB66 Cell Bank Characterization
 - PK15 Cell Bank Characterization
 - Gene Edited Cell Bank Characterization

With years of experience and well-developed protocols, **Creative Bioarray's Cell Bank Characterization** ensures that your biological production process complies with international guidelines. Guaranteed quality enables us for worldwide partnerships to accelerate innovation.

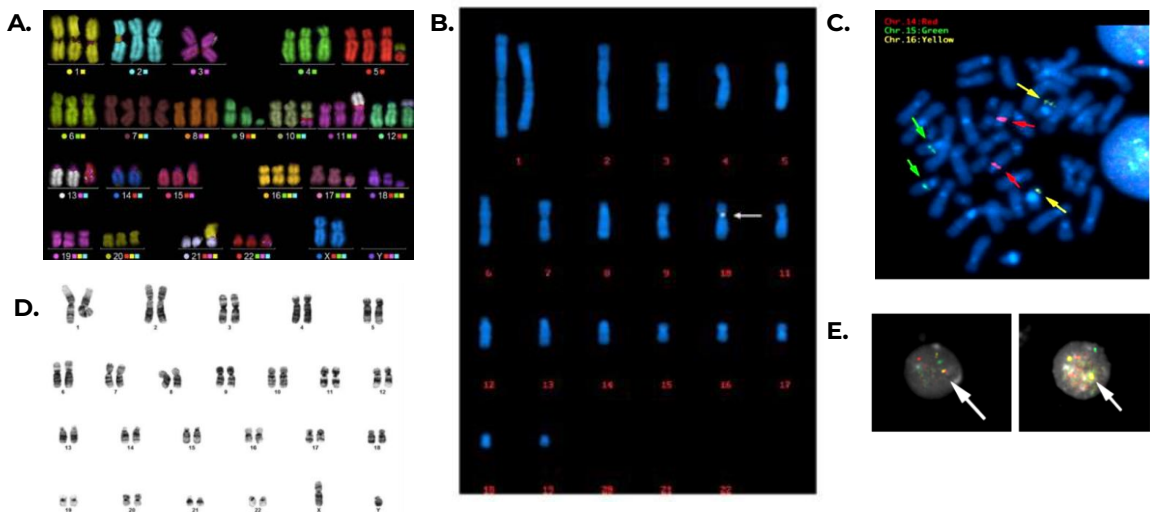


Figure 1. Cell Line Characterization Data. A. Representative M-FISH karyotype of K562 cell. B. CHO cell line clonality analysis. Probe signals from the HC probe and LC probe were observed at the same position. C. Three FISH probe signals on metaphase cells. D. Normal Karyotype generated from human male cultured cells (46, XY). E. FISH probe signals on interphase nuclei



Cell and Gene Therapy Analysis

Cell and gene therapy development requires a comprehensive understanding of the unique aspects of these products in relation to their therapeutic potential and *in vivo* safety profiles. Biodistribution and viral shedding assays are two critical means by which such safety can be assessed. The methods used and considerations required are both biologic- and product-specific, and demand expertise and experience.

Biodistribution assays are performed to determine the *in vivo* distribution or localization of a drug product in selected species to support early biotherapeutic drug development.

Our CELL & GENE THERAPY ANALYSIS SERVICES are featured with:

- Measure target at single-cell level
- Full cGMP facility ready for Cell & Gene Therapy Analysis
- Various cells and vectors, including CAR-T cells, CAR-NK cells, AAV, lentivirus, etc.
- Comprehensive quality assurance process
- Fully characterized to meet regulatory requirements

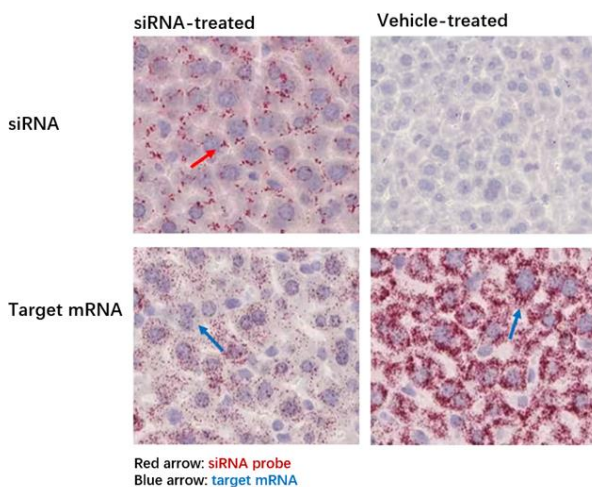


Figure 2. The targeting siRNA was detected using the siRNA probe in the siRNA-treated mouse liver tissue samples and not in the vehicle tissue samples using the RNA ISH assay, indicating successful delivery of the siRNA-based therapy. Expression of target mRNA was detected using the RNA ISH assay and appeared significantly reduced in the siRNA-treated tissue compared to vehicle-treated tissue suggesting successful knock-down of the target mRNA expression with the siRNA-based therapy.



Cell & Gene Therapy Analysis Tests Available From Creative Bioarray:

Gene Therapy Analysis

- AAV Biodistribution
- Adenovirus Biodistribution
- Lentivirus Biodistribution
- Lipid-DNA Complex Biodistribution
- siRNA/ASO Biodistribution
- mRNA Biodistribution
- Naked DNA Biodistribution

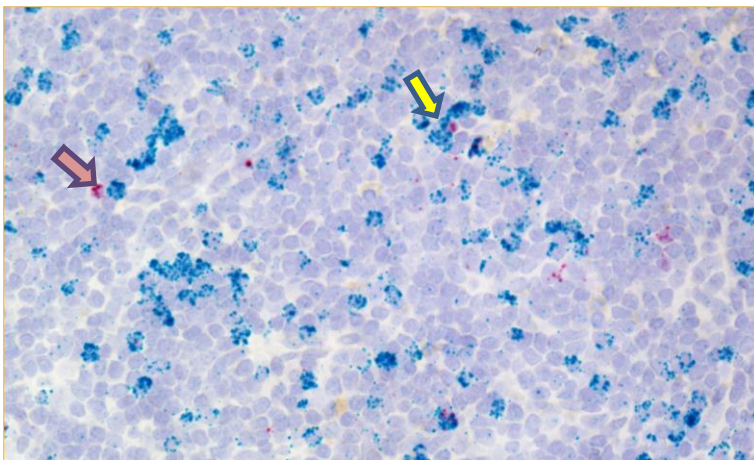
Cell Therapy Analysis

- CAR-T Biodistribution
- CAR-NK Biodistribution
- CAR-Macrophage Biodistribution


With years of experience and well-developed protocols, **Creative Bioarray's Cell & Gene Therapy Analysis** ensures that your biological production process complies with international guidelines. Guaranteed quality enables us for worldwide partnerships to accelerate innovation.


For more details, please feel free to contact us for project quotations and more detailed information.

IFN γ RNA Expression By Infiltrating CD8⁺ T Cells In Lung Cancer Microenvironment



RNA Probes:
Hs-CD8A (Green)
Hs-IFN γ (Red)

 IFN γ expressed by infiltrating CD8⁺ T cells in tumor microenvironment

 IFN γ expressed by infiltrating CD8⁻ negative immune cells in tumor microenvironment



Animal Model Analysis

The animal model deals with the species other than the humans, as it can imitate the disease progression, its diagnosis as well as a treatment similar to human. Discovery of a drug or component, equipment, their toxicological studies, dose, and side effects are *in vivo* studied for future use in humans considering its ethical issues. RNA *in situ* hybridization (ISH) and Immunohistochemistry (IHC) is the method of choice for the assessment of targets and toxicity-related biomarkers. Apart from that, RNA ISH assay can be used to detect animal gene expression with morphological context in a multitude of animal models.

Creative Bioarray has extensive experience in Animal Model Analysis. We offer a broad range of **Animal Model Analysis services** allow you to efficiently streamline your preclinical safety assessment processes and accelerate animal model studies.

Our ANIMAL MODEL ANALYSIS SERVICES are featured with:

- Animal models of human disease, including cardiovascular disease, diabetes and obesity
- Models of embryonic development and stem cell function
- Pre-clinical studies for the *in vivo* assessment of newly developed drug therapies
- Confirmation of targeted gene deletion in whole-body or conditional knockout (KO), knockdown (KD), or knock-in animal model
- Humanized and patient-derived xenograft (PDX) animal model that require characterization of species-specific cell types

Animal Model Analysis Services Available From Creative Bioarray:

Animal Model Analysis

- Transplanted Cell Analysis
- Targeted Integrations QC (FISH)
- Transgene Integrations QC (Locus Amplification & Sequencing)
- Cell Line Transgene Integrations QC (FISH)
- Preclinical safety assessment



Creative Bioarray



Creative Bioarray support all leading pharma companies and research institutes in the characterization and QC of their biopharmaceutical cell line development, cell and gene therapy products and genetically engineered animal models.

Get in touch

For a free consultation that can help guide your project to success

We provide our customers with high quality development services worldwide

fish.creative-bioarray.com

CONTACT US

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