KROMATID

Single-Cell Genomic Insight That De-Risks Cell & Gene Therapy

Design safer therapies.
Select better edits.
Release with confidence.

KROMATID provides high-resolution, single-cell genomic integrity analysis to help cell and gene therapy teams move confidently from discovery to patient dosing.

Our **KROMASURE™ platform** delivers ground-truth insight into:

- Structural variation
- Integration events
- Copy number
- Clonality
- Genome stability

Where traditional assays infer – we measure.

Clear, actionable reports guide decision-making, reduce rework, save time and cost, and de-risk regulatory progression.

Genotoxicity & Starting Material

The Biggest Risks in Cell & Gene Therapy Are Genomic

GENOTOXICITY PROFILING

A whole-genome, single-cell view of genomic stability.

- CRISPR, TALEN, viral, transposon editing
- Structural variants
- Chromosomal abnormalities
- Long-term expansion effects

Supports IND / CTA readiness and vector safety justification.

STARTING MATERIALS & DONOR QUALIFICATIONS

Build a reproducible process on a stable foundation.

- Pre-existing abnormalities
- Donor variability
- Risky parental clones

Avoid months of work on compromised material.

SINGLE-CELL & CELL LINE CHARACTERIZATION

Ensure identity, stability, and reproducibility over time.

- Detect mixed or drifting populations
- Monitor genomic stability during expansion
- Confirm phenotype-linked genomic consistency
- Support comparability studies and cell banking

MANUFACTURING & RELEASE

Batch Release Testing

Release consistent, safe product – every lot.

- Confirm genomic stability prior to dosing
- Prevent unsafe or unstable product release
- Support regulatory expectations
- Reduce batch rejection and supply disruption

Application Overview

One Platform – Across the Entire Development Lifecycle

APPLICATION	STAGE	OUTCOME
Edit Optimization	• Discovery • Early Development	Select scalable, safe engineering strategies
Starting Material & Donor Qualification	• Early Development • Development • Engineering • Characterization	Build on a stable genomic foundation
Genotoxicity Profiling	• Development • Engineering • Characterization	Understand structural & stability risks
Insertional Mutagenesis Risk	• Discovery • Early Development • Development • Engineering • Characterization	Measure integration location & copy number
Single-Cell & Cell Line Characterization	• Discovery • Early Development • Development	Ensure identity & stability
Batch Release Testing	• Manufacturing	Release consistent, compliant product

Insertional Mutagenesis & Editing

Understand Integration – Not Just That It Happened

INSERTIONAL MUTAGENESIS RISK

Direct Measurement of:

- Integration site location
- Copies per cell
- On- vs off-target insertation
- Structural genome impact

Avoid:

- Oncogene activation
- Loss of regulatory genes
- Heterogenous products
- IND delays

EDIT OPTIMIZATION

Direct Measurement of:

- Large deletions, duplications, inversions, translocations
- Multi-copy insertions
- Hidden instability missed by NGS

Avoid:

- Endless optimization cycles
- Late-stage failures
- Non-scalable processes

Why It Matters

The Biggest Risks in Cell & Gene Therapy Are Genomic

SAFETY RISKS

- Tumorigenesis
- Disruption of tumor suppressor genes
- Hidden chromosomal abnormalities
- Long-term instability

REGULATORY DELAYS

- Additional FDA/ EMA study requests
- IND / CTA holds
- Vector safety concerns

LOSS OF EFFICACY

- Reduced potency
- Phenotype drift
- Unpredictable biology

MANUFACTURING FAILURE

- Batch inconsistency
- Unstable clones
- Poor scalability
- Failed release testing

KROMATID
Genomic Innovation, Cytogenetic Precision

Experience the Next Generation in Structural Genomic Analysis

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