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DATA SHEET

Cytogenetic Assays Supporting Genomic Integrity Assessment

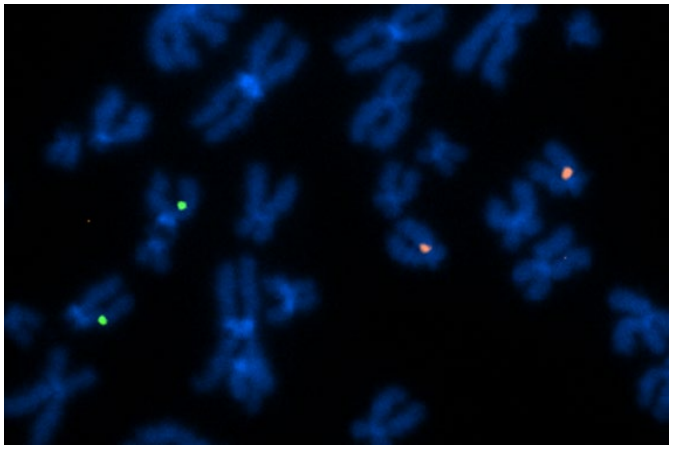
KromaTiD's specialized suite of assays provides a combination of unbiased and targeted genomic analysis supporting superior product pipeline QC, designed for unparalleled genomic integrity data for use in IND filings and other regulatory processes.

We collaborate with you to select the right combination of assays, creating customized datasets to provide information for quality control and to help answer your questions about genomic integrity.

dGH in-Site™ provides direct, single-cell visualization of structural outcomes from genome engineering. dGH probes are manufactured using synthetic oligonucleotides complementary to unique sequences identified via bioinformatic techniques. As a result, rearrangements like translocations, deletions, copy number variations, sister chromatid exchanges and inversions can be detected in targets as small as 2 kb in any dividing sample type.

Key Features:

- Probes can be designed to target unique sequences in any locus of interest, whether endogenous or inserted.
- Multi-channel fluorescence capability enables flexible, multiplex assay design.
- High signal-to-noise ratio provides clean signals even from complex or diverse cell populations.
- Yields precise data for on- and off-target integration events and resulting structural variations.
- Serves as an orthogonal and complementary technique to traditional sequencing methods.
- Analysis of 200 or more cells per sample available.



Left: GM12753 control lymphoblastoid cell line targeted by dGH in-Site probes for TRAC (red) and B2M (green) loci.

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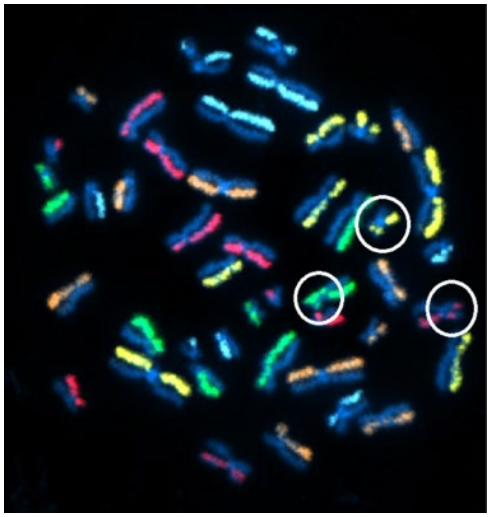
dGH SCREEN™ covers every available unique sequence in the genome for the ultimate unbiased assessment of structural variants. The assay allows visualization of structural rearrangements across the genome on a cell-by-cell basis, enabling unbiased detection of previously unsuspected variants without requiring predictive bioinformatics.

Key Features:

- A 5-color whole genome karyotyping assay.
- Provides an unbiased, high-resolution analysis of genomic integrity.
- Identifies rearrangement events including translocations, deletions, insertions, and inversions.
- Reveals changes in strand orientation.



Left: dGH SCREEN™ detecting an inversion event in the p-arm of chromosome 8 (green), and sister-chromatid exchanges in the p-arms of chromosomes 11 (red) and 16 (yellow) in a metaphase cell from a genetically modified cell line.

Genomic Integrity G-Band Karyotyping: This assay package provides classical insights into the structural characteristics of your samples as well as detailed analytics designed to meet your specific project needs.

Key Features:

- Karyotyping is performed by certified cytogenetic technologists.
- Analysis can be customized to support low-prevalence variant detection.
- Identifies rearrangements like translocations, CNVs, and inversions.
- Genomic Integrity Reports provide key analytics for a sample pair and include a side-by-side statistical comparision of a treated sample to a reference sample for assessment of genomic integrity.

Digital PCR
Digital PCR applications include vector copy number, transgene copy number, percentage of modified cells and contaminant testing. The dPCR process is a reproducible and reliable method which can be applied at multiple steps during the cell therapy manufacturing process.

Study Design Support
KromaTiD scientists, with deep expertise in study design for cell and gene therapy product development will work closely with you to understand your unique research requirements. If needed, a customized release test specification and plan will be developed.

Get in touch with us today to get started!

EMAIL: SALES@KROMATID.COM

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Customer Notification

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