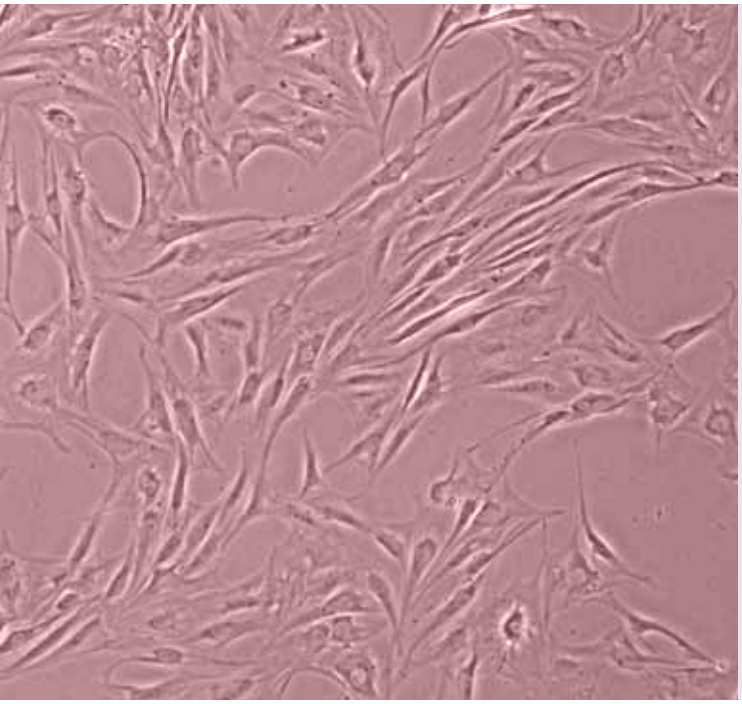
NIMGenetics
New Integrated Medical Genetics

KaryoNIM® Stem Cells

Array-CGH designed to detect aneuploidies in therapeutic cells



Cell therapy consists of using adult or embryonic stem cells to treat diseases associated with tissue degeneration caused by autoimmune diseases, trauma or ageing.

Before being used in therapy, stem cells are generally expanded over 15-20 cell divisions under replicative and metabolic stress so as to obtain sufficient quantity to proceed with the treatment. This expansion can significantly increase the amount of chromosome aberrations which reduce the suitability for use in cell therapy. [1,2,3]

This is the reason why the **European Medicines Agency (EMA)** recommends the genetic screening of stem-cell based medical products[4].

NIMGenetics, leading company in genomic medicine, has developed KaryoNIM® Stem Cells, an array CGH platform that analyses the molecular karyotype of stem cells. In addition, KaryoNIM® Stem Cells has been design using the most recent literature and data bases, and includes 407 genes with duplications or dele-tions associated with genomic instability and abnormal growth.

ADVANTAGES OF KaryoNIM® Stem Cells

1. Analyzes the complete genome to diagnose possible deletions and amplifications, thus improving the diagnostic resolution of a conventional array CGH.

2. Uses DNA. No need to use metaphase cells, as only 50,000 frozen cells are needed or 0.5 micrograms of DNA.

3. A resolution 20 times higher than that of conventional karyotyping (250 kilobases against 5 megabases) with 5 to 20 probes per region of interest.

4. Identifies and reports on all the genes involved in genomic alterations.

5. Specifically designed for genomic identification of therapeutic cells in order to provide information on critical regions for biosecurity (TP53, hTERT, C-MYC, PTEN, CDKN2A, BRCA1…)

6. The results, ready in only 5 to 10 days, are prepared by board-certified medical geneticists from the Cytogenetics European Quality Association (CEQA), experts in genetic stability of stem cells.

7. Provides detailed information about aneuploidies from the total population of a cell culture against the 10 cells usually analyzed with conventional Karyotyping.

THE REPORT

The report includes a detailed analysis of the presence or absence of genomic alterations. The complete genome is studied and any chromosomal alteration involving genomic gain or loss of more than 250 kilobases is reported, with particular attention paid to those regions associated with cell biosecurity.

This report also takes into account the limitations of array CGH. This technique does not permit the detection of alterations caused by uni-parental disomies, point mutations of genes, balanced chromosomal translocations, complete polyploidies or alterations in mosaicism of less than 20% of the total cell culture. Moreover, mosaicisms at a lower percentage rate will be reported with the recommendation of carrying out subsequent validations using FISH.

TECHNICAL INFORMATION

- Customs array design utilizing 60,000 probes.
- Covers 407 genes included in the GENE CANCER CENSUS (GCC) using a minimum of five probes per gene.
- Detection capacity in the rest of the genome is of approximately 250 kilobases.

BIBLIOGRAPHY

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