

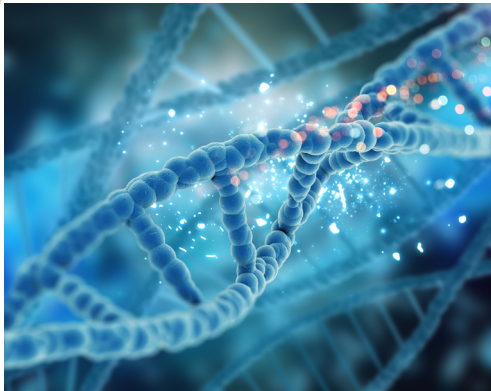
METHOD FOR DETERMINING LEVEL OF DNA INTEGRITY

Method for determining the level of integrity of DNA molecules in a DNA-containing sample by multiplexed digital PCR.

PRESENTATION

Assessing DNA integrity is a crucial step to characterize the quality of biological samples prior to in-depth genomic analysis, especially applicable in reproductive medicine, prenatal diagnosis and cancer research. Although many methods have been proposed for the assessment of DNA integrity (by electrophoresis, quantitative PCR and, more recently, microfluidic-based procedures), there is still a need to apply more sensitive and precise methods. The invention relates to a method for determining the level of integrity of DNA molecules in a sample containing DNA by multiplexing Digital PCR, which involves amplifying DNA fragments from the sample with amplification primers designed to produce different and predetermined sizes of overlapping amplicons of the same DNA target region, and oligonucleotide probes which can produce detectable and differential signals upon hybridization. Proof of concepts in two main applications have been carried out to date on human clinical samples (small cohort studies):

- By evaluating the ability of the developed clinical trial to discriminate plasma DNA samples from healthy subjects (n=25) and cancer patients (colorectal cancer (n=23), gastric cancer (n=22), pancreatic cancer (n=11))
- By evaluating the quality of DNA after storage in different blood collection tubes



DNA Quality Index - DNA Integrity Method - Multiplexed Digital PCR
Liquid Biopsy - Cancer Diagnosis

APPLICATIONS

- DNA Quality Index
- Diagnosis of cancer (circulating cell-free DNA, colorectal cancer, pancreatic cancer, gastric cancer)
- DNA quality assessment for liquid biopsy applications, including Next Generation Sequencing and Digital PCR
- Evaluation of blood storage and processing methods before genomic analysis
- Evaluation of plasma DNA storage and processing methods before genomic analysis

COMPETITIVE ADVANTAGES

- Ability to perform different fragment size analyzes and identify mutation status in a specific hotspot region in a single step (same reaction well)
- Very high sensitivity (0.01 ng) for fragment analysis and mutation detection
- The fragment analysis could represent a universal marker of the disease (e.g. digestive cancers such as colorectal or gastric cancers) that do not require prior knowledge of tumor mutation status

PUBLICATIONS

One publication to be submitted (expected on october 2022)

DEVELOPMENT PHASE

- ☑ TRL 4-5 : Proof of concept in small cohorts assays.

INTELLECTUAL PROPERTY

Patented (priority : 11.2020).

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