



ACGT, INC.

Genetic Stability Testing

A dietary supplement manufacturer needed to provide product certificate for its probiotic bacterial product.

Client's Challenge:

Attempted to show the uniformity and stability, genetically, of the finished product lot. Did not have molecular biology testing capability in-house.

ACGT, Inc.'s Solution:

Provided scientific expertise in designing and conducting a custom protocol study with full sequencing analysis on 16S rRNA gene. Demonstrate that all randomly selected samples from production lots had the same sequence as the reference positive control (seed culture).

Outcome:

Client was able to show that the product lots contained same bacteria as the reference seed culture and there was no contamination in the product lots.



A biotech company needed to show genetic stability of master cell bank (MCB), working cell bank (WCB), and end of production cells (EOP).

Client's Request:

Evaluation of MCB, WCB, and EOP to demonstrate that the stability of recombinant insert.

ACGT, Inc.'s Solution:

Analyzed selected samples (clones) of MCB, WCB, and EOP by restriction mapping and Southern blot analysis, also performed sequencing analysis on PCR products of the sequence of interest from the samples.

Outcome:

Results indicated that test articles were genetically stable since sequencing results and patterns of restriction mapping and Southern blot were consistent.

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