



Regulatory Submission

A plant biotech company required confirmatory sequencing service for USDA submission.

Client's Request:

Full length sequencing of a 6 kb PCR product without revealing any sequence information.

ACGT, Inc.'s Solution:

Proposed a custom protocol with primer walking method for the project. Performed primer design, sequencing with 6-8 fold redundancy, primer walking, and assembly to final consensus sequence. Stringent study requirements and QAU audit were followed.

Outcome:

The consensus sequence was checked in conformity with originally targeted sequence. Client included the study report in submission package.

A biotech company required independent genotyping evaluation on polymorphism of human subjects recruited in a clinical trial.

Client's Request:

Confirmation of genetic polymorphism identified by internal clinical support teams.

ACGT, Inc.'s Solution:

Transferred and validated test conditions for restriction fragment length polymorphism (RFLP) and sequencing analysis of the test articles (whole blood collected from human subjects). Conducted RFLP and sequencing analysis on the samples.

Outcome:

Findings were in agreement with those from client's internal support team and were included in the submission as supportive evidence.

A biopharmaceutical company needed to demonstrate the stability of recombinant insert in working cell bank (WCB) and end of production cells (EOP).

Client's Request:

Sequencing evaluation of PCR products from several WCB and EOP to demonstrate that they were the same as a reference sequence.

ACGT, Inc.'s Solution:

Performed sequencing analysis on every test article with 6-8 fold redundancy to achieve PHRED 40 quality call on every base. Assembled and compared final consensus sequences.

Outcome:

Results indicated that all test articles evaluated had same sequence as the reference sequence. Reports were included in product characterization package to support stability claim.

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