

Cell Line Characterization

DNA Fingerprinting

DNA fingerprint profiling, first described in 1985¹, provides detailed sequence specific information that can be utilized for the authentication of mammalian cell lines². The Multi-Locus Probe (MLP) 33.15 is derived from specific hypervariable mini-satellite regions in the human genome and will hybridize to repetitive DNA sequences distributed throughout the genomes of a diverse range of species e.g. human, hamster (CHO, BHK), simian. The individual specificity and multi-species hybridization of MLP 33.15 renders it a powerful tool for the quality control of cell banks with the ability to detect inter- and intra-species cell contamination.

To produce a DNA fingerprint, the genomic DNA of interest is digested with restriction endonuclease(s) prior to size separation and immobilization onto a membrane. MLP 33.15 is then hybridized under conditions of suitable stringency to produce DNA fingerprint profiles that are unique for individual cell lines³ (Figure 1).

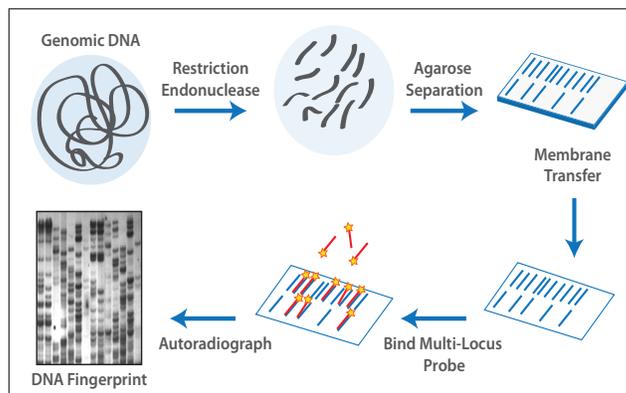


Figure 1. DNA Fingerprinting Process.

104023GMP.BUK: DNA fingerprinting of cell lines with a single multi-locus probe – an appropriate assay for cell line identity testing

This DNA fingerprinting assay uses a single restriction endonuclease (*HinfI*) with MLP 33.15. In addition to the test article, a positive control standard consisting of cells of the same origin and an unrelated negative control are analyzed. *HinfI* is the restriction endonuclease of choice as it has been validated for the NICE™ (Non-Isotopic Chemiluminescent Enhanced) MLP probe system used and is considered to be the industry standard for forensic and paternity testing.

(continued)

DNA fingerprint profiling can be used as a technique for cell line identification.

Confidence in your cell identity testing – DNA fingerprinting provides information at the individual clone level.

Industry leading experience with DNA fingerprinting as part of regulatory submissions over many years.

GMP assays enabling easy regulatory submission.

BioReliance

Biologics Safety Testing Services

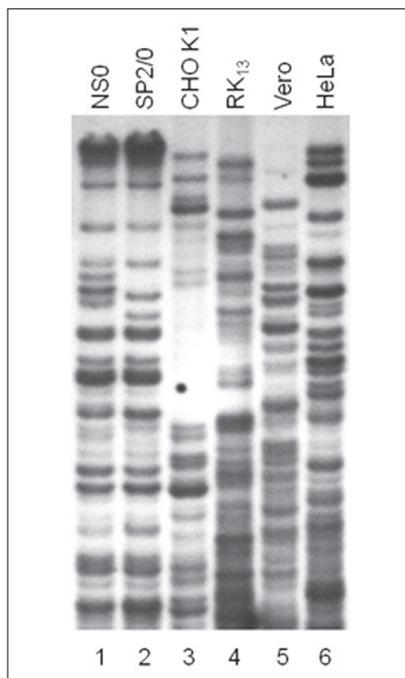


Figure 2. DNA Fingerprint Profile of Various Cell Lines. 5µg genomic DNA is digested with *HinfI* endonuclease and probed with MLP 33.15. Cell identity is confirmed by visual comparison against a standard. Lanes 1 and 2 have similar profiles, with many shared locus bands, as NS0 and SP2/0 are closely related.

A confirmation of identity is provided with visual comparison to a suitable control cell by matching between 10 to 20 individual loci, as visualized by bands on an autoradiograph. **Figure 2** shows the DNA fingerprint profile of various cell lines. Closely related lines such as NS0 and SP2/0 will have similar profiles, as seen in lanes 1 and 2. Unrelated lines or species will have very different profiles, for example Vero and HeLa in lanes 5 and 6.

This assay is ideal for cell line identity and authentication testing as it utilizes a method which is considered acceptable to the regulatory authorities.

Conclusion

DNA fingerprinting is a powerful technique for cell line identification as it provides identity testing down to the specific clone level. Other assays may only provide functional level information which can confirm species.

BioReliance has many years of experience with DNA fingerprinting, and this technique has been part of product safety submission packages that have been reviewed and accepted by the regulatory authorities.

Ordering Information

Assay Number	Assay Description	Regulatory Compliance	Controls	Sample Requirements	Duration
104023GMP.BUK	DNA Fingerprinting of Cell Lines with a Single Multi-Locus Probe	GMP	Same origin standard positive control Unrelated negative control	1 vial of 5×10 ⁷ cell pellet	28 days

References:

1. Jeffreys AJ, Wilson V and Thein SL. (1985). Hypervariable 'minisatellite' regions in human DNA. *Nature*, 314, 67–73.
2. Thacker J, Webb MB and Debenham PG. (1988). Fingerprinting cell lines: use of hypervariable DNA probes to characterise mammalian cell cultures *Som. Cell. Genet.*, 14, 519–525.
3. Gilbert, et al. (1990). Application of DNA fingerprints for cell line individualisation. *Am. J. Hum. Genet.*, 47, 499–514.

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