BODE ARMOR™: A DEVELOPMENTAL VALIDATION OF A ROBUST PRESERVATIVE SOLUTION

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Introduction

DNA is a biological material, cellular breakdown and degradation can occur over time if steps are not taken to preserve the sample. Degradation of a reference sample can cause interpretation issues if reprocessing needs to occur.

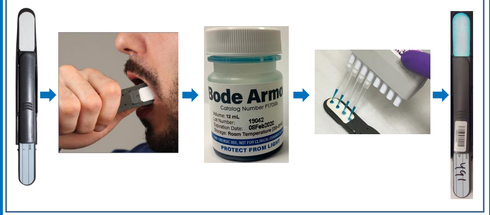
Bode Armor is a preservative solution that can be applied to reference samples after collection to enhance sample stability by inhibiting nucleases and significantly reducing the growth of bacteria.

The adoption of any new method or technology requires careful consideration to ensure that it does not impact any down stream processing in the laboratory. This developmental validation evaluated Bode Armor treated reference samples and their ability to yield a complete DNA profile following both traditional processing (extraction, quantification, and amplification) and direct amplification procedures.

This validation included the required studies for accuracy, artifacts, contamination, knowns, precision, repeatability, reproducibility, sensitivity, and stability. All experiments listed were performed using the ThermoFisher GlobalFiler™/GlobalFiler™ Express, QIAGEN® Investigator 24plex QS/24plex GO! and Promega PowerPlex® Fusion 6C amplification kits.

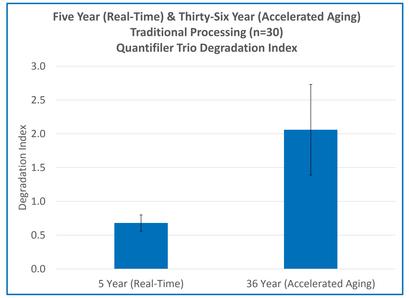
All amplified samples were separated on an Applied Biosystems™ 3500xL capillary electrophoresis instrument and analyzed utilizing appropriate analytical and stochastic thresholds for each amplification kit in GeneMapper® ID-X.

Materials



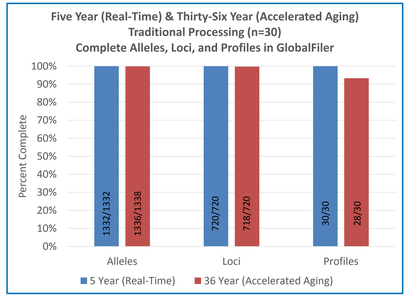
Direct Amplification	Traditional Processing
1.2mm punch	4.7mm punch
Amplification (with lysis pre-treatment)	QIAsymphony Extraction
Capillary Electrophoresis using 3500xL	Quantifiler Trio Quantification
GeneMapper ID-X	Amplification
--	Capillary Electrophoresis using 3500xL
--	GeneMapper ID-X

Stability



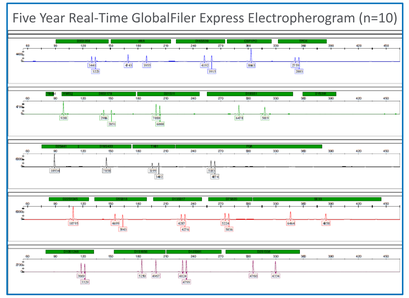
Degradation Index (DI) – Traditional Processing

- DI of 0.68 at five years indicates DNA is not likely degraded.
- To simulate extended room temperature storage samples were stored in a 56^{o}C incubator for 3.4 years.
- DI of 2.06 at thirty-six years indicates slight to moderate DNA degradation.



Profile Results – Traditional Processing

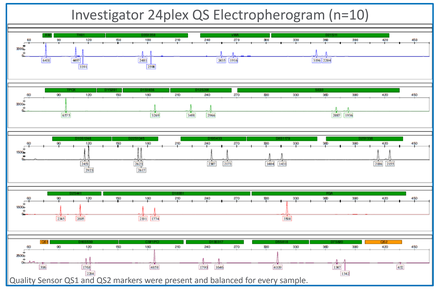
- Complete profiles achieved for all five-year samples with no signs of degradation within electropherograms.
- Thirty-six-year samples provided twenty-eight out of thirty complete profiles.



Profile Results – Direct Amplification (Five Year Real-Time)

- Complete profiles achieved for all ten samples in three different amplification kits.
- Intracolor Balance values were within optimal and expected RFU ranges for all chemistries.

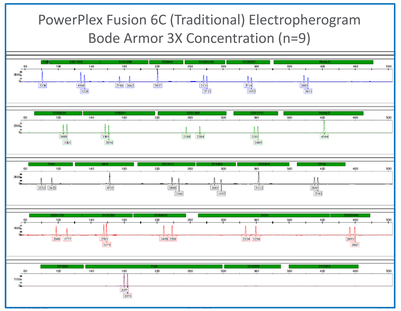
Knowns

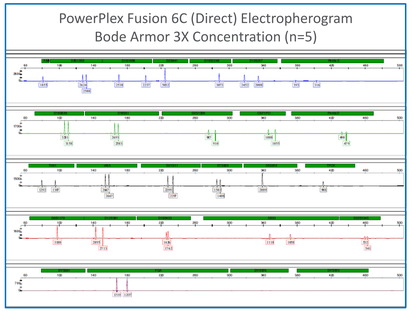


Quality Sensor QS1 and QS2 markers were present and balanced for every sample.

Chemistry	Bode Armor	Complete Profiles	Profile Concordance	Inhibition
GlobalFiler	100 µL	✓	✓	None
GlobalFiler Express	100 µL	✓	✓	None
Investigator 24plex QS	100 µL	✓	✓	None
Investigator 24plex GO!	100 µL	✓	✓	None
PowerPlex Fusion 6C	100 µL	✓	✓	None
PowerPlex Fusion 6C (Direct)	100 µL	✓	✓	None

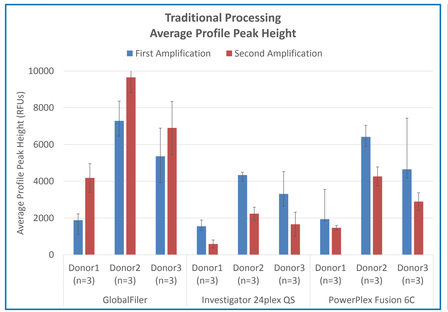
Sensitivity

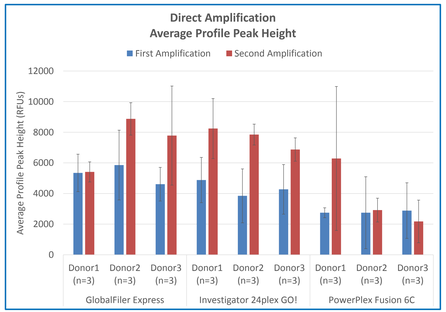




- 100 µL Bode Armor (1X) is the optimal application.
- Applying up to 3X Bode Armor to a sample did not prevent a complete DNA profile from being obtained during traditional and direct amplification in all chemistries.

Reproducibility





- On a separate day with a different thermal cycler and 3500xL from the initial amplification, the same samples were re-amplified in triplicate.
- Average profile peak heights for both amplifications for each chemistry were within optimal RFU ranges.

Conclusion

- Bode Buccal DNA Collectors treated with Bode Armor can produce stable, accurate, sensitive, repeatable and reproducible results.
- Bode Armor is compatible with both traditional and direct amplification chemistries.
- Five year real-time Bode Armor treated samples display no signs of degradation.
- Over 99.5% of all alleles were successfully typed at an accelerated age of 36 years.

Thank you to all volunteers that donated samples for this study.