EVALUATION OF BIOMATRICA'S FORENSIC DNA STABLE LABORATORY VALIDATION KIT

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Objective: The objective of this validation was to provide validation data that the forensic DNA community will need to implement a new method of DNA storage, DNAStable (SampleMatrix) that improves DNA evidence preservation by conducting evaluations of the DNAstable Validation Kit.

Introduction: "Validation is the process by which the scientific community acquires the necessary information to

(a) Assess the ability of a procedure to obtain reliable results.
(b) Determine the conditions under which such results can be obtained.
(c) Define the limitations of the procedure.

The validation process identifies aspects of a procedure that are critical and must be carefully controlled and monitored." [1] Before any laboratory can implement new technology, the process must be validated through a series of tests. Many laboratories have limited resources and time to conduct validation due in great part to the backlog of cases and shrinking budgets. Without the ability to conduct validation, new and improved methods that have been developed and tested (by the scientific community) are not implemented in crime laboratories because of the lack of validation.

The Biomatrica Forensic Validation Kit is designed to enable the DNA section of a forensic laboratory to quickly and easily validate the long-term storage of DNA extracts at room temperature in Biomatrica's DNAstable. The kit and protocols meet many of the validation criteria established by the Scientific Working Group on DNA Analysis Methods (SWGDAM) and by the Federal Bureau of Investigation Quality Assurance Standards (FBI/QAS) for achieving quality assurance standards for forensic DNA testing laboratories.

Methods: Replicates of DNA standards (2.4, 1.2, 0.3, 0.15 and 0.075 ng) were stored in both DNAStable and freezer so that periodic sampling and qPCR analysis could be performed. Replicate plates were stored either at -20^{o}C as liquid, dried down without DNAstable, or dried down in DNA stable, covered and held at RT in a humidity controlled chamber (RH <50%). Samples were rehydrated and quantified using Plexor® HY on an ABI 7500Q at t=0 to set a baseline. Additional DNA standard samples at varying concentrations were also stored and tested using Plexor® HY qPCR for 1 week and 1 month storage.

Results and Discussion: Recovery of DNA samples stored at room temperature in DNAstable provided the same or increased recovery of samples versus freezer storage as well as better recovery stored at room temperature dry without DNAstable. Results are discussed below as they relate to the SWGDAM validation criteria cited above.

2.9 Precision and accuracy- *DNA recovered after 1 month stored in DNA stable was reproducible and better than freezer storage.*

2.10.4 Positive and negative controls must be validated for use. Positive and negative control samples provided expected results*. Note that we also stored Plexor DNA standards and negative controls that provided better recovery that those stored in freezer storage.*

[1] Revised Validation Guidelines. Scientific Working Group on DNA Analysis Methods (SWGDAM). Downloaded from: http://www.fbi.gov/about-us/lab/forensic-science-communications/fsc/july2004/standards/2004_03_standards02.htm

3.2 Reproducibility and precision. *Recovery of control samples was reproducible*

3.4 Sensitivity and stochastic studies: The laboratory must conduct studies that ensure the reliability and integrity of results. For PCR-based assays, studies must address stochastic effects and sensitivity levels.

Replicate samples of known control DNA were stored at 5 concentrations from 0.075ng to 2.4ng and recovery was better than freezer storage.

Recovery of low quantity samples demonstrated the highest fold increase over freezer storage: 2.9 and 2.55x more DNA recovered in DNAstable versus freezer for the 0.15ng and 0.075ng replicate samples.

Conclusions: Results of this study provide support for the use of the DNAstable Validation Kit for forensic DNA laboratory validation studies and demonstrate improved recovery of DNA in DNA stable over freezer storage. The results corroborate previous research reported (Lee et al. 2012 and Lee et al. 2010).

References:

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