BIO: Procedure Validation

New procedures

For general issues regarding the in-house validation of new procedures, refer to *13 Technical Procedures, PRO: Validation of New Procedures* in the *Quality Manual*.

Internal validation

Prior to implementing an analytical procedure that has been developed and validated externally by another laboratory, the unit will conduct an internal validation.

The purpose of internal validation is to establish performance criteria, identify critical parameters, and verify that the procedures produce reliable results in this laboratory.

Additional considerations

In addition to the topics listed in the *Quality Manual,* validation studies for Biology should also address the following additional considerations, as applicable

- human specificity
- stochastic effects
- detection thresholds
- environmental effects
- matrix effects
- opportunities for contamination

These studies can use

- known samples
- non-probative samples
- mixtures
- NIST standards

Procedures used in the DNA Section will be validated according to the current version of the *FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories* before being implemented in casework.

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BIO: Procedure Validation, Continued

Modified procedures

Modified procedures will be validated by testing identical samples using both the modified and original procedures.

Evaluation

In addition to the steps listed in *13 Technical Procedures, PRO: Validation of New Procedures, General validation process* in the *Quality Manual*, the Technical Lead must document his or her approval of the validation study prior to submission to the Biology Supervisor.

All analysts in the unit should become familiar with all newly validated procedures.

PCR kit validation

Before validating PCR amplification kits, the inheritance, chromosomal location, nature of the polymorphism, and the molecular basis for detection of the loci used must be known.

DNA analyst training and competency

After validation and prior to casework use, analysts who will use a new or modified DNA procedure may be required to successfully complete a series of training samples which may satisfy the competency test requirement.

Participation in the validation study can substitute for a competency test and will be recorded by the DNA Technical Lead with the validation.