NIJ National Forensic Science Technology Center
President's DNA Initiative - Workshops

Validation Workshop

Material Modifications and Performance Checks

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Presentation Outline

Introductions: Presenters and Participants

Day #1
- Validation Overview (John)
- Introduction to DAB Standards (Robyn & John)
- Developmental Validation (John)

Day #2
- Inconsistency in Validation between Labs (John)
- Internal Validation (Robyn)
- Method Modifications and Performance Checks (Robyn)

Day #3
- Practical Exercises (Robyn)

Material modification per the Revised Validation Guidelines

4. Material Modification: A material modification is a substantial and/or consequential alteration of a physical or analytical component in an integrated procedure. The modified procedure must be validated as concomitant with the nature of the alteration.

4.1 Commercial manufacturers should notify users of any material modifications made to products.

4.2 Modified procedures must be performance evaluated by comparison with the original procedure using similar DNA samples.

Performance check per the Revised Validation Guidelines

5. Performance Check of Established Procedures: A performance check is an evaluation of a validated procedure existing in the laboratory system to ensure that it conforms to specifications. If a laboratory changes its physical location or its infrastructure has been substantially changed, a performance check regarding reproducibility and sensitivity must be completed.

5.1 Each new instrument or software change (including upgrades) requires a performance check.

So, what is the difference????

Material Modification

- Decrease in reaction volume from manufacturer's specifications
- Centricon tube membrane change
- Minimum peak threshold
- Injection times for genetic analyzers
- Increased amplification cycle numbers
- Others?

Performance Check

- Relocation of lab to a new facility
- Change of laser or other critical component on a genetic analyzer
- Software changes
  - Mac-based GS/GT to NT-based GS/GT
  - Mac-based collection software to NT or Windows-based collection software
- Additional instrumentation (i.e., 2nd 3130)

How would you evaluate each of these?