

Purpose:

To annually verify that the entire PCR system is functioning within accepted criteria by the use of a standard that is traceable to the NIST Standard Reference Material (SRM) or a lab designated standard reference material. **Each** ~~amplification kit~~ technology utilized for casework must be checked annually for NIST traceability.

According to FBI QAS Audit document (2009)

“The laboratory must demonstrate performance through an annual check of its laboratory procedures (at a minimum from amplification to characterization) to generate typing results for each technology (technology is used to describe the type of forensic DNA analysis performed in the laboratory, such as RFLP, STR, YSTR, or mitochondrial DNA).”

“Laboratories are not required to purchase a NIST SRM kit each year to comply with Standard 9.5.5. Laboratories may identify controls and run these against the NIST SRM, which in turn makes these controls NIST-traceable. For those laboratories that use a bloodstain control, a “lot” is identified as the bloodstain(s) that are tested against the NIST SRM, not the person from whom the blood was drawn. This lot may be used annually to verify the controls and DNA procedures in use by the laboratory. This annual check of typing results must be assessed separately from any use the NIST SRM may have within casework traceability (e.g., if a laboratory uses 9947A as a part of its internal positive control for casework). A laboratory must demonstrate a designated NIST SRM laboratory check of its procedure annually or whenever a substantial change is made to the procedure. A substantial change would be a change in test kit, platform, or software.”

Procedure:

1. Amplify samples (using proper controls) with a NIST Standard, for each ~~kit~~ technology currently being used in casework. NIST Standard can be a SRM Profiling standard or a lab designated standard.
2. Run samples on 3130xl Genetic Analyzer following laboratory protocol.
3. Compare results to the known results for the NIST standard.
4. There is a NIST Traceability binder where results are kept in. Please memo QM or TL with results. Record on QR-266 and include data with record worksheet in binder.