Addendum to Quality Assurance Standards to Address Rapid DNA Analysis and Modified Rapid DNA Analysis effective December 1, 2014

The FBI Director has approved an Addendum to the Quality Assurance Standards for DNA Databasing Laboratories to address Rapid DNA analysis and Modified Rapid DNA analysis that will take effect on **December 1, 2014**. This Addendum was recommended to the FBI Director by the Scientific Working Group on DNA Analysis Methods (SWGDAM) following approval of a draft Addendum and public comment period.

An Addendum to the Audit Document for the Quality Assurance Standards for DNA Databasing Laboratories has also been approved by the FBI Director and will take effect **December 1, 2014**.

If your laboratory is performing or planning to perform Rapid DNA Analysis or Modified Rapid DNA Analysis, please review the Addenda to the QAS and QAS Audit Document in their entirety so that you are familiar with these new revisions. These Addenda will be available on the FBI's web site at http://www.fbi.gov/about-us/lab/biometric-analysis/codis and the SWGDAM web site at http://swgdam.org/docs.html.

A summary of the additional Standards specific to Rapid DNA analysis and/or Modified Rapid DNA analysis follow:

Standard 2. Definitions for the following terms have been added:

Cartridge lot number
Modified Rapid DNA analysis
Negative sample control
Positive sample control
Rapid DNA analysis
Rapid DNA cartridge
Rapid DNA instrument
Reference samples

Standard 5. Two additional standards have been added to require that analysts and technicians have documented training for operating the Rapid DNA instrument and that their successful completion of a competency test is documented prior to their independent operation of a Rapid DNA instrument.

Standard 6. Standard 6.1.4 is not applicable to a Rapid DNA instrument. Standards have been added to authorize the use of a Rapid DNA instrument for processing reference samples if validated in accordance with Standard 8; such analysis must be performed in a pre-amplification room.

Standard 9. Standards 9.5.1, 9.5.2 and 9.5.3 are not required for a Rapid DNA instrument. Standards have been added to: include a Rapid DNA cartridge as a critical reagent; require an annual check of the procedures against an appropriate NIST standard; to require documented procedures for the use of positive and negative sample controls for Rapid DNA instruments, including Internal Lane Standards (ILS) and allelic ladders. Standards have been added for Modified Rapid DNA analysis: to require verification of the ILS and allelic ladder; and perform manual interpretation of the data.

Standard 10. Standards 10.2.1 through 10.2.1.8 and 10.4.1.1 through 10.4.1.5 are not applicable to a Rapid DNA instrument. Standards have been added to include a Rapid DNA instrument as critical equipment requiring a quarterly recertification and/or performance check, recertification and/or performance check following repair, service or calibration, or if the instrument remains idle longer than recommended instrument specifications or a period established by the laboratory.

Standard 12. Standards have been added to allow the review of DNA types by an internally validated Rapid DNA instrument that uses an NDIS-approved expert system; and that the review include all controls, Internal Lane Standards and allelic ladders. A Standard has been added to require a manual technical review of the data for Modified Rapid DNA analysis.

Standard 13. A Standard has been added to require that analysts or technical reviewers that perform Modified Rapid DNA analysis be proficiency tested on the interpretation of data generated by a Rapid DNA instrument at least once per year.

Standard 17. Standards have been added to require that a vendor laboratory using a Rapid DNA instrument with an approved STR typing kit and NDIS–approved and internally validated expert system verify the correct specimen category as part of the technical review; that a technical review include, for Modified Rapid DNA analysis, a review of all notes, worksheets and the electronic data supporting the results; and that a technical review include, if using a Rapid DNA instrument, a review of the data associated with applicable performance checks.