



Laboratory Services

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Planned Process and Timeline for Implementation of Additional CODIS Core Loci

Coinciding with the revision of the FBI Director's Quality Assurance Standards and an examination of the procedures for operation of the National DNA Index System, the FBI Laboratory empanelled a CODIS Core Loci Working Group in May 2010 to evaluate the necessity for additional loci. Almost 12 years earlier, the FBI's original STR Standardization Project had recommended the 13 CODIS core loci required and still being used for DNA data uploaded to NDIS. Despite the different environments in which the original STR Project and the current Working Group were and are operating, both recognized the importance of balancing the privacy issues attendant to storing genetic information with ensuring the effectiveness of CODIS to assist criminal investigations. Among its first tasks, the current Working Group recommended criteria for acceptance of any new CODIS loci, including no known association to medical condition or defects (refers to whether or not the loci is diagnostic of any known medical condition or disease status.).¹

In a Letter to the Editor of *Forensic Science International Genetics* announcing the proposed additional loci under consideration for CODIS, the Working Group identified the following three factors in support of expanding the current CODIS core loci: 1) facilitates greater discrimination, 2) assists in missing person investigations, and 3) encourages international data sharing efforts by having more loci in common with other countries for comparison purposes.² The Chair of the Working Group updated the DNA community on the selection of the potential additional CODIS Core Loci at the 22nd International Symposium on Human Identification, the 15th- 17th National CODIS Conferences, the European Network of Forensic Science Institutes' 2011 DNA Working Group meetings, and the 2011 semiannual meetings of the Scientific Working Group on DNA Analysis Methods (SWGDM). As the Working Group addresses the validation and then implementation phases of the project, the attached process and timeline for determination of additional CODIS core loci were developed to keep the community apprised of the Group's progress and provide an outline for what remains to be accomplished. The Working Group has continued discussions with STR kit manufacturers (subject to non-disclosure agreements) on the development of STR kits that incorporate some or all of these proposed loci. Additionally, the Working Group has identified the following statutory and operational requirements for adding new loci:

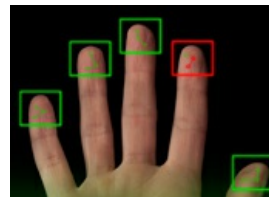
- The Federal DNA Identification Act of 1994 [42 U.S.C. §14132], requires compliance with the quality assurance standards issued by the FBI Director. The "Quality Assurance Standards for Forensic DNA Testing and DNA Databasing Laboratories" define the minimum requirements for validation.
- The Justice for All Act [Pub. Law 108-405 §203(f)] requires that the Department of Justice provide Congress with notice of the proposed use of new core markers 180 days in advance of any such implementation.
- Operational Procedures for the National DNA Index System (NDIS) also contain minimum criteria for approval of additional loci or kits that will be acceptable at NDIS, such as concordant studies, mixed samples, non-probative samples, population studies, and precision studies.

Process for Determination of Additional CODIS Core Loci Selection of Laboratories to Participate in Validation Studies

- Based upon recommendations from the CODIS Core Loci Working Group, the FBI will select laboratories representative of the forensic DNA community (i.e., casework, database, missing person, instrument platforms, kits, etc.), to participate in a validation project for the proposed CODIS core loci using criteria derived from the *Quality Assurance Standards* and NDIS Procedures.
 - Participating laboratories will be responsible for:
 - Management approval of participation agreement
 - Dedicated personnel for the length of the project
 - Instruments required for the validation
 - Samples for analysis
 - The FBI will be responsible for:
 - Costs of the STR kits used by participating laboratories
 - Definition and coordination of validation experiments, data evaluation and assessment

Validation of Proposed Additional CODIS Core Loci

- Congress will be notified of the proposed additional CODIS core loci.
- Participating laboratories will conduct validation experiments/studies in accordance with the *Quality Assurance Standards*.
- Successful validation efforts will be dependent on as yet undetermined factors, such as:



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- Latent Print
- Mitochondrial DNA
- Nuclear DNA

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- Evidence Response Team
- Hazardous Evidence Response
- Operational Response
- Scientific Response
- Technical Hazards Response

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- Forensic Imaging

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- Explosives

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- Ability of kit manufacturers to make robust versions of kits available for purchase
 - Ability to include additional loci within existing 5-dye chemistry
 - Ability to configure existing instruments to run 6-dye chemistry
 - Separate validation tracks for casework and known database samples
 - Availability of federal funding
- Compilation, review, and evaluation of validation results
 - Feedback to kit manufacturers and incorporation of any resulting changes to kits in the validation plan
 - Publication or posting of the validation results
 - Ongoing progress reports to DNAcommunity and other stakeholders

Selection of CODIS Core Loci

- **Input will be obtained from and progress reports will be provided to the DNA community and other stakeholders,**
- Assessment and selection of new CODIS core loci will be performed.

Implementation of New CODIS Core Loci into NDIS Operations

- § The DNA community will be involved in review and development of the following:
 - Ongoing progress reports
 - Sufficient lead time necessary for implementation
 - Searching Strategies
 - Match Strategies
 - Confirmation Strategies
- § Congress will be notified of the new CODIS core loci required for upload and searching at NDIS.

Timeline for Determination of Additional CODIS Core Loci

What	Why	Who/How	When
Form a Working Group (WG) to discuss initial selection	Establishes target goals	CODIS Core Loci Working Group with FBI Chair and 5 members; Web meetings	May 2010 - present
Announce proposed additional CODIS core loci	Sets desired target goals and informs manufacturers	WG Chair; Publish proposed listing of CODIS core loci	April 2011 online (published Jan 2012)
Ongoing Progress Reports	Provides updates for DNAcommunity	WG Chair; Present updates on status of CODIS Core Loci project at meetings	2010-2012
Implementation Considerations & Strategy	Identify issues for implementation and timeline	WG	June 2011 - present
Manufacturers develop prototype kits	Creates tools to meet target goals	Manufacturers; Provide status reports to WG for timeline	2011-2012
Test and validate prototype kits	Examines if target goals can be met	Validation Laboratories; Follow QAS compliant validation plan	Beginning in 2012
Review and evaluate data from validation	Evaluates if desired performance is obtained	NIST, SWGDAM and FBI; Provide feedback, if any, to Manufacturers	In conjunction with and at the conclusion of validation
Selection of new CODIS core loci	Allows protocols to be established	FBI; seek input from DNA community and stakeholders; Notify Congress	After evaluation of validation data and kit production factors
Implementation of new CODIS core loci at the National DNA Index System	Enables target goals to be met	All NDIS-participating labs	~ 24 months after selection of new CODIS core loci

¹ For the complete list of criteria, please refer to *Expanding the CODIS Core Loci in the United States*, D.R. Hares, *Forensic Sci. Int. Genet.* 6 (2012), e52-e54.

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² This formal notification of the additional loci proposed by the Working Group for consideration as CODIS core loci was announced in the April 2011 on-line edition of Forensic Science International (FSI) Genetics and published in the January 2012 edition of FSI Genetics (D.R. Hares, Forensic Sci. Int. Genet. 6 (2012), e52-e54). An addendum (*in press*) is available online, D.R. Hares, *Addendum to expanding the CODIS core loci in the United States*, Forensic Sci. Int. Genet. (2012), doi:10.1016/j.fsigen.2012.01.003.

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