## B191 The Development of the National Institute of Standards and Technology (NIST) Polymerase Chain Reaction (PCR) -Based DNA Profiling Standard (Standard Reference Material 2391d): Where Are We Now?

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**Learning Overview:** After attending this presentation, attendees will understand the comprehensive nature of the data associated with the candidate NIST Standard Reference Material 2391d: PCR-Based DNA Profiling Standard and how this will aid the forensic community.

**Impact on the Forensic Science Community:** This presentation will impact the forensic science community by demonstrating the benefits of such an extensively characterized standard reference material with all commercially available forensic DNA markers at the time of certification. The certified reference material enables the calibration of the typing process for Short Tandem Repeat (STR) and other sequence-based markers for human identity testing.

There have been multiple iterations of the NIST Standard Reference Material (SRM) 2391: PCR-Based DNA Profiling Standard since 1995 when it was first produced. The authors are currently working on SRM 2391d, the fifth installment in a long line of predecessors. The DNA forensic community has progressed greatly in the 23 years since the first release of SRM 2391, which was certified initially for variable number tandem repeat (VNTR) and dot-blot hybridization markers and was later updated with autosomal short tandem repeat (STR) markers. The subsequent two iterations, 2391a and 2391b, were certified for only autosomal STR markers, but it wasn't until the currently available SRM 2391c was released in 2011 and later updated in May of 2018 that other forensically-relevant markers were added to the Certificate of Analysis (COA), including Y-STR markers, X-STR markers, insertion/deletions (indels), and single nucleotide polymorphism (SNPs).[1] The goal for SRM 2391d is to provide a highly characterized set of genomic samples for all commercially available forensic DNA markers at the time of certification, comprised of all the markers previously included in SRM 2391c as well as mitochondrial DNA (mtDNA) whole genome sequences, insertion/null alleles (INNULS), and microhaplotypes (pending availability). The range of certified, reference and information values that will be associated with this SRM, how these values are assigned, as well as the various methods used to obtain these values including capillary electrophoresis (CE) and next generation sequencing (NGS) will be discussed.[2]

The original plan for the development of SRM 2391d has slightly changed throughout the production and certification process. Therefore, these changes will be highlighted and explained in this presentation.

Finally, the question, "Where are we now?" will be answered. The currently available SRM 2391c is expected to be depleted in April 2019 based on reported sales. This SRM is used to address the U.S. Federal Bureau of Investigation's (FBI) Quality Assurance Standards (QAS) for laboratories conducting forensic DNA testing that were published in 2000 and updated in 2011 (Sect. 9.5.5): which currently states, "The laboratory shall check its DNA procedures annually or whenever substantial changes are made to a procedure against an appropriate and available NIST standard reference material or standard traceable to a NIST standard."[3] This is one reason of many that there must not be a lapse in availability for this SRM. The plans moving forward for future updates will also be outlined.

**Reference(s):**

1. SRM 2391c:PCR-Based DNA Profiling Standard Certificate of Analysis (2015). Available online at https://www-s.nist.gov/srmors/certificates/2391c.pdf. Accessed July 27, 2018
2. Thompson, A.; Taylor, B.N.; Guide for the Use of the International System of Units (SI); *NIST Special Publication* 811; U.S. Government Printing Office: Washington, DC (2008); available at https://www.nist.gov/physical-measurement-laboratory/special-publication-811. Accessed July 27, 2018
3. Quality Assurance Standards (QAS) for Forensic DNA Laboratories (2011). Available online at https://www.fbi.gov/file-repository/quality-assurance-standards-for-dna-databasing-laboratories.pdf/view. Accessed July 27, 2018

**Forensic DNA, Standard Reference Material, STR Markers**