Statement for the Record of
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On
The Widespread Adoption of Rapid DNA Technology in the United States

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Subcommittee on Crime, Terrorism, Homeland Security, and Investigations
Washington, DC

Good morning Chairman Sensenbrenner, Ranking Member Jackson Lee, and members of the Committee: My name is Jody Wolf and I am the President of the American Society of Crime Laboratory Directors. On behalf of the 600 laboratory directors represented by ASCLD and the over 15,000 crime laboratory practitioners represented by the Consortium of Forensic Science Organizations, of which ASCLD is a member, I would like to thank you for the opportunity to discuss the topic of Rapid DNA technology and provide comments on H.R. 320, the Rapid DNA Act of 2015.

The introduction of Rapid DNA technology has been an exciting one for the forensic science community. Several of our members helped with the initial development of the technology, and several more are currently participating in pilot programs to determine how best to successfully implement this human identification technology in the criminal justice system. Rapid DNA is a new and innovative technology that is designed to deliver a DNA profile within a few hours. The potential of this technology is exciting and both ASCLD and the CFSO support the continued development of this novel application of forensic DNA analysis for use in the criminal justice system.

The original design and development of this instrument was to analyze high quantity, single-source biological samples (e.g. blood, saliva) within two (2) hours of sample introduction with minimal operator intervention both in a laboratory and non-laboratory setting. The primary proposed application is to analyze known reference samples collected from arrestees during the booking process for direct upload to the Combined DNA Index System (CODIS). This could allow for the early identification of investigative leads when the arrestee’s profile is searched against other DNA profiles developed from crime scenes enabling law enforcement to further criminal investigations and potentially prevent future crimes from occurring.

The only Rapid DNA application currently approved by FBI and SWGDAM is a “Modified Rapid DNA Analysis.” The modification requires a trained and proficiency tested DNA analyst to review the profile prior to upload to CODIS in an accredited laboratory that meets the FBI’s Quality Assurance Standards for Forensic DNA Testing. This is necessary because the expert

1 Current vendors provide a basic description of the rapid DNA technology and they can be found at be found at http://integenx.com/rapidhit-system/ and https://promo.gelifesciences.com/g/lRAPID-DNA/misc/law%20Enforcement%20data%20file.pdf

2 Effective December 1, 2014, the FBI Director and SWGDAM provided an Addendum to the Quality Assurance Standards for DNA Databasing Laboratories performing Rapid DNA Analysis and Modified Rapid DNA Analysis Using a Rapid DNA Instrument. http://swgdam.org/docs.html
systems or computer software programs used in the rapid DNA instrumentation is not currently approved for use in the interpretation of DNA data for direct upload to CODIS. The quality of results obtained using these instruments must at a minimum meet the quality currently obtained using traditional methods of DNA analysis.

To ensure the potential of this technology is fully achieved, we believe a methodical and measured approach is critical to its successful and widespread implementation. In addition to field assessments studies of the technology, appropriate levels of secure information infrastructure need to be built, meaningful policy must be developed, and appropriate training programs need to be devised.

As I stated earlier, several of our members are currently participating in pilot programs and validation studies to develop best practices and model programs for the widespread deployment of these systems. Overviews of these programs and studies are provided in Attachment 1. As policy makers consider the implementation of this technology in the criminal justice system, it is critical the following issues are addressed.

- **Scientific Validity** – Peer reviewed scientific studies, not marketing materials, should guide the discussion. Rigorous validations performed by crime laboratory scientists and researchers are critical to demonstrating the scientifically valid application of rapid DNA technology to the appropriate types of forensic samples. Currently, these devices are best suited for use with single-source, high quantity biological samples (e.g., blood or buccal swabs), thus limiting the usefulness for crime scene samples, which often contain mixtures of multiple DNA profiles and/or trace amounts of DNA. These instruments are not designed for the routine testing of rape kits, trace DNA or any forensic sample that may contain DNA from multiple donors. Therefore in their current state, they will not be helpful with the reduction of rape kit backlogs.

  Protocols, procedures, and training manuals that describe how these devices can be employed in a crime lab or law enforcement environment need to be developed and standardized across the forensic community. Users of these devices must be sufficiently trained to correctly interpret results, recognize non-conformities, and troubleshoot technical issues involved in the DNA profile acquisition and operation of these instruments.

- **Compliance with Best Practices** – This technology must be compliant with the Scientific Working Group on DNA Analysis Methods (SWGDAM) guidelines and must be interoperable with the CODIS database.

  SWGDAM and the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories have provided best practices and standards for forensic DNA testing for almost 20 years. ASCLD looks to these groups for guidance with rapid DNA technologies and we encourage vendors to seek full compliance with these standards or any new standards or guidelines developed by this group.

  To maximize the usefulness of rapid DNA devices, these instruments must be interfaced with the CODIS database. Without access to both national offender and crime scene samples, the potential to quickly generate a meaningful investigative result may be significantly hindered.
Operational Funding Limitations – ASCLD recommends that a careful cost/benefit analysis be performed prior to widespread implementation. The purchase price for most Rapid DNA devices is currently over $200k. The supply cartridges themselves can exceed hundreds of dollars per DNA sample, which does not include costs for maintenance contracts, quality assurance, training, upgrades, or the cost of the instrument itself. The best estimate of a laboratory currently using the rapid technology is $250.00 per sample.\(^3\) By comparison, FORESIGHT, a national study of crime laboratory operational costs and performance metrics led by the West Virginia University, reported the median cost for a DNA database offender or arrestee sample is under $85 using traditional laboratory methods.\(^4\) This traditional cost estimate includes personnel, capital expenditures, consumables, and overhead costs. Clearly, the current costs of traditional DNA databasing analysis is significantly less than that of the analysis of reference samples using the Rapid DNA technology.

Additionally, ASCLD and CFSO believe Federal funding levels in existing DNA backlog reduction and capacity enhancement programs need to be increased to allow for the continued success of these programs and accommodate requests for additional testing methodologies and applications. The scope of existing grant programs should not be expanded without commensurate increases in funding levels. These increased funding levels would allow laboratories to continue their current efforts and collaborate with local stakeholders on moving forward with newer technologies to provide meaningful and timely answers to the criminal justice system.

Technology Transfer – Perhaps the most important consideration for crime laboratories and practitioners is the successful transfer of the technology from the vendors. While the FBI is currently working on the supporting IT and other infrastructure for this implementation, it is important that other measures are taken to validate this technology in the community. As I stated earlier, ASCLD and the CFSO acknowledge the importance of this new technology and the possibilities it possesses for the future. As such, we fully support the careful approach taken by several of our members to validate, implement and oversee the deployment of this technology in their regions. ASCLD has presented three rapid DNA webinars addressing these topics during the past year, and the ASCLD Forensic Research Committee has been charged with developing guidance and best practices for our membership.\(^5\)

ASCLD and CFSO support Rapid DNA legislation with revision and stand ready to aid in moving the legislation forward once modified for the universal adoption of this technology. An in-depth review of HR 320 can be found in Attachment 2. In summary, the legislation must include the following:

\(^3\) The per sample cost estimate cited here was provided as a result of the implementation of the Rapid DNA technology by the Arizona Department of Public Safety’s Crime Laboratory described in Attachment 1 and does not include the initial start-up costs or the cost to validate the equipment. Additionally, this program has been presented in multiple national meetings most recently at the 14\(^{th}\) Annual DNA Technical Conference – Bode East, May 26-29, 2015 titled, “Use of Rapid DNA Technology with Local Law Enforcement” presented by Vince Figarelli, Superintendent, Arizona Department of Public Safety Crime Laboratory.

\(^4\) The median cost per database sample is provided in the Project FORESIGHT Annual Report, 2013-2014 Forensic Science Initiative, College of Business & Economics, West Virginia University, published in May 2015. The median cost per database as provided by FORESIGHT was $56, $66, and $85 for the last three years respectively.

\(^5\) ASCLD in collaboration with RTI provided a three-part webinar series in 2014 addressing the many facets of Rapid DNA analysis and its implementation. It was attended by more than 350 participants representing all 50 states and countries across the globe. The archived webinars can be viewed at http://www.ascld.org/meetings-and-training/forensic-conferences/.
• a definition of Rapid DNA analysis/instruments that grants authority for the generation and uploading of known offender and arrestee samples utilizing an NDIS approved Rapid DNA platform, chemistries, and expert interpretation system by a criminal justice entity in a laboratory or non-laboratory environment;
• authority for the maintenance of DNA known offender/arrestee records generated by FBI approved Rapid DNA instruments operated by any criminal justice entity in coordination with the appropriate NDIS participating lab that services their jurisdiction (local/state);
• authority for the FBI to establish procedures and approval/certification for Rapid DNA instruments with a specific requirement that any approved criminal justice entity comply with all current and applicable NDIS requirements and FBI Quality Assurance Standards

As we reviewed HR 320, we had concerns with some of the definitions, the practical implementation of blind proficiency testing, and the protection of confidential information within the database. Not only is it important that any legislation have authorizations and requirements for the technology and operators, but also safeguards for the appropriate use and storage of the acquired data. Legislation must absolutely include language to protect the confidentiality of the database, contents within the database, or any personal information. As mentioned, Attachment 2 lists more specific examples of how the legislation should be edited to move this technology forward.

In closing, Mr. Chairman, we encourage the development of partnerships between law enforcement agencies, crime laboratories, and regulatory agencies for a careful and well thought out approach to the implementation of this promising technology. We believe that a methodical and measured approach to its deployment is vital to the criminal justice system in order to deliver the best forensic science possible.

Again, I thank the committee for its time today, I have submitted a longer statement to the record which includes case studies from some of our laboratories currently working with rapid DNA and I would be happy to answer any questions.
The ASCLD Forensic Research Committee is working to identify and develop best practices for the implementation of this technology in both laboratory and field settings such as booking stations. In this effort, several state and local labs are using the instruments in limited pilot studies with different scopes to evaluate the reliability, efficiency and effectiveness of this technology. Brief descriptions of the pilot projects are provided below.

**Arizona Department of Public Safety (DPS)**

The Arizona DPS pilot project began in 2013 and has generated the most data to evaluate thus far. The Laboratory has setup both an officer field testing program and a program for the analysis of Arestee and Convicted Offender samples in the lab. The officer field testing project was designed by the AZ DPS laboratory and was implemented in May 2014. The project included the development of a Basic Training Course for law enforcement officers in Rapid DNA analysis. The trained officers can utilize the Rapid DNA instrument to generate a DNA profile from high quantity DNA crime scene samples such as blood or saliva. Developed DNA profiles are then searched against the standalone Arizona DNA database of qualified Arrestees and Convicted Offenders. All samples are also run concurrently by the Arizona DPS crime laboratory. To date, samples from 59 cases have been run by officers on the Rapid DNA Instruments in Phoenix and Tucson, quickly generating investigative leads of previously unknown suspects in several of the cases. The AZ DPS Laboratory is compiling the first year's data of the field testing program for publication in the near future, and the Laboratory's DNA Database Unit recently uploaded the first Arrestee samples to NDIS using the validated Rapid DNA laboratory instrument.

**Philadelphia Police Department (PPD)**

The PPD initiated two projects in 2015 to separately evaluate both of the instruments available on the market today. This project is being handled by the Office of Forensic Science, an ISO 17025 accredited crime laboratory, within the PPD. To date, internal validation of one instrument has been successfully completed for the processing of reference samples. The internal validation of the second instrument for the processing of reference samples is in its final stages. Based on a preliminary review of data, the second validation project is anticipated to be successfully completed within the next two weeks. Phase two of these projects will involve a pilot program of these instruments by the OFS to analyze routine laboratory reference samples, as well as, expedited reference samples collected during the investigative process through court order or consent. The PPD will not evaluate this technology in the booking station environment, as Pennsylvania does not have approved legislation for arrestee collections.

The PPD/OFS will also perform an internal validation study of the two instruments, pending receipt of appropriate instrument cartridges from the vendors, to examine the potential for analyzing lower quality or quantity samples, similar to evidentiary samples. These studies will evaluate the capabilities and limitations of this technology, with current instruments, to handle non-reference samples. Based on the results of these studies, the PPD may consider pilot programs to further evaluate the limited use of this technology as a screening tool for appropriate evidence in specific cases.

**Miami-Dade Police Department (MDPD)**
The MDPD will evaluate both instruments available on the market today. To date, only one instrument has been delivered and installed. Internal validation is currently underway. The second instrument is expected to be delivered and installed within approximately 30 days. Once validated, the instruments will be utilized in the crime laboratory to analyze reference samples. At this time, it is anticipated that a second instrument will be utilized by an investigative entity either within the MDPD or at a separate municipal agency within Miami-Dade County to evaluate the reliability of the Rapid DNA technology for the analysis of reference samples taken by consent.

\textit{Colorado Bureau of Investigation (CBI)}

The CBI Forensic Services will also evaluate both instruments. Once an internal validation has been successfully completed, a two part pilot project will commence to determine the feasibility of implementing Rapid DNA technology in both the laboratory and a booking station. The first part of the pilot will evaluate the use of Rapid DNA in the crime laboratory to confirm CODIS matches within the CBI’s Database laboratory. Additionally, CBI’s largest DNA casework laboratory will evaluate the use of Rapid DNA technology for single source samples. The second part of the pilot will be conducted in partnership with a local sheriff’s booking station to assess the feasibility of utilizing Rapid DNA technology to analyze these samples.

A cost benefit analysis will be performed by PPD, MDPD and CBI to compare the costs of Rapid DNA analysis to the costs of traditional DNA analysis for these pilot projects.
CFSO Position Statement on HR 320: Rapid DNA Act of 2015

The Consortium of Forensic Science Organizations (CFSO) is a premiere organization representing over 15,000 forensic science practitioners. The membership of includes the American Academy of Forensic Sciences (AAFS), the American Board of Forensic Toxicology (ABFT), the American Society of Crime Laboratory Directors (ASCLD), the International Association for Identification (IAI), the International Association of Forensic Nurses (IAFN), the International Association for Identification (IAI), the National Association of Medical Examiners (NAME), and the Society of Forensic Toxicologists (SOFT).

The Consortium of Forensic Science Organization opposes the H.R. 320-Rapid DNA Act of 2015 as currently written for the following reasons:

1) **Backlog Reduction**: In the introductory section, the bill notes that the integration of Rapid DNA instruments will “reduce the current DNA analysis backlog.” The Rapid DNA Instrument cannot currently be used on rape kit evidence besides the reference samples, as the instrument itself cannot separate out male and female DNA from swabs found in the rape kit. In addition, the instrument cannot currently be used for any sample containing a mixture of two or more individuals such as those collected at crime scenes or on touch DNA evidence (firearms, knives, doorknobs, etc.). The primary purpose of this technology is to reduce the “time” of analysis for only the sample types (presumed single source) suitable for analysis on the Rapid DNA instrument. There will be minimal impact on the backlog due to this limitation.

2) **Booking Station Oversight**: The deployment of Rapid DNA instruments to local jurisdiction’s booking stations will likely necessitate some type of close supervision and/or support to ensure that the instruments are used to analyze only those sample types that have been validated. The responsibility for this obligation could default to that jurisdiction’s local accredited crime laboratory. Both a policy and implementation mechanism needs to be developed for the Rapid DNA interface to ensure that all Rapid DNA testing is done according to any future, developed accreditation guidelines.

3) **Definition “Reference DNA sample”**: This term is defined in the proposed legislation as applicable to any individual on which a DNA analysis can be carried out. The drafters may wish to consider qualifying this definition in order to distinguish it from the...
definition of “DNA sample” in 42 U.S.C. Sections 14135a and 14135b by substituting the following language:

The term “Rapid DNA reference sample” means a buccal swab sample of an individual on which a DNA analysis can be carried out and uploaded to the national identification index pursuant to section 14132(a)(1) and (4) of this title.

4) **Definition “DNA Analysis”**: This definition is similar to the definitions contained in 42 U.S.C Sections 14135a and 14135b, but the drafters may wish to consider changing the “from” to “in” in order to be consistent with these existing sections.

5) **Definition “Sample-To-Answer”**: This term is not synonymous with the type of Rapid DNA analysis that is used in the forensic science industry and is more closely associated and identified with the genetic testing community. In addition, this term is used by one of the manufacturers of the Rapid DNA Instrument and is not appropriate for legislation, since this could be misconstrued as an endorsement for a particular manufacturer. Hence, the definition of “sample-to-answer” should be altered to another term, such as “Rapid DNA instrument.” If this term is changed, a change would also be needed to the definition of “operators” and in Sections 3, 4 and 5 of the proposed bill. Whichever “alternate term” is adopted, it will require a more detailed definition that defines the anticipated end product, a CODIS Core STR profile, as well as the necessary sample preparation and analysis steps (extraction, amplification, separation, detection and allele calling). Such a definition would be consistent with the information provided on Rapid DNA available at the FBI’s web site [http://www.fbi.gov/about-us/lab/biometric-analysis/codis/rapid-dna-analysis](http://www.fbi.gov/about-us/lab/biometric-analysis/codis/rapid-dna-analysis).

6) **Definition “Qualified Agencies”**: The Federal Bureau of Investigation has invested a significant amount of effort and resource to implement this technology in the booking station and other law enforcement agency environments. Infrastructure, technology, and policy are still being actively developed that are critical for implementation. It is extremely important for the success of the program that the infrastructure necessary to support this technology be properly developed, tested, and validated before legislation is adopted. Until these critical steps have been completely addressed, our organizations do not recommend any legislative changes.

7) **Definition “Operators”**: It is extremely important that the term “trained” be defined in the legislation. Although it is implied that little training is required for the operation of the “Rapid DNA Instrument,” that is not an accurate assessment. The people impacted by this technology are non-technical, law enforcement personnel with little to no scientific background. Proper training for operators is critical for the standardized use of this technology. While these law enforcement operators likely do not need to be fully trained DNA examiners, they will need some type of standardized training and the
FBI needs to have time to develop an appropriate training program. Without adequate oversight, validation, and training of these operators, improper use on limited or incorrect sample types could jeopardize casework samples.

8) **Federal DNA Advisory Board**: The Federal DNA Advisory Board’s five year statutory term expired in 2000. The bill references a Board that is no longer in existence.

9) **Blind Proficiency Testing**: Blind proficiency testing has proven to be an elusive goal for the majority of the forensic community. While the community has proactively investigated the feasibility of a “blind” proficiency program, there have been barriers that have prevented its implementation. For instance, in order for a proficiency test to be blind, the test must be submitted to the laboratory system (or the law enforcement agency) without the operator and/or submitter realizing that it is a test. This one obstacle (of many) cannot be overcome without a significant investment of resources. Indeed, research from the National Institute of Justice (NIJ) concluded that blind proficiency testing is not feasible.

10) **Section 14132(B)(2)**: This particular section is referenced in *Section 4 Qualifying Agencies* of the bill and appears to only address the upload of individuals charged or convicted of qualifying offenses and excludes arrestee sample uploads. In addition, the section is too broad and should be only limited to Rapid DNA instruments that are approved by the National DNA Index System (NDIS).

11) **Section 14135b**: This section referenced in *Section 5 District of Columbia DNA Analysis* fails to mention the Federal and military collection programs and does not provide similar authorization for these two programs as currently enacted and described in Section 14135a.

12) **Probative Value**: Any results from such instrumentation in a field setting should be reproduced in an accredited forensic science laboratory and performed by certified forensic scientists if introduction into court as probative evidence is contemplated.

CFSO looks forward to working with the author of the bill, the federal agencies responsible for developing and implementing the technology, and the vendors of the technology. Rapid DNA is an exciting advancement for forensic science and law enforcement; however, it must be appropriately implemented. CFSO appreciates the author’s effort to improve law enforcement and the forensic community and is available for continued dialogue.