

The Emergence of **Rapid DNA Technology**



International
Biometrics+Identity
Association

Overview

IBIA strongly supports biometrics and forensic applications of DNA, and offers this white paper as a primer for those desiring to know more about rapid DNA analysis technology.

Deoxyribonucleic acid (DNA) carries the genetic instructions that make each person unique. Since its discovery in 1953, DNA has found many applications in the fields of biometrics and forensics, among others. Since the 1970s, DNA analysis technology has evolved considerably. It is now considered the “gold standard” for biometric and forensic identification purposes.

DNA is the only biometric that can infer familial relationships— an extremely valuable tool in scenarios such as missing person and disaster victim identification, lost-child and counter-human-trafficking applications, paternity and maternity testing, and determinations of eligibility for immigration benefits. Like fingerprints, DNA is one of the few biometrics that can be “left behind” at a crime scene.

While highly accurate for identification purposes, DNA can be cumbersome and time-consuming to process. Traditional methods of forensic and biometric DNA analysis require a certified laboratory with at least six expensive instruments, two trained and certified technicians, and about a day per sample of processing time. When the months of waiting in lab backlogs are considered, the timeframe for obtaining DNA test results can be quite long.

Rapid DNA analysis technology is a compelling new development that can significantly shorten analysis times and backlogs, putting less expensive and easy-to-use portable alternatives in the field. Field locations are closer to the points of need, thus relieving and speeding the work of the central laboratories that are still needed for complex forensic analysis.

Advancing Rapid DNA Technology

Current rapid DNA offerings typically consist of a desktop instrument to process single-use cartridges that contain chemical processing agents and analysis materials. The analysis operation is self-calibrating, and proceeds automatically after samples are inserted into the instrument. The self-calibrating system allows people who are not lab technicians to operate the equipment with about an hour of training.

Rapid DNA processing times are typically 75 to 90 minutes, which facilitates faster identification of criminals who might otherwise only be held for two hours or more. Expanded availability of rapid DNA technology could play a critical role in exonerating or excluding suspects, allowing far more efficient investigations when time is critical.

A number of companies around the world are developing rapid DNA analysis technologies to address growing needs for DNA in forensics and biometrics. (See the appendix for brief descriptions of noteworthy companies with technologies to offer.) Instrument costs are on the order of \$250k to \$350k, with single-use processing kits ranging from \$250 to \$350 each. As the market for such capabilities grows, the cost will likely go down rapidly.

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Most DNA sequences are common in all humans, making just a small fraction relevant for identification purposes. There are known locations within the genome where these relevant sequences occur. The rapid DNA analysis process isolates twenty of these key points so they can be measured.¹

The innovations that helped to advance rapid DNA technology to the current state are numerous, but often revolve around micro-fluidic processing techniques. This technology uses much smaller amounts of chemicals to reduce cost, speed reactions, and compress instrument and cartridge sizes. Previous laboratory-based processes of sample DNA extraction (cell lysing), purification, amplification (also called polymerase chain reaction or PCR), separation (also called electrophoresis), and detection are now all accomplished within one rapid DNA instrument, often on one microfluidic chip.

¹ Traditionally, and since 1997 within the FBI's Combined DNA Index System (CODIS), 13 of such STR loci were analyzed, along with a marker for gender called amelogenin. However, in late 2015 the FBI announced an expansion of the original 13 loci to 20 core loci effective as of 2017. More loci means that the set selected can be a superset of the U.S. and international core loci, facilitating international data sharing. In addition, more loci means not only better identification of individuals, but also more assured family relationship testing.

Federal Regulatory Advancement Supporting Rapid DNA

From 2015 to early 2017, Congress considered a number of amendments to the DNA Identification Act of 1994 designed to hasten the field deployment of rapid DNA technology. The Rapid DNA Act of 2017 (S.139 and HR.510) amends the DNA Identification Act of 1994 to permit the use of automated rapid DNA instruments in addition to traditional laboratory-based processing mechanisms. This bill cleared the Senate and the full House, and was signed into law on August 18, 2017 by President Donald Trump.

The 1994 law uses a DNA Advisory Board to develop standards for agencies and operators to analyze DNA samples. The National Institute of Justice then certifies DNA processing centers based on the board's standards. The new law will dissolve the DNA Advisory Board, empowering the Director of the FBI to directly issue standards and procedures for the use of Rapid DNA instruments and resulting analyses.

The Rapid DNA Act of 2017 also facilitates law enforcement exchange of DNA identification information, to include information on DNA identification records and DNA analyses. This index applies to agencies that engage in rapid DNA analysis with respect to the intake, processing, booking, detention, or incarceration of individuals charged with or convicted of qualifying offenses.

The ultimate goal of this legislation is to allow rapid DNA devices in the field to be connected to the FBI's CODIS database.



Rapid DNA Technology: Uses, Benefits, and Limitations

In December 2015, FBI Director James Comey testified before the House Judiciary Committee and articulated his vision of rapid DNA technology use by law enforcement agencies at booking stations across the U.S.

This technology could also be used by law enforcement and other government agencies for humanitarian purposes:

- Reunite families separated during mass migration of persons fleeing conflict zones or disaster areas;
- Prevent human trafficking by criminals who falsely claim familial relationships with their captives when intercepted by authorities;
- Assist authorities in natural disaster or conflict situations in identifying mass casualty victims.

Rapid DNA technology has already produced benefits to society. The Tucson Police Department in Arizona ran a pilot program that integrates rapid DNA analysis with the state's DNA database. In use since 2015, the system has helped police solve numerous cases, including burglaries, sexual assaults, and other violent crimes.

While the benefits of rapid DNA analysis are evident, there are still some challenges for the industry to overcome:

- Current technology does not support all sample types, although the scope of supported types is increasing.
- Pre-processing is still required for some sample types.
- Yield rates (percentage of samples tested that result in a usable output) are still not 100%.
- Although the technology overall is cheaper than other traditional DNA options, it is still too expensive for some market segments, particularly cost-constrained police departments.²
- While lawmakers and law enforcement praise rapid DNA for its ability to help with the backlog of rape kits, the technology may have limited use in this arena, depending on how degraded the kits are (perhaps due to age). However, by allowing booking stations and laboratories to test with a rapid platform for more routine enrollment applications, it may free other resources to work on the harder forensic cases and rape kits in backlog.



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² When first introduced to the market, rapid DNA tests cost approximately \$350 per sample. However, second-generation rapid DNA technology has enabled pricing to fall below \$100 per sample, making widespread use more feasible.

Rapid DNA and Privacy

Some privacy advocates oppose the use of rapid DNA technology. Immigrants' rights and civil rights groups raise concerns about unauthorized and invasive biometric collection. Others believe that rapid DNA technology will pave the way for development of a nationwide DNA index.

These concerns are consistent with arguments that have been made about biometrics in general for decades. IBIA's perspective is that DNA used for identification purposes is no different from a fingerprint—a view consistently upheld in the courts. Yet DNA is different in one key and very useful respect—it can be used to infer familial relationships, which can be useful for government applications where benefits are based on connection to an eligible relative.

Commercial DNA databases should follow the same best practices that the IBIA advocates for all biometrics.³ For government applications within the U.S., 29 Federal laws and acts currently govern various aspects of privacy protection for American citizens. Unfortunately, criminals use these laws to their advantage, hiding behind the veil of anonymity or false identity. By lifting this veil, rapid DNA technology denies criminals the ability to exploit systemic loopholes.

For more information, visit www.ibia.org.

³ See www.ibia.org for a listing of the IBIA recommended best commercial practices.



Appendix: Select Suppliers in the Marketplace

Network Biosystems (<http://netbio.com/>): NetBio's flagship technologies are their ANDE™ and DNAscan™ systems, which accelerate DNA profile generation to completion in less than 90 minutes. One common method of collecting DNA samples from cooperative subjects is with a cotton swab used to collect saliva from the inside of the subject's cheek. The NetBio DNAscan Rapid DNA Analysis™ system claims to be the first and only fully automated system for "swab in, profile out" Rapid DNA analysis approved by the FBI. The FBI gave DNAscan its National DNA Index System (NDIS) approval earlier this year. This approval allows NDIS labs to upload samples processed by DNAscan to match with the FBI's Combined DNA Index System (CODIS). When performed in an NDIS laboratory, DNA matching can be completed without manual interpretation or technical review of profiles unless the profile is tagged for review. Through NetBio's development of the High DNA Content Flexplex BioChipSet Cassette, the DNAscan 6c now can process four 27-loci samples in less than 90 minutes.

IntegenX (<https://integenx.com/>): IntegenX entered the market with its first Rapid DNA instrument, the RapidHIT™ 200 system, which also provides DNA profiles in up to 90 minutes. Although its chemistry has been approved by the NDIS, the system itself has yet to receive such acceptance. However, the RapidHIT 200 system has been used to upload more than 1,000 profiles to CODIS and other national databases with DNA profile review. The RapidHIT system is slightly

smaller than NetBio—both are about the size of a desktop printer. RapidHIT can run up to eight samples at a time, while the NetBio DNAscan machine can run up to five samples at once. IntegenX also has introduced a second-generation product, the RapidHIT ID. It is 10 inches wide, and is priced at about half of the cost of the RapidHIT 200 or DNAscan. It uses chemistry and software approved by NDIS. Both RapidHIT systems use the GlobalFiler Express kit, which can process 24 loci independently. Additionally, both RapidHIT systems offer NGMSelect 17, a format popular in some European markets.

NEC (http://in.nec.com/en_IN/products/public-safety-security/product/portable-dna-analyzer.html): NEC entered the rapid DNA market with the Portable DNA Analyzer. This solution was one of the world's first fully integrated portable DNA capabilities designed to help speed up criminal investigations and aid crime prevention efforts. Portable enough to be carried to crime scenes, it integrates all five steps of the DNA analysis process: cell collection, DNA extraction, Polymerase Chain Reaction (PCR), electrophoresis and STR analysis. The entire analysis process requires only about 25 minutes. This solution is largely sold in Asian markets.

LGC (<https://www.lgcgroup.com/products/paradna-technology/#.WJ4-KcLHxD9>): LGC entered the market with their ParaDNA® Instruments, which provide a simple, fast and reliable way to profile DNA samples. Their equipment provides rapid options to identify individuals, screen and triage biological samples, improve submissions success rates, and effectively allocate investigative personnel to gain rapid investigational outcomes in the quickest possible time.

Identity Matters



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