

Building and Evolving a Proficiency Testing Scheme in Forensic and Kinship Genetics: Thirty Years of Innovation and Challenges



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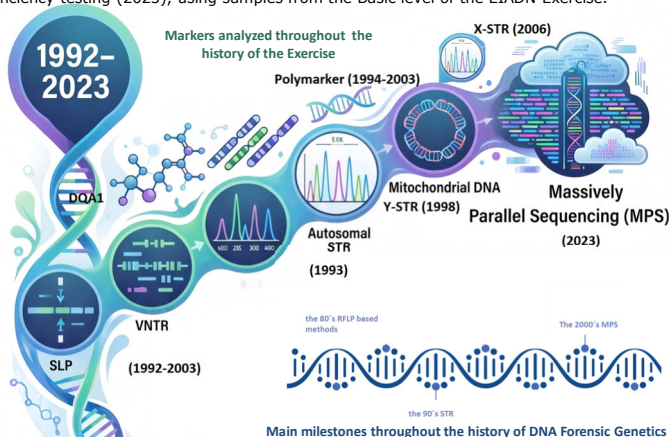
This work reviews the progressive development of the scheme of the Proficiency test "**Analysis of DNA polymorphisms in blood stains and other biological samples**" also known as EIADN and how has evolved to adapt to technical advances and the practical needs of forensic casework. It has incorporated different markers and technologies, It has also expanded the diversity of samples analyzed, as well as theoretical exercises to assess statistical interpretation in kinship and forensic casework. Accreditation of the Basic level in 2014, together with the organization of the remaining modules in accordance with ISO/IEC 17043, has strengthened the quality and reliability of the scheme.

BACKGROUND

Since 1992, the National Institute of Toxicology and Forensic Sciences in Madrid (INTCFM) and the Spanish and Portuguese-Speaking Working Group of the International Society for Forensic Genetics (GHEP-ISFG) have organized a collaborative DNA profiling exercise that became a proficiency testing program (PT) in 1995 for kinship and forensic laboratories: "**Analysis of DNA polymorphisms in bloodstains and other biological samples**". Over more than 30 years, the scheme has evolved from a collaborative exercise into a long-standing quality assurance tool, supporting laboratories in the assessment of analytical performance, result interpretation, and methodological competence.

TECHNICAL AND ANALYTICAL EVOLUTION

Various systems have been evaluated throughout the Exercise, from the early SLP, DQA1, and VNTR markers assessed between 1992 and 2003, and Polymarker between 1994 and 2003, to autosomal STRs, which were introduced in 1993. Y-chromosome STR markers and mitochondrial DNA have been assessed since 1998, while X-chromosome STR markers, the most recent polymorphism included, were incorporated in 2006. The expansion of massively parallel sequencing (MPS) technology in forensic genetics led to the inclusion of MPS proficiency testing (2023), using samples from the Basic level of the EIADN Exercise.



EXPANDED SAMPLE DIVERSITY, SPECIES IDENTIFICATION, AND STATISTICAL INTERPRETATION

Although the Exercise initially involved testing blood samples, additional sample types, including saliva and semen, were later incorporated for genetic analysis and body fluid identification. Hair analysis was introduced in 2000. Finally, in 2011 a non-human testing item was incorporated.



With regard to theoretical studies, the statistical assessment of kinship cases was introduced in 1996, followed in 2007 by the incorporation of data sets for forensic case interpretation.

ORGANIZATIONAL RESTRUCTURING AND QUALITY STANDARDS IMPLEMENTATION

The most significant change occurred in 2011, when the Exercise was divided into two levels: Basic and Advanced, allowing the scheme to accommodate laboratories with different scopes, experience and technical capabilities.

The need to improve and ensure the quality of our services, as well as to demonstrate our competence, led us to seek accreditation of the **Basic Level of this Exercise** under ISO/IEC 17043. In 2011, the first quality management actions were implemented, including the incorporation of ISO/IEC 17043 requirements into the Department's Quality Policy and Quality Manual. Although the Exercise had a well-established track record as an interlaboratory testing scheme, it was necessary to review all technical and management competencies. Existing processes were evaluated, updated, and formally documented to ensure compliance with the requirements of ISO/IEC 17043. Many additional technical and management improvements such as the formal assessment and documentation of test item homogeneity and stability, enhancements in communication with participants or the implementation of improved procedures for handling and resolving complaints and appeals were also introduced.

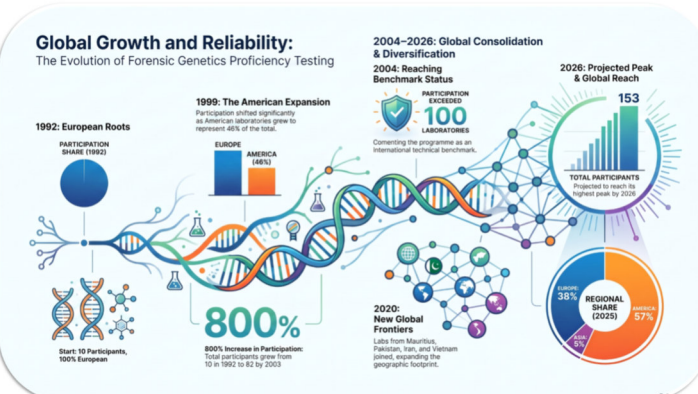
Finally, in December 2014, the Spanish Accreditation Body; ENAC granted ISO/IEC 17043 accreditation to the INTCFM as a proficiency testing provider.



INCREASED PARTICIPATION AS A MEASURE OF RELEVANCE

The relevance of any proficiency test is measured by the number of participants: the higher the number, the greater its statistical validity, confidence, and reliability. In its early years, the Exercise involved a small number of participants, mainly from Spain and, to a lesser extent from Portugal. The subsequent quality improvements and its adaptation to new forensic genetics tools helped establish the exercise as an international benchmark. Since 2004, the total participation surpassed one hundred laboratories across the Americas and Europe. Recent years have seen further diversification with the inclusion of laboratories from Africa and Asia, including nations like Mauritius, Pakistan, Iran, Iraq, Vietnam, or Lebanon.

All of them have relied on this proficiency test as evidence of their technical competence and as a means of meeting the quality requirements set by higher-level oversight or regulatory bodies, ultimately contributing to justice and societal well-being.



CURRENT PROFICIENCY TESTING SCHEME

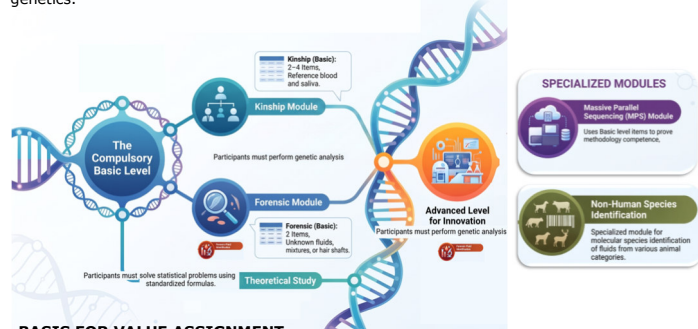
Registration is open to all interested laboratories, whose staff can be members of the Spanish and Portuguese-speaking working group of ISFG (GHEP-ISFG) or not, both public or private laboratories that carry out biological research of paternity and/or analysis of DNA polymorphisms for use in the forensic field.

It is compulsory for participating laboratories to take part in the Basic level in order to participate in the Advanced level or in any of the optional modules.

The Basic level includes reference items (kinship module) and forensic items (forensic module) as well as theoretical statistical calculations (kinship and forensic). The Advanced level includes only challenging forensic items. Both levels assess competence in identifying DNA polymorphisms using different markers, including autosomal, Y-chromosome, and X-chromosome STRs, as well as mitochondrial DNA. The Program optionally also includes a Non-Human item module and a Massively Parallel Sequencing (MPS) module.

Results are evaluated against consensus or known values to ensure accuracy in paternity and forensic investigations.

Although only the Basic level is accredited, the Advanced level, the MPS module, and the Non-Human item module are organized in accordance with ISO/IEC 17043 requirements, ensuring that the testing scheme remains a rigorous tool for quality assurance in forensic genetics.



BASIS FOR VALUE ASSIGNMENT

Consensus value among participants	Known value	Expert laboratories
Basic level: - Kinship practical study Advanced level: - Forensic practical study	Basic level & Advanced level: Forensic practical study (body fluid ID) Non Human item module	Basic level: - Kinship theoretical study - Forensic practical study - Forensic theoretical study MPS module

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GRUPO DE LÍNGUAS ESPANHOLA E PORTUGUESA DA ISFG

Detailed timetables and registration procedures can be found at:



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