

STRMIX POSITION STATEMENT ON INDEPENDENT VERIFICATION AND VALIDATION

1. Purpose

This position statement describes the STRmix team's ("The Team") approach to Verification and Validation (V&V) and the role of Independent Verification and Validation (IV&V). IV&V activities provide assurance that the software applications STRmix™, DBLR™, FaSTR™ DNA, STRmix™ NGS, and STRmix™ Y developed by The Team satisfy specified requirements and intended use.

2. Position Regarding IEEE 1012

IEEE (Institute of Electrical and Electronic Engineers) is a professional association that develops industry standards and publishes technical literature across engineering and technology disciplines including computer engineering. IEEE Standard 1012 [1] specifies the processes and activities for the verification and validation (V&V) of any system, software, or hardware.

IEEE 1012 recognises three dimensions of independence for the development and testing of software; technical, managerial, and financial ([1] Annex C).

Confidence in the performance of any software is strengthened when V&V activities are performed by personnel who are independent of the development activities being assessed. Independence supports objective evaluation of software behaviour, documentation, and suitability for intended use. Accordingly, the principles and intent of IEEE 1012 have informed our approach to V&V activities for the development of software.

The Team does not claim compliance, certification, or accreditation to IEEE 1012.

3. Independence

The Team's software coding development ("Coding") and V&V activities are performed by different personnel with distinct responsibilities. The Coding for STRmix™ (since 2017) and FaSTR™ DNA is undertaken by an external software development organisation, while V&V activities are undertaken by members of The Team.

Where Coding is undertaken within The Team (for example .NET-based software DBLR™, and the very early versions of STRmix™), V&V activities are undertaken by members of The Team who have not been involved with Coding, and do not undertake Coding at any stage. This independence establishes a fresh technical viewpoint during review and testing, reducing the likelihood that assumptions made during software development influence verification outcomes.

For all software, V&V personnel use independently derived methods, calculations, test data, analyses, and expected results to assess software behaviour. V&V activities may include independent assessment of algorithms, testing, validation studies, documentation review, and evaluation of anomalies. Effective communication between Coding and V&V personnel is encouraged, however, responsibility for V&V conclusions remains with the independent V&V personnel. Personnel assigned to V&V activities are responsible for providing objective

and independent conclusions regarding whether the software satisfies its specified requirements and intended use. All documentation is retained within The Team's records.

For STRmix™ and FaSTR™ DNA, managerial independence is maintained through separate organisational structures for Coding and V&V. Financial independence is achieved through separate budgets for Coding and V&V, and a formal, documented change/approval process. External software developers are engaged through contractual agreements, whereas V&V personnel are employees whose compensation is not linked to project deliverables or testing outcomes.

For DBLR™, both Coding and V&V are undertaken within The Team and therefore are not managerially or financially independent. However, strict separation of responsibilities and personnel undertaking Coding and V&V activities ensures technical independence is maintained.

The Team's V&V arrangements provide a degree of separation between development and verification activities, although we do not claim full managerial or financial independence as described in Annex C of IEEE 1012.

4. Assurance Statement

The Team considers that the combination of:

- a defined V&V approach;
- independent V&V personnel;
- objective documented evidence; and
- documented governance and oversight

provides a robust basis for establishing confidence in the probabilistic genotyping software STRmix™, STRmix™ Y, and STRmix™ NGS, the likelihood ratio assignment software DBLR™, and the analysis software FaSTR™ DNA.

V&V activities independent to Coding provide an additional and deliberately separate assessment of whether the software satisfies its specified requirements and is suitable for its intended use.

Definitions

- Verification is defined by IEEE as the process of providing objective evidence that the system, software, or hardware and its associated products conform to requirements (e.g., for correctness, completeness, consistency, and accuracy).
- Validation is defined by IEEE as the process of providing evidence that the system, software, or hardware and its associated products satisfy requirements allocated to it, solve the right problem, and satisfy intended use and user needs.
- Independent Verification and Validation (IV&V) is defined by IEEE as Verification and Validation (V&V) performed by an organisation that is technically, managerially, and financially independent of the development organisation.
 - Technical independence requires the V&V effort to use personnel who are not involved in the development of the system or its elements.

- Managerial independence requires that the responsibility for the IV&V effort be vested in an organisation separate from the development and program management organisations.
- Financial independence requires that control of the IV&V budget be vested in an organisation independent of the development organisation.

Reference

[1] 1012-2024 - IEEE Standard for System, Software, and Hardware Verification and Validation. 2025.