

Policy for the accreditation of Whole Genome sequencing (WGS) and Next Generation sequencing (NGS) techniques

PS29

Introduction:

Whole Genome Sequencing (WGS) and Next Generation Sequencing (NGS) techniques can be applied to a range of activities across medical and non-medical testing laboratories. The technology underlying these techniques is similar across all areas, however the type of result generated and the implications of this result, in some cases, have been identified as a potential risk within the INAB assessment process.

The main risk is associated with the capture, storage and use of human genetic data (which constitutes a special category of personal data under GDPR). While INAB has engaged with the medical professional bodies on this matter, there are no national guidelines for the reporting and interpretation of test results in this area at present. This document outlines INAB policy for accreditation of these techniques, in the absence of national guidelines.

Policy:

INAB will assess WGS and NGS testing, subject to the following conditions:

1. The technical assessment will require a combination of a scientifically / medically qualified technical assessor in conjunction with a technical assessor specifically for the technique. For example if it is in use in a Microbiology laboratory, the INAB assessment team will consist of a Microbiology technical assessor and a WGS/NGS technical assessor. Bio-informatics expertise may also be necessary on the assessment team, as deemed necessary by INAB.
2. For medical testing laboratories, the laboratory will need to provide the following:
 - a. Documented policy for the storage of data, the destruction of data and the communication of results including unclear findings to the requesting clinician. This policy should also include clear guidelines for potential future review of findings, recognising the possibility of evolution in medical understanding of specific mutations (as applicable).
 - b. The laboratory shall have documented competence requirements for provision of clinical advice for these techniques. The responsibility for the communication of results / unclear findings relating to these tests shall also be documented.
 - c. Responsibility for obtaining patient consent for the testing shall be defined.
 - d. Where data is stored off-site or in the cloud or where data is imported/exported for analysis, clear documentation of governance arrangements and responsibilities shall be available, including IT back-up arrangements. The laboratory shall be responsible for ensuring that all personal data is stored in accordance with EU law.
 - e. The laboratory (and where relevant, the hospital) should ensure it complies with all of its obligations under applicable data protection law in respect of its use of WGS and NGS techniques. (Involving the processing of genetic data, which

constitutes a special category of personal data). The review of any documentation, policies or procedures by INAB is not intended to provide, and does not provide, any confirmation that such documentation, policies or procedures are compliant with applicable data protection law.

- f. Evidence of sign off from clinical director and hospital manager as agreement to the policy statement as per (a) - (e) above and acceptance and responsibility for the risks involved in the use of these techniques specifically in relation to the governance and any future use of the data generated. This evidence will need to be provided to INAB at application stage.
3. For ISO 17025 testing laboratories section 1 will apply. For section 2, parts a, b, d, e and f will apply at a minimum, with evidence of signoff by senior laboratory management in the case of f.
 4. Flexible scope does not apply to these types of techniques.
 5. Example of scope information to be provided below, (Appendix I).
 6. For further information, please contact your INAB assessment manager.

Implementation and Review:

The policy is effective immediately.

INAB will review the policy no later than 12 months after issue or sooner if there is a significant change in national policy or guidelines.

Appendix I - Format of scope of accreditation

For guidance on the scope format, please click the link below.

<https://www.inab.ie/Documents-Forms/>

Use ST 6 CRM scope template for medical laboratories, sheet / tab 7. (All human samples)

Use ST 2 CRM scope template for testing laboratories, Genetics testing. (other samples)

Example as follows for ISO15189 laboratory.

Specimen type	Test / Assay	Technique	Equipment	Method
Blood DNA	Detection of germline mutations in 23 genes associated with Limb-Girdle Muscular Dystrophy : ANO5 CAPN3 CAV3 DAG1 DES DNAJB6 DYSF FKRP FKTN ISPD LMNA MYOT PLEC POMGNT1	Next generation sequencing	Name of Equipment	SOP / CE Marked / In house etc.
Blood DNA	Non invasive pre-natal test (NIPT) : Trisomie 21	Next generation sequencing	Name of equipment	SOP / CE Marked / In house etc.