1 INTRODUCTION

1.1 Genseq Diagnostics Limited (Genseq) is an accredited laboratory that provides clinical genetic testing services to health practitioners who order one or more specific genetic tests on behalf of their patients.

1.2 A health practitioner is required to order the test and is responsible for test selection. A patient's tumour tissue sample is referred to Genseq, together with a completed Test Request Form specifying the test(s) to be performed and a signed Informed Consent Form confirming patient consent, or in the case of a child the patient's legal guardian(s) consent, to the test(s).

1.3 The Test Request Form completed by the patient's health practitioner also provides Genseq with relevant patient information including the relevant cancer diagnosis, subtype and stage, tissue biopsy site and relevant prior test results of the patient. Genseq relies on the adequacy and accuracy of the information provided by the health practitioner in the Test Request Form.

1.4 Genseq performs Comprehensive Genomic Profiling (CGP) on patient DNA which has been extracted from a tumour tissue sample utilising a panel of 335 target genes which based on current scientific knowledge are known to be associated with the relevant cancer. Genseq uses several technologies including the AVENIO Tumor Tissue CGP V2 in-house test assay and Next Generation Sequencing (NGS) systems to generate raw genetic sequencing data. The raw sequencing data is uploaded to an external third party service provider's software (Avenio connect from Roche) for secondary processing to generate CGP test results. Genetic variant data is analysed using the Foundation One analysis platform to generate a clinical report which is returned to Genseq via Roche Navify mutation profiler software. Further details regarding the third party service provider and their role is at paragraph 3.8. Genseq reviews the clinical report content and issues a report on the test result(s) to the patient's health practitioner(s) whose contact details are provided in the Test Request Form, including those registered under the patient's health practitioner's account.

1.5 A patient's health practitioner is responsible for the clinical interpretation of the test results and the future management of the patient.

2 WHAT IS TUMOUR TISSUE COMPREHENSIVE GENOMIC PROFILING

2.1 Genseq offers comprehensive genomic profiling of DNA from formalin-fixed paraffin-embedded (FFPE) solid tumour tissue based on a panel of 335 target genes using the AVENIO Tumor Tissue CGP V2 assay. This is a next-generation sequencing assay that facilitates the simultaneous detection of genetic variants (including single nucleotide variants, insertions and deletions, copy number variants and gene fusions) and genetic biomarkers (microsatellite instability (MSI), tumour mutation burden (TMB), Loss of heterozygosity (LOH) and homologous recombination deficiency(HRD)). Access to the large proprietary datasets and clinical support functionality maintained by Roche facilitate Genseq to provide a CGP report based on the analysis of extensive datasets to provide the patient's health practitioner with information to identify potentially relevant treatment options and support future clinical decision making.

2.2 Understanding the genomic profile of a tumour based on the analysis of large data sets facilitates precision medicine by providing information on tailored treatment options, diagnosis and prognosis.

3 INFORMED CONSENT, DATA PROTECTION AND CONFIDENTIALITY

Informed Consent

3.1 Under Irish law, the informed consent of a person undergoing genetic testing must be obtained prior to the testing and the processing of associated genetic data. There is a legal presumption that persons who have reached the age of 16 have capacity to give consent. Legal guardian(s) can give consent on behalf of persons who are under the age of 16, or on behalf of persons who are 16 years but not yet 18 years of age and lack capacity to consent.

3.2 If a patient is 18 years of age or older and their decision making capacity is in question or they have been assessed by their health practitioner as lacking capacity to give informed consent to genetic testing, the patient's health practitioner, who is organising the genetic testing, can contact Genseq to discuss the individual patient's circumstances and the appropriate assisted decision making arrangements that are or will be put in place consistent with the requirements of the Assisted Decision Making (Capacity) Act 2015, (as amended) (the 2015 Act).

3.3 Genetic testing and genomic profiling are entirely voluntary. Before making a decision, the patient or the patient's legal guardian(s) where the patient is a child is /are entitled to receive all appropriate information concerning Tumour tissue CGP and processing of genetic data, including indication(s), purpose and scope, risks, potential outcomes, implications, and alternatives. Obtaining informed consent for genetic testing and genomic profiling of DNA extracted from tumour tissue and the processing of the associated genetic data is the responsibility of the patient's health practitioner under whose responsibility the genetic testing and genomic profiling has been ordered from Genseq.

3.4 By signing the Informed Consent Form, the patient, or the patient's guardian(s) (as applicable), acknowledge that he / she / they have received and understand all the relevant information and agrees to the genetic testing and genomic profiling specified in the Test Request Form and processing of associated genetic data by Genseq. By signing the Informed Consent Form the patient or the patient's legal guardian(s) where the patient is a child, consents to the disclosure by Genseq of the CGP genetic test results to the health practitioners whose details have been provided in the Test Request Form including those registered under the patient's health practitioner's account.

3.5 By signing the confirmation of health practitioner, the patient's health practitioner confirms that all appropriate information concerning the tumour tissue CGP test has been provided to the patient / the patient's guardian (as applicable), that all the patient's / legal guardian's questions/ queries have been answered and that the patient or where the patient is a child his / her legal guardian(s) has / have voluntarily given informed consent to tumour tissue CGP testing and processing of associated genetic data including the secondary processing and retention of genomic sequencing data by the sub-processors as set out in paragraph 3.8 below. The patient's health practitioner also confirms that patient consent has been obtained for Genseq to issue the CGP test results to the ordering health practitioner(s) whose details are provided in the Test Request Form including those registered under the patient's health practitioner's account, via its online portal.

3.6 The patient or where the patient is a child his or her legal guardian(s) has / have the right to withdraw consent at any time. To do this the patient / legal guardian(s) (as applicable), should inform the patient's health practitioner, who organised the test, of the patient's / patient's legal guardian(s) decision. The health practitioner is responsible for notifying Genseq of the patient's / the patient's legal guardian(s) decision, as applicable. On receipt of notification of the patient's / the patient's legal guardian(s) decision to withdraw consent Genseq shall take reasonable operational steps to cease further testing and processing of personal data as soon as is reasonably practicable. Genseq will destroy the patient's samples and all of the patient's genetic data generated and retained by Genseq prior to the cessation of services. Genseq will also notify Roche of the patient's / patient's legal guardian's decision to withdraw consent using the patient's LabID as the relevant identifier of the patient and instruct Roche to anonymise the patient's data. For clarity, it will not be possible for Roche to identify patient data after it has been anonymised. Genseq reserves the right to charge for the services it has provided prior to notification to Genseq of the patient's / patient's legal guardian(s) withdrawal of consent to testing.

Data Protection

3.7 For data protection purposes, the requesting health practitioner listed in the Test Request Form is the controller of the patient's personal data (i.e., data processed in order to perform and report on the testing sought by the health practitioner). The patient or where the patient is a child his / her guardian(s) should direct any queries about the processing of the patient's personal data to the requesting health practitioner. Genseq, as the appointed genetic testing services provider, acts as a processor on behalf of the requesting health practitioner. Genseq processes patients' personal data, health data and genetic data on the

instructions of the health practitioner as controller of the personal data and retains personal data and samples for such period(s) of time as may be specified by the patient's health practitioner as data controller or for the period required by law, prior to destruction.

3.8 Genseq contracts with Roche to assist with the genomic sequencing described above. From a data protection perspective, this involves Genseq appointing Roche as a sub-processor of the patient's personal data and requiring it to comply with various obligations in connection with its processing of such data, including a requirement to only process the personal data in accordance with the documented instructions of the controller (i.e. the relevant health practitioner). Separately, Roche will then retain certain anonymised patient data for its own research purposes, which include furthering clinical and research understanding in cancer and its causes and treatments (including in relation to other individual patients). For clarity, it will not be possible for Roche (or other third parties) to identify the patient data relating to you from the data that Roche retains for such purposes.

3.9 The processing of personal data relating to the patient is undertaken on the basis of consent (specifically given in the Informed Consent Form) by the patient or where the patient is a child by the patient's legal guardian(s) on behalf of the patient. Associated consent is also sought to the necessary processing of the names of the legal guardian(s) in connection with the processing of the personal data of the patient.

3.10 Roche will generally retain your pseudonymised patient data for up to 10 years for quality control and record keeping purposes before it is anonymised.

3.11 Further information may be sought on the processing of such personal data from the health practitioner.

Confidentiality

3.12 All CGP genetic test results are confidential and will be disclosed by Genseq only to the health practitioner(s) named in the Test Request Form, and those registered under the patient's health practitioner's account, unless otherwise authorised by the patient or required by law.

3.13 By signing the Consent Form the patient or the patient's legal guardians, as applicable, consents to the disclosure by Genseq of the CGP genetic test results to the health practitioners whose details have been provided in the Test Request Form including those registered under the patient's health practitioner's account. The patient or the patient's legal guardian(s), as applicable, should discuss and agree approved recipients with the patient's health practitioner. Genseq relies on the information in the Test Request Form and the signed Informed Consent Form to determine the appropriate recipients.

4 REPORTING RESULTS OF TUMOUR TISSUE CGP

4.1 The report for Onco CGP testing will include any identified clinically actionable findings, including genomic and biomarker results, that are associated with treatment options or with altered treatment responses. Results are listed, along with associated treatment options for the tumour type which the test was requested for and for other tumour types.

4.2 **Findings are classified using a tiering system based on the level of scientific and clinical evidence available, with "Tier I" being variants or biomarkers of strong clinical significance and "Tier II" being variants of potential clinical significance.** Only variants, variant combinations or biomarkers determined to be Tier I or Teir II are generally included in the report. The laboratory does not formally report variants of unknown significance (VUS) or variants in genes of unknown significance (GUS). In addition, Loss of heterozygosity (LOH) is not defined for all cancer types.

4.3 A "No clinically actionable findings were identified" result means that the DNA sample tested did not identify any relevant Tier I or Tier II genomic variants or biomarkers. A negative result does not exclude the possibility of a clinically relevant finding. It is possible that a particular variant may not be recognised as clinically significant due to insufficient evidence at the time of the report. It is also possible that the classification of variants may change in the future due to improvements in scientific understanding.

4.4 A 'failed result' means that the results failed to meet quality standards. This may occur due to several factors including limitations of laboratory methods or poor sample quality. In this case, the health practitioner may request a new test by submitting a new specimen or make other recommendations to the patient.

4.5 The report will also include potentially relevant clinical trials based on the results. These are clinical trials for treatments currently being developed. The health practitioner may assess if clinical trials are suitable and make a decision in consultation with the patient.

5 LIMITATIONS AND RISKS OF TUMOUR TISSUE CGP

5.1 The technology used by Genseq for Onco CGP testing is AVENIO Tumor Tissue CGP V2 in house assay along with Illumina NextSeq 550Dx instrument for sequencing. Associated automated platforms are used for bioinformatics and variant assessment.

5.2 In the case of a "no clinically actionable findings were identified" result or a "failed result", the absence of an identified disease-causing variant does not exclude the possibility of a clinically relevant finding for the patient. It is possible that a particular variant may not be recognised as relevant to the patient's tumour type as the clinical implications of this variant may not be known at the time of the testing and report. Genseq relies on information which is currently available in the healthcare literature and scientific databases, and selected bioinformatic platforms. It is also possible that the classification of variants may change in the future due to improvements in scientific understanding and/or new knowledge / information being discovered and published to the scientific community. Future testing would involve the submission of a new sample and Test Request Form.

5.3 This test is not intended to detect cancer related germline variants. The genomic variants and biomarkers identified are interpreted as somatic (found in tumour cells) findings and not as germline (inherited). This test is not able to differentiate between somatic and germline findings. It is therefore possible that some variants found within the tumour tissue may be a germline (inherited) variant, however, the presence of a germline variant cannot be confirmed without further testing.

5.4 The patient's health practitioner is responsible for the patient's clinical management including the interpretation of the test results, recommendations regarding healthcare treatment or participation in any clinical trials, recommendation of any appropriate further testing and future clinical management. Test results should always be interpreted in the context of clinical diagnosis and findings, family history, and other relevant laboratory data. Inaccurate, or incomplete information may lead to misinterpretation of the results.

5.5 The assay may not detect some genetic abnormalities, including variants in untargeted regions of the genome and variants in regions with suboptimal coverage. The assay limit of detection for small variants is 1% mutant allele frequency where minimum coverage is 250X and all quality metrics are passed.

5.6 Although genetic test results are usually accurate, several sources of error are possible, including clinical misdiagnosis of a condition, inaccurate clinical information concerning the patient provided to Genseq and sample mislabelling or contamination and limitations of the genetic and genomic data available to Genseq including that provided by Roche in the databases maintained by them.

5.7 Further testing based on the submission of a new sample may be required in the future, including for the reasons and in the circumstances outlined above, and these are decisions to be made by the patient's health practitioner in consultation with the patient as part of the patient's future management.

Last updated: 6th November 2025