XING
GENOMIC SERVICES

Enabling precision treatment outcomes by empowering you and your medical team.

Patient Information Sheet

1 Introduction

The Patient Information Sheet provides you with information regarding the process of genetic testing, how it may potentially benefit you and your current cancer diagnosis and the risks involved. Should you choose to proceed with genetic testing, this document will outline how your results will be shared with you and who else may have access to these results.

Please consult with your treating doctor regarding the genetic testing process and ensure that all of your questions are suitably answered before proceeding.

If you decide to proceed with the genetic test, you will be asked to sign the Consent Form with your doctor.

By signing the Consent Form, you are telling us that you:

- Understand what you have read
- Consent to have the test performed
- Agree to pay for the cost of the test
- Consent to the use of your personal and health information

2 About XING Genomic Services

At XING Genomic Serivces, we are dedicated to improving the treatment outlook of people with cancer. We are a team of health professionals who believe in a personalised approach to both diagnosis and treatment. We exist to empower patients and their medical teams to make as informed a decision about their treatment as possible.

We are an Australian-owned and operated company located in Brisbane, Australia. Your test will be performed by our diagnostic pathology laboratory which is accredited for human pathology testing by NATA (National Association of Testing Authority) and the Royal College of Pathologists of Australasia (RCPA) under ISO15189/NPAAC.

> *"The XING team lives and breathes to empower and improve the quality of life for those dealing with cancer."*
>
> Dr Paul Mainwaring - Chair and Co-Founder

3 Background

Our bodies are made up of cells containing deoxyribonucleic acid, more commonly known as DNA. We inherit our DNA from our parents and it is unique to us as individuals. DNA contains a code to help your body function and when a person develops cancer it is due to an alteration in that code. Most of the time these alterations are caused by damage to the DNA. This damage may have been caused by external factors such as sunburn, cigarette smoke, alcohol use and/or diet choices. Alternatively, it may have occurred as part of the aging process; DNA is constantly replicating and repairing itself and, as we age, errors that lead to alterations are more likely to occur. Some of the time, alterations are inherited from a parent. Whatever the cause of the alteration, it is important to understand that each alteration is unique and will respond to treatment differently.

Cancer is currently treated based on a physical diagnosis. For example, two lung cancer patients will likely receive similar treatment options as they both have the same origin of disease. However, by identifying the unique alterations in the DNA of each patient's cancer cells we can gain a better understanding of the genetic causes to each individual's lung cancer. Two different and targeted treatment plans can then be developed based on an understanding of what each patient's alteration is most likely to respond to. This is known as precision medicine.

We can attempt to identify the alterations in your individual cancer through a cancer gene panel test. This is a process where we sequence (identify the unique code of your cancer cell's DNA) based on an analysis of a sample from your tumour. We can also sequence non-cancer cells from your blood in order to improve the quality of the information about your cancer cell DNA alterations.

Genes are made up of DNA. Approximately 4000 genes have been linked to disease and of those, approximately 1000 have been linked to cancer. At XING Genomic Services, we offer genetic testing of a subset of these cancer genes which may reveal clinically actionable alterations that can be treated with precision medicine. Additionally, the test may inform your eligibility for a clinical trial.

Cancer genetic tests must be ordered by your treating doctor, your doctor will receive a copy of your results and consult with you regarding the outcome.

4 What are the potential risks of having a cancer gene panel test performed?

If you consent to providing a blood sample, the only physical risks are the same as those involved with any blood test. You may experience pain, swelling, bruising, or infection at the site of where your blood is collected. You may feel dizzy or faint.

There is a financial risk. It is possible that you may not see a benefit in having carried out the test if the results do not identify a potential treatment or clinical trial. It is also possible that the test may take too long to be useful if we are unable to use your blood or tissue samples and need to acquire new ones.

It is possible to test a poor-quality tumour and possibly obtain some information knowing that there may be some missing information. This will be presented in the report, however as the test result will be interpreted in the context of what is known at the time of testing, it is important to understand that there is a risk that a potentially treatable alteration may be missed.

Currently, in Australia genetic testing does not affect your ability to obtain private health, disability or life insurance, although waiting periods or increased premiums may apply if you have a pre-existing condition. If this changes in the future, there is a risk that your ability to obtain new insurance may be affected because you undertook genetic testing.

Finally, there is a risk that your test results may have an impact on your family which could cause you, or your family members, distress. This is discussed further below.

There may be additional risks that are not known at this time.

5 Will my test results be relevant to my family?

Genetic testing can potentially identify inherited alterations that are associated with a risk of cancer and may be clinically actionable. These alterations may have implications for your family members, particularly your direct descendants.

Your family members may want to know the results of your test to determine if they may have relevance to them. Other family members may not want to know the results of the test. You may feel obligated, uncomfortable, or conflicted in sharing this information with your family members. This can upset family dynamics.

To help you manage this, you will be given the choice of whether you want your blood sample tested or not. Testing your blood sample will determine if any genetic alterations were inherited and could be passed onto future generations. Not testing your blood sample will prevent the laboratory from determining if the genetic changes found in your tumour were inherited. Not testing a blood sample will also complicate the interpretation of any alterations present in your tumour by reducing the accuracy of the test and, therefore, the potential usefulness and the benefit of the test.

You may decide to test your blood sample and not share the test results with your family. This will ensure the test's maximal usefulness and value to your cancer treatment. If you decide to have your blood sample tested and an inherited genetic alteration is identified, you will be advised to seek a referral to a Clinical Genetics Service. They will be able to guide you through the issues and options.

The results will not be given to family members without your permission, even if the results may be of relevance to them. This would be a breach of your privacy and confidentiality. Your doctor will advise you if there are findings related to your family, unless you elect not to have your blood sample tested. You will need to decide if you wish to share this information with your family.

Due to the nature of the data generated by this cancer gene panel test, data may be generated that can identify alterations that are not related to your cancer. However, the laboratory will restrict its analysis to the regions of your genome that are linked to cancer. This will minimise the possibility of finding unexpected genetic alterations that are not directly relevant to your cancer or relevant to the risk of family members developing cancer. This data will be stored in the laboratory, but it will not be analysed and interpreted and the results will not appear on the test report.

These measures will decrease the chances of an unanticipated finding that is not related to the purpose of the test. It is important to remember the aim of the test is to discover new options to help you fight your cancer.

Implications of findings that are associated with your family members is a secondary outcome of the test. In these circumstances, consideration of your family members should be of secondary importance. However, this cannot be completely ignored. These considerations should not delay or prevent you from having the test done for your personal benefit.

In accordance with applicable privacy and other relevant laws, you have the right to request access to your information collected and stored by the testing laboratory. You have the right to request any information you disagree with to be corrected.

6 What steps are taken to maintain confidentiality?

To protect your privacy and confidentiality, XING Genomic Services has put various measures in place.

By signing the Consent Form, you are agreeing to the below processes.

a) Assignment of a Laboratory ID Number

It is vital that the identity of your samples, DNA, and data are tracked throughout the testing process. The results of your test will be given to your doctor and could potentially affect your clinical management. XING Genomic Services has implemented strict practices and procedures to establish traceability and prevent sample mix-ups. Your blood and tissue samples will be allocated unique Laboratory Identification Numbers to allow your samples, DNA, and data to be tracked throughout the testing process and re-linked to you when the test is complete.

This allows healthcare professionals involved in performing the test to link the unique ID numbers to your name at any stage to ensure that your doctor receives your results and can act on them with confidence. These processes are secure and mandated by the National Pathology Accreditation Advisory Council (NPAAC) and are audited by the National Association of Testing Authority (NATA) and the Royal College of Pathologists of Australasia (RCPA).

b) Assignment of a Participant Identification Number

A Participant Identification Number will be used by our researchers to link you to your Laboratory ID Number and analyse the data for your test. The codes that link your ID numbers with your name are kept in a separate secured area with authorised access only. This ensures that researchers are not able to re-link your Participant or Laboratory ID Numbers to your name or identity. This process is known as de-identification and allows our researchers to collect, compile and analyse aggregated data from all patients without exposing their identity, thereby protecting your privacy and confidentiality.

c) Restricted access to your samples

Your samples will be securely stored in a DNA repository at the XING Genomic Services laboratory in accordance with NPAAC and NATA requirements.

d) Restricted access to results

Your test results will be securely stored in password-protected computer databases at the XING laboratory. Unless the law requires it, your individual results will not be given to anyone who is not listed above.

7 Can I withdraw my consent?

You may withdraw your consent to testing at any time. If you withdraw your consent before your tumour and/or blood samples have been analysed, your DNA samples will be destroyed. If you withdraw your consent after your samples have been analysed, your samples and any material or data extracted from them will be destroyed. No further analysis of your samples will occur. It will not be possible to withdraw any published data.

8 What am I being asked to do?

You are being asked whether you agree to the testing of your tumour and blood samples. DNA will be extracted from these samples and tested. The tumour sample will most likely be taken from a biopsy samples. The total amount of blood collected for this genetic study is 10 mL (approximately two teaspoons). Blood is not required for this test, but we recommend providing it as it does improve the quality of the test result.

9 Will the results of this test be published?

The aggregated results from the laboratory may be published in scientific and medical literature. The published data may refer to individual case studies but will be anonymised. Your identity will never be revealed.

10 How much do the cancer gene panels cost?

ASSAY COMPARISON TABLE

TEST	GENES ANALYSED	DESCRIPTION	COST	
			TUMOUR SAMPLE	PAIRED NORMAL SAMPLE
Homologous Recombination Deficiency (HRD), genetic test	27 genes	Multi-gene test that analyses the entire coding regions of 27 key genes involved in homologous recombination repair deficiency. Aimed at breast, ovarian, prostate, and pancreatic cancers.	AUD1500	(included)
Homologous Recombination Deficiency (HRD), epigenetic tests	1 or 2 genes	One or two gene test that analyses epigenetic alterations in the BRCA1 or RAD51C promoter region. These alterations are also involved in homologous recombination repair deficiency. Aimed at breast, ovarian, prostate, and pancreatic cancers.	AUD500 per gene	N/A
Solid Tumour Panel (STP)	47 genes involved in solid tumours	Multi-gene test that analyses hotspot alterations considered to be driving mutations in solid tumours; includes hotspots in 47 genes involved in colorectal, thyroid, melanoma, NSCLC, pancreatic, GIST, and glioma.	AUD1500	N/A

11 Payment

Authority for full payment will need to be provided in advance. Full payment will be made on completion of the testing and payment can be made in two stages:

Stage 1: Logistical component of sample retrieval and determining the suitability of the sample for further analysis.

Stage 2: Cancer gene panel test and bio-informatics reporting completed.

Should the sample retrieved be unsuitable for analysis, you will only incur the logistical costs of retrieval.

12 Am I eligible for a rebate?

No. The cost of the XING Genomic Services cancer gene panel tests are not covered by Medicare, the Federal or State Governments or Health Insurance providers. You will not be eligible for any rebates.

The cost of the cancer gene panel tests are an entirely out of pocket expense.

13 How does it work?

1. Download the XING Genomic Services Test Request Form, Patient Information Sheet, and Patient Consent Form located in the Request Forms page.

2. Once you have read through the Patient Information Sheet, complete the Patient Consent Form in the presence of your treating doctor– ensuring both you and the doctor sign the form.

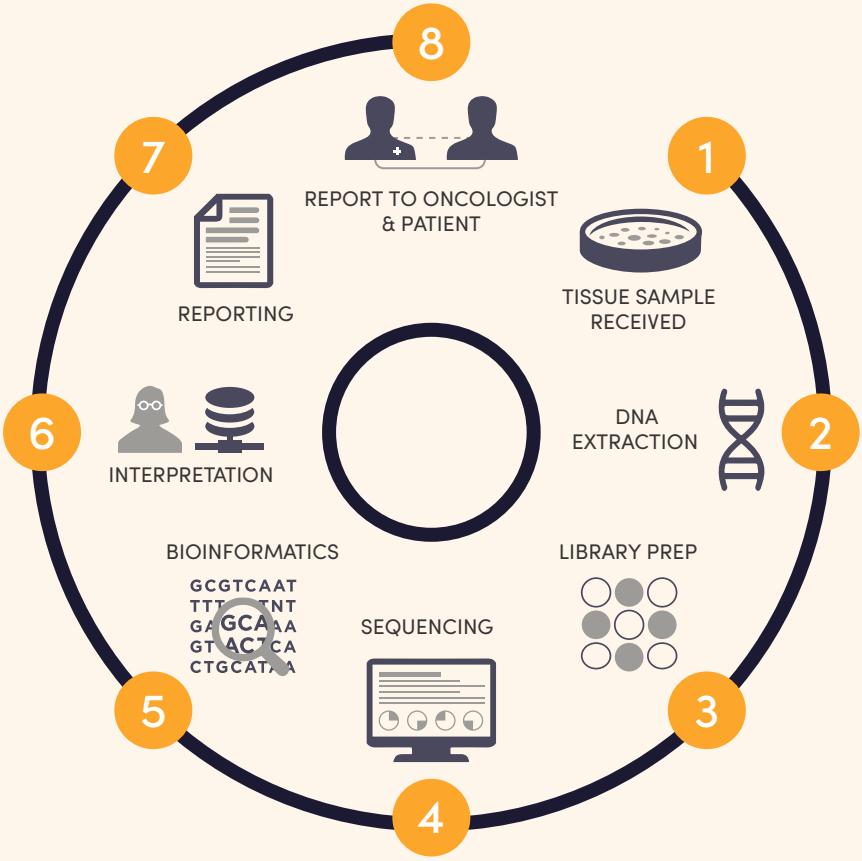
3. Your treating doctor must sign and complete the Test Request Form in full. The Test Request Form must always be completed by a clinician.

4. Once completed, send the Test Request Form and signed Patient Consent Form along with other required attachments (e.g. pathology report) to XING Genomic Services. The sample retrieval process will begin once all completed forms are received by XING Genomic Services.

5. Once samples have been retrieved and they have arrived at XING Genomic Services, you and your treating doctor will be notified that the testing process will commence.

6. Your personalised test result will be sent to your treating doctor within 2 weeks from receipt of samples and your doctor will notify you.

14 XING Genomic Services Reporting Process



15 Whom should I contact if I need more information or help?

If you have any further questions, please call XING Genomic Services on **(07) 3186 6740** or email **clinicallab@xingtech.com.au .**

Visit **www.xingtech.com.au** for more information

XING Genomic Services

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