



# Informed consent for genetic testing

Patient name: \_\_\_\_\_

Test requested: \_\_\_\_\_

Date of birth: \_\_\_\_\_

Sex: \_\_\_\_\_

Clinical status of patient:  Affected  Unaffected

**This test raises specific issues that warrant consideration. The following matters have been discussed with the patient.**

- ▶ The reason for testing, as well as the benefits and limitations.
- ▶ The medical significance of the likely test outcomes has been discussed, including the possibility of an abnormal result, equivocal result and uninformative result.
- ▶ The laboratory's report reflects the knowledge available at the time the test is reported; the laboratory does not undertake to provide updated interpretations unless requested by the patient's doctor.
- ▶ The test may provide genetic information that does not relate to its primary purpose.
- ▶ Genetic tests of members of a family may confirm or exclude supposed relationships, e.g. paternity, in that family.
- ▶ The test result may have implications for other family members. The patient is aware that family members should be advised of these implications.
- ▶ The test result will be provided to the recipients specified on the request form and, if requested, a genetic counsellor. The sharing of this information with other parties will be by agreement between the patient and the patient's doctor.
- ▶ Under Australian law, there is potential legal provision for a patient's doctor to release confidential genetic information to relatives under strict conditions and without the consent of the patient.
- ▶ The laboratory will not release this information unless required by law or with written consent of the patient (or delegate).
- ▶ This test result may have implications for any new or revised applications for some types of insurance.
- ▶ The patient's genetic sample will be stored for the mandatory period specified by national regulatory agencies; the laboratory does not undertake to store the sample for a longer period.
- ▶ The patient is aware of the cost of this investigation and agrees to pay this amount, if not covered by Medicare.
- ▶ Errors in sample collection and labelling can result in an incorrect test report. The patient has been advised to review and confirm the details on the sample collected for the test.
- ▶ The patient may choose to withdraw from this test process before the test has been reported. Cancellation fees may apply.

## Release of genetic test results

I give permission for Sonic Genetics to contact me when the test has been reported to discuss the implications and communication of relevant information with the family (if potentially relevant).

YES

NO

I give permission for Sonic Genetics to provide the test result on request to a relevant healthcare professional involved in the care of a family member (genetic relative of the person tested).

YES

NO

If I cannot be contacted within 4 weeks once the test has been reported, I give permission for the test result to be provided to the person nominated below.

YES

NO

Name: \_\_\_\_\_ Phone: \_\_\_\_\_ Relationship to patient: \_\_\_\_\_

## Consent by Patient

I confirm that the issues listed above have been discussed with me in a way I understand. I agree to have the nominated test.

PATIENT SIGNATURE \_\_\_\_\_ Date \_\_\_\_\_

## Consent by Parent or Guardian (if under 18 years)

I confirm that the issues listed above have been discussed with me in a way I understand. I agree for the nominated test to proceed.

PARENT/GUARDIAN NAME & SIGNATURE \_\_\_\_\_ Date \_\_\_\_\_

## Clinician/Genetic counsellor

I confirm that the issues listed above have been discussed and that the Patient/Parent/Guardian agrees to the test proceeding.

CLINICIAN/GENETIC COUNSELLOR NAME \_\_\_\_\_ Date \_\_\_\_\_

## Interpreter

Was an interpreter present? YES  NO

Name \_\_\_\_\_

Signature \_\_\_\_\_

Employee ID/Provider \_\_\_\_\_

# Issues to consider before you sign this consent form

This is a brief review of issues you should consider before agreeing to have a genetic test. The headings below are included on the consent form overleaf.

- ▶ **The reason for testing, as well as the benefits and limitations.**  
You should have had an opportunity to discuss the test with an appropriately qualified healthcare professional and clarify any questions you have regarding what could be expected. This may include the provision of additional information, such as patient brochures.
- ▶ **The medical significance of the likely test outcomes has been discussed, including the possibility of an abnormal, equivocal and uninformative result.**  
The laboratory may identify variations in your genetic code which have different significance for your health or family. An *abnormal* variation (or 'mutation') can cause a genetic condition. A *benign* variation has no medical consequences. The significance of an *equivocal* variation is unknown; there is simply not enough known about the variation to draw a conclusion. The presence of a *benign* variation, an *equivocal* variation or a normal gene sequence is an *uninformative* result, i.e. it does not identify the underlying cause of the patient's condition. An *uninformative* result does not exclude an underlying genetic cause.
- ▶ **The laboratory's report reflects the knowledge available at the time the test is reported; the laboratory does not undertake to provide updated interpretations unless requested by the patient's doctor.**  
Genetic knowledge is changing rapidly. We will provide your doctor with the most reliable information that we can at the time of your test, but research in the future may change our understanding of your result. We do not promise to contact you if this should happen, but we would be pleased to review your result on request from your current or future doctor.
- ▶ **The test may provide genetic information that does not relate to its primary purpose.**  
The relationships between genes and conditions are not straightforward. A condition may be due to any one of a number of genes, and any gene can potentially cause multiple conditions. Your genetic test may identify a mutation that causes a condition that is different from that experienced by you or your family.
- ▶ **Genetic tests of members of a family may confirm or exclude supposed relationships, e.g. paternity, in that family.**  
Genetic tests in families are done on the assumption that the relationships between relatives being tested have been correctly described to the doctor and laboratory. If the results of the test are inconsistent with this description, we will advise your doctor of this.
- ▶ **The test result may have implications for other family members. The patient is aware that family members should be advised of these implications.**  
If you are diagnosed as having a familial condition, or having a familial mutation, it is essential that this information be shared with your immediate genetic relatives. Such information can be life-saving.
- ▶ **The test result will be provided to the recipients specified on the request form and, if requested, to a genetic counsellor.**  
This result may also be available to other healthcare providers involved in caring for you. We will not provide this information to anyone else outside of Sonic Healthcare without your consent. It will be for you and your doctor to manage the release of this information to other parties.
- ▶ **Under Australian law, there is potential legal provision for a patient's doctor to release confidential genetic information to relatives under strict conditions and without the consent of the patient.**  
We encourage patients to share important genetic information with their relatives. Changes to Section 95AA of the Privacy Act 1988 (Cth) potentially give your doctor (not Sonic Genetics) authority to release your information to help reduce the risk of harm to relatives. The doctor is not obliged to do so, and must comply with strict national guidelines.
- ▶ **The laboratory will not release this information unless required by law or with written consent of the patient (or delegate).**  
The laboratory may be required to release a test result to a third party without your consent, e.g. in response to a legitimate subpoena, or as a requirement under Government Health regulations.
- ▶ **This test result may have implications for any new or revised applications for some types of insurance.**  
If you make an application for new or revised personal insurance, the insurance company has a right to know what you know. You are legally obliged to share this information if asked. Please note that this does not apply to private health insurance.
- ▶ **The patient's genetic sample will be stored for the mandatory period specified by national regulatory agencies; the laboratory does not undertake to store the sample for a longer period.**  
Your sample may be stored for a longer period as part of routine laboratory quality control procedures. We would not use or release your sample for other purposes without your consent.
- ▶ **The patient is aware of the cost of this investigation and agrees to pay this amount, if not covered by Medicare.**  
Our prices are presented on our website. You may be eligible for a Medicare rebate for some tests. Please discuss any concerns regarding price with your doctor.
- ▶ **Errors in sample collection and labelling can result in an incorrect test report.**  
The patient will review and confirm the details on the sample collected for the test. Please check the labelling of your sample at the collection centre. It must be labelled correctly.
- ▶ **The patient may choose to withdraw from this test process before the test has been reported.**  
We reserve the right to charge you for costs we have incurred in handling your sample, even if the test is cancelled.