



# Consent Form for diagnostic testing

**The result of a genetic test can raise important and unexpected issues that should be considered by a doctor/clinician and the patient before the test is ordered.**

This consent form may assist in this discussion. It is recommended for use in diagnostic genetic testing of an affected patient who may have a heritable disorder.

Patient name:

Test requested:

Reason for test:

## This test raises specific issues that warrant consideration.

The following matters have been discussed with the patient:

- ▶ The medical significance of the likely test outcomes has been addressed, 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.
- ▶ The test result may have implications for other family members. The patient is aware that family members should be advised of these implications.
- ▶ Genetic tests of members of a family may confirm or exclude supposed relationships e.g. paternity, in that family.
- ▶ The test result will be provided to the recipients specified on the request form and to a genetic counsellor. The sharing of this information to other parties will be by agreement between the patient and the 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 (excluding 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.
- ▶ The patient is aware of the cost of this investigation and agrees to pay this amount.
- ▶ The patient may choose to withdraw from this test process after consultation with genetic counsellor. Cancellation fees may apply.
- ▶ Errors in sample collection and labelling can result in errors in a test report. The patient will review and confirm the details on the sample collected for the test.

## Patient

I agree that the issues listed above have been discussed, I agree to have the nominated test under these conditions and I agree that a copy of the results will be sent to the genetic counsellor.

× PATIENT NAME

Date

## Clinician/genetic counsellor

I agree that the issues listed above have been discussed and that the patient agrees to have the test under these conditions.

× CLINICIAN/GENETIC COUNSELLOR NAME

Date

# 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 medical significance of the likely test outcomes has been addressed, including the possibility of an abnormal result, equivocal result 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 disorder. 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 disorder. 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 disorders are not straightforward. A disorder may be due to any one of a number of genes, and any gene can potentially cause multiple disorders. Your genetic test may identify a mutation that causes a disorder that is different from that experienced by you or your family.
- ▶ **The test result may have implications for other family members. The patient is aware that family members should be advised of these implications.** This is important. If you are diagnosed as having a familial disorder, or having a familial mutation, it is essential that this information be shared with your immediate genetic relatives. Such information can be life-saving.
- ▶ **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 will be provided to the recipients specified on the request form and to a genetic counsellor.** This result may also be available to other doctors 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 the Federal Privacy Act (2006) 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 (excluding health 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 when requested by the laboratory.** Our prices are presented on our website. Please discuss any concerns regarding price with your doctor.
- ▶ **The patient may choose to withdraw from this test process after signing this form, but may still remain liable for the agreed test cost.** We reserve the right to charge you for costs we have incurred in handling your sample, even if the test is cancelled.
- ▶ **Errors in sample collection and labelling can result in errors in a 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 has to be labelled correctly!