

Stick patient's label

**Molecular Diagnosis Centre
Department of Laboratory Medicine**
**INFORMED CONSENT FOR
GENETIC/GENOMIC TESTING**
Information for patient and/or family

1. The cause of the condition affecting you or your family member(s) is thought to be genetic. Therefore, a molecular genetic test has been recommended to evaluate this.
2. This form of testing is voluntary, and your consent is required to proceed. You should take time to ask all questions you may have in order to make an independent personal decision. If you wish to think this over, you may make another appointment. After you have given consent, you may withdraw your consent at any time or postpone the disclosure of the results. Fees should be paid prior to the tests and are non-refundable.
3. The following issues would have been explained to you and you have had the opportunity to clarify any queries you may have prior to you giving consent:
 - a. The major medical facts of the disorder (diagnosis, prognosis, treatments available, inheritance pattern, and risks of recurrence in the family) and the nature and purpose of the genetic test (prenatal testing, germline testing or somatic testing) and alternatives to genetic testing.
 - b. The implications of genetic testing (effectiveness, limitations, potential risks and benefits, implications to other family members, detection of non-paternity, possibility of psychological stress, adverse effect on certain insurance).
 - c. The sample required: A blood sample will be collected via venepuncture (5 to 20 mL depending on the age of the person and test required). Possible side effect includes faintness, inflammation, pain, bruising, or bleeding at the site of blood taking. Other sample types such as cheek swab, body fluid or tissue may be used depending on your doctor and the indication of the genetic test.
 - d. The authorised test procedure for molecular genetic testing: Nucleic acid will be extracted, analysed and stored.
 - e. The remaining DNA may be used for validation, process development, medical education and/or quality control after de-identification of all protected personal information. No tests other than those authorised will be performed.
 - f. Results: A direct molecular genetic test will detect the presence of particular variant(s) with a sensitivity and specificity of approximately >95%. The accuracy of an indirect genetic test (including genetic linkage analysis) varies, depending on the condition and type of test involved. In rare circumstances, an incidental finding that is not related to the diagnosis originally considered e.g., non-paternity may be detected. Your data will be stored and your anonymized data may be shared on clinical databases, e.g., ClinVar, which may be used for research and clinical purposes.
 - g. Confidentiality: Your test results are strictly private and confidential and the results will be reported only to the referring physician –named on the requisition form. Your test results will be part of your medical records and will be protected as required under the Personal Data Protection Act of Singapore and other relevant legislations such as the Private Hospitals and Medical Clinic Act.
 - h. In order to help you understand the test results, you may be referred to a genetic counsellor, geneticist or a doctor who is well versed in the reported condition for further management and genetic counselling.



**National University
Hospital**

REFERRING PHYSICIAN:

I, _____(name) have explained the above and answered the patient's / guardian's questions satisfactorily.

Signature: _____ MCR no: _____

Date: _____

PATIENT:

I, _____(name)
_____(NRIC/passport no.) have read and understood the above information. I have been informed by _____
and consent to molecular genetic testing for _____(condition/gene).

Signature: _____ Date: _____

PATIENT GUARDIAN:

I, _____(name), _____
(NRIC/passport no) have read and understood the above information. I have been informed by _____
and consent to molecular genetic testing for _____
(condition/gene) to be done on my child/ward
_____(name), _____(NRIC/passport no).

Signature: _____ Date: _____