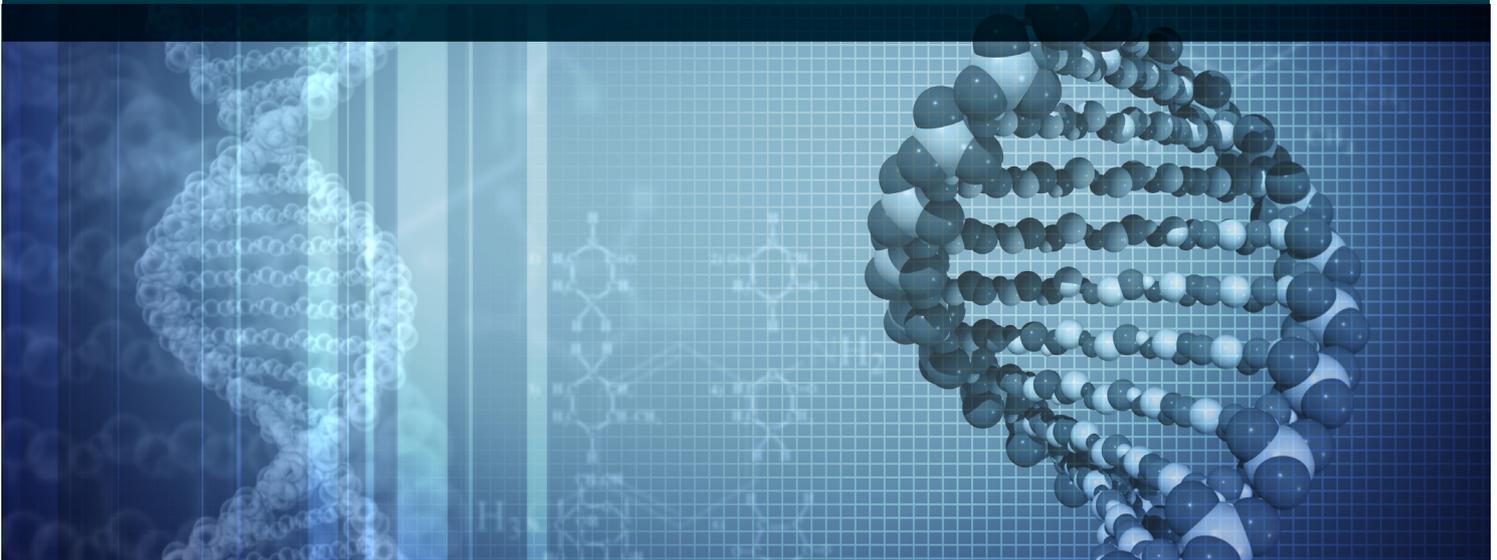




Australian Government
National Health and Medical Research Council

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Understanding Direct-to-Consumer
Genetic DNA Testing
An Information Resource for Consumers

WORKING TO BUILD A HEALTHY AUSTRALIA

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UNDERSTANDING DIRECT-TO-CONSUMER GENETIC DNA TESTING – AN INFORMATION RESOURCE FOR CONSUMERS

FOR INFORMATION PURPOSES ONLY

Introduction

Direct-to-consumer (DTC) genetic tests can be purchased directly by you, often without the involvement of your doctor. DTC genetic tests can be used to establish parentage or to trace one's ancestry. Some DTC genetic tests may also have health implications.

In recent years, there has been a significant increase in the number of DTC genetic tests that you can purchase. NHMRC has developed this information resource to help you better understand this type of testing.

What is a DTC genetic test?

DTC genetic tests are usually purchased over the internet. You will be asked to send a sample such as saliva or a swab from the inside of your mouth to a laboratory. The laboratory will extract DNA (your genetic material), analyse the sample and provide the results directly to you, often without the involvement of your doctor.

Important issues to consider if you are planning to purchase a DTC genetic test

You might like the idea of DTC genetic tests because they don't involve a blood test, are simple to do and can allow you to keep the results private. Such a test might also appeal to your curiosity to discover more about yourself. Whatever the case may be, it is important to know that while DTC genetic tests can be taken for fun or personal interest, there are factors such as test accuracy and privacy, which you should consider if you, or someone you know, is thinking about having a DTC genetic test.

Are DTC genetic tests accurate?

The NHMRC encourages individuals interested in undertaking a DTC genetic test to exercise caution. Companies offering DTC genetic tests are mostly located overseas, even if the initial delivery address is within Australia. All medical testing laboratories in Australia are required to be accredited. To ensure quality and reliability, you should ensure that overseas laboratories are accredited to international standards equivalent to the Australian standards. Some DTC genetic tests also come with disclaimers that release the company from responsibility for inaccurate test results. You should carefully read the terms and conditions of your chosen DTC genetic testing company.

Medicare benefits are not available for DTC genetic tests

How useful are DTC genetic tests?

Your DNA is inherited from your parents and it contains genetic information that contributes to your development and how you function. DTC genetic tests look for specific variations (changes in your DNA) which have been linked to diseases or personal characteristics. There are many variations that are yet to be understood. In the case of tests that claim to assess your risk of developing a particular disease, the variations tested often only have a small influence on your overall risk of developing a disease. This is because your genes are not the only things that determine your future health, and even genetic tests that meet high quality laboratory standards may not provide you with any medically useful information. Lifestyle, environmental factors and normal ageing have an important influence on your risk of developing a disease.

Before undertaking any genetic test – DTC or not – it might be worthwhile to consider whether the information the test provides will make a difference to you. Is there something that you hope to be able to do after getting the test result that you can't do now? In the case of health-related predictive tests, for example, unless you are willing to make changes to your lifestyle based on the test results, such tests may not be of much benefit to you.

If you have a concern about your current health status or how it might change in the future, consult your doctor

Your doctor will be able to give you advice on the most appropriate tests for you. For example, standard, non-genetic clinical tests, such as tests to measure cholesterol levels, can already provide you with a good indication of your future risk of heart disease.

Talking to your family can also be a useful way of finding out more about your family's medical history. Should you have a family history of a condition you are concerned about, speak to your doctor.

If genetic testing is suggested by your doctor you will be referred to a clinical setting in Australia. You will be provided with genetic counselling and doctors will interpret the results of your testing. More information on this kind of testing, known as medical genetic testing, is available from the NHMRC website.

DTC genetic tests should not be used as the sole basis for clinical decision making and health care

Protection under Australian law is limited for purchase of DTC genetic tests

Australian law protects your privacy rights for services provided in Australia, but these protections do not apply to overseas services.

Some DTC companies also sell information about you and your genetic results to pharmaceutical and other companies. It is important to understand that DTC genetic testing companies may ask if your sample and results can be used for other purposes, such as research.

You should carefully read the privacy policies and terms and conditions to make sure these are acceptable to you

Possible implications for obtaining risk rated insurance

In Australia private health insurance is not “risk rated”. This means that everyone can access health insurance and that insurers cannot discriminate on the basis of health status, claiming history or other factors.

However, products such as life insurance or income protection insurance are “risk rated”. When applying for such risk rated insurance products, you have to declare whether you have any conditions that may increase your health risks. You are also required to declare whether you (or your immediate biological relatives) have had any genetic testing for which the result is known. This is another reason why you need to be confident in the quality and accuracy of any genetic test that you have. You should make sure that the testing laboratory is accredited to Australian (or equivalent international) standards.

Possible implications for your family members and certain groups

Obtaining your own genetic test results may reveal unexpected information about you and your blood relatives. Similarly, genetic test results on your blood relatives may reveal information about you. You or your relatives may or may not wish to know this information. You may wish to discuss this with your family and relatives. It is important to consider this before you access DTC genetic testing.

There may also be social, cultural and legal issues that need to be considered for certain groups. For example, Aboriginal and Torres Strait Islander Peoples believe that information about heritage is often collectively owned. In this situation, a decision to be tested may have implications for an entire community.

What if you have already purchased a DTC genetic test?

DTC genetic tests that are not medically relevant (such as tests of your ancestry) can be a source of interesting information. However, if your DTC genetic test result includes any medically relevant information, you should visit your doctor with the results and tell him or her why you wanted to have the test done. Your doctor can then decide whether further action is needed. This may include actions such as repeating or confirming the genetic testing in another accredited laboratory, referral to a genetics specialist or genetic counsellor, or arranging for additional non-genetic tests.

Additional information on genetics:

- Direct-to-Consumer Genetic Testing: A Statement from the National Health and Medical Research Council <http://www.nhmrc.gov.au/guidelines/publications/g9>
- Medical Genetic Testing: Health Information for You and Your Family <http://www.nhmrc.gov.au/guidelines/publications/ps3>
- Use and disclosure of genetic information to a patient’s genetic relatives under Section 95AA of the Privacy Act 1988 (Cth) – Guidelines for health practitioners in the private sector <http://www.nhmrc.gov.au/guidelines/publications/pr3>
- Discussing Direct-to-Consumer Genetic DNA Testing with Patients: A Short Guide for Health Practitioners <http://www.nhmrc.gov.au/guidelines/publications/g7>
- The Provision of Direct-to-Consumer Genetic Tests: Guiding Principles for Providers <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-path-bestpractice>