Position Statement

HGSA Position

It is the position of the HGSA that both individuals and health care professionals/providers should be supported to make informed choices about online DNA testing. This means adequate and ongoing education and resources should be available for consumers and health care professionals before, during and after testing. Health care professionals/providers should be appropriately trained, have relevant experience and should be able to demonstrate (or provide evidence of) a current certification in their field of practice.

Within the Australian health care system there are regulatory and accreditation standards for genomic tests and processes. When individuals are concerned about their health they should consult with an appropriate health care professional to decide whether an online DNA test is appropriate and discuss how useful test results could be in making health-related decisions.

Online DNA testing

Genomic tests\(^1\) are becoming widely available beyond clinical settings. The term online DNA test describes a range of different commercially-available tests that are marketed to individuals and can be accessed directly, either online or through health care professionals/providers who do not practice within clinical genetics services. Examples are provided in Appendix 1.

People who seek genomic information may include: members of the public, patients, physicians and other health care professionals/providers.

In this Statement we focus on genomic information provided by companies offering online DNA testing where the test is one or more of the following: (a) marketed directly to individuals/consumers; (b) available to individuals/consumers outside a clinical context; and (c) available to individuals/consumers in a clinical context but in the absence of clinical indications to suggest testing is necessary. This Statement aims to be specific to the legal,

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\(^1\) Although the term genetics has been used in the past, these tests look at more than one gene to include a range of genomic variants. Thus, throughout this statement, we will use the term genomic to include both genetic (single gene) and genomic (more than one gene) tests.
regulatory and social context of Australia. However, many of the ideas presented here offer approaches that could be useful in Australasia².

**HGSA position**

The HGSA recognises that online DNA tests are (and will most likely continue to be) available to people in Australia.

It is the position of the HGSA that both individuals/consumers and health care professionals/providers should be supported to make informed choices about online DNA testing. This means adequate and ongoing education and resources should be available for individuals/consumers and health care professionals/providers before, during and after testing. Health care professionals/providers should be appropriately trained, have relevant experience and should be able to demonstrate (or provide evidence of) a current certification in their field of practice.

Results from online DNA tests may have an impact on an individual’s perception of their health and/or wellbeing, or the relationship between an individual/consumer and a health care professional/provider and/or the wider health system. To best support and engage with individuals considering (or who have already undergone) online DNA testing, discussions about the following key issues are encouraged:

- **Choosing to test and choosing an appropriate test:** online DNA tests and their results can be used for a range of purposes; it is important to consider whether testing is appropriate and how to choose a test that will provide the information sought.
- **Expectations:** individuals can overestimate the utility of results from online DNA tests; it is important to have realistic expectations of the actions that can be taken.
- **Support and information:** online DNA tests and results can be hard to interpret and understand. It is important to know where, and with whom, help can be obtained.
- **Actionability:** online DNA test results may be more useful personally than medically. Individuals should consult with their health care professional/provider if they are concerned about their health; and to seek advice and confirm any health-related online DNA test results from an accredited provider before acting on the results.
- **Family implications:** online DNA tests generate information both about the individual being tested but also about their family members. Family members may not want this information generated and may not want to know this information. Discussions within families about these issues are encouraged.
- **Evidence:** some online DNA test results and related associations may not be supported by strong scientific evidence.
- **Rapid change:** online DNA testing is still a developing field where the evidence base is incomplete. An individual's results may differ between companies and/or change over time as new information becomes available.
- **Regulation:** online DNA tests may be offered by Australian and overseas companies. The availability of these tests and the techniques used may differ from laboratory to laboratory, and the level of regulation applied to testing companies differs in each country. This makes it difficult to ensure that results are analysed consistently by different testing laboratories and this may raise questions about reliability of results. It is also difficult to determine what legislation or regulation will be applied to how DNA

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² This statement is specific to Australia and does not try to provide recommendations applicable to New Zealand or the Australasia region due to different regulatory frameworks around direct-to-consumer advertising and health system diversity.
can, or has been, stored, shared and used; this may depend on the country in which the company and laboratory are based – as that could be in different locations.

- **Privacy and commercial interests**: data generated from online DNA testing may be shared or sold to other research groups or companies. It is important to be aware of how much the Australian law can protect an individual's data, and when it cannot.
- **Discrimination**: online DNA test results may affect an individual's ability to obtain risk-rated insurance products, such as life insurance.

Within the Australian health care system there are regulatory and accreditation standards for genomic tests and processes. When individuals are concerned about their health they should consult an appropriate health care professional to decide whether an online DNA test is appropriate and discuss how useful test results could be to make health-related decisions.

**Who pursues online DNA testing and why?**

Individuals may seek online DNA testing for a variety of reasons. These can include:

- To explore health (explain past illnesses, present conditions/diagnoses or predispositions to conditions that have not yet manifested)
- to explore or understand family history (health and/or genealogical)
- to explore personal genetics and genomics in more depth, such as to satisfy curiosity
- to guide lifestyle or fitness regimes.

Individuals seeking online DNA testing will do so for different reasons and they may have more than one reason. In addition, individuals may encourage relatives and friends to undergo testing. It is the position of the HGSA that testing should only be done by individuals who are well-informed, aware of the risks and benefits of testing, and able to consent for their DNA to be collected and analysed.

There is also an emerging market for DNA testing in children. This includes testing in newborns and young children for a range of health conditions and other characteristics. It is the position of the HGSA that decisions about having a child tested should be well-informed, based on good scientific data, and that parents should have access to support and counselling about this decision or the results. For further information about genetic testing in newborns and children, please refer to the following HGSA positions statement: Supplemental, Online (Direct to Consumer) DNA Newborn Screening Tests.

**How do people access online DNA testing?**

Online DNA tests can be accessed in a number of ways.

- Individuals can order tests directly from an online DNA testing company – the increasingly common ‘direct-to-consumer’ pathway. In this approach, the test is ordered online, the individual collects their own DNA sample or with the assistance of a pathology service) and the DNA samples are sent directly to a laboratory for processing. The laboratory may, or may not, be located Australia.
- An online DNA testing company may strongly recommend and/or require that the test is ordered on the individual’s behalf by a trained health care professional/provider or by a health care professional/provider who may be an employee of/on contract with the testing company.
• Individuals may initiate the test through their health care professional/provider, who refers to the online DNA testing company or orders the online DNA test on behalf of the individual.

**What format are online DNA test results available in?**

Information from online DNA testing companies can be returned to individuals in a variety of formats. Different approaches to testing and/or interpretation are used by each company. This can range from providing raw genomic data to interpreted reports generated by the company, containing results of analyses for the traits and variants they include in their product. This means individuals could potentially receive different or conflicting results and/or advice from different companies. Currently, there are no regulations or rules governing how samples are collected and processed by online DNA testing companies, or how data should be analysed or interpreted.

Increasingly, online DNA testing company websites and independent online applications (‘apps’) offer consumers ways to do further analyses on their raw or unprocessed DNA data. These apps enable people to generate results for purposes beyond the remit of the original test. For example, results of online ancestry DNA testing could be used to generate health-related information with potential consequences for the individual, their own health care decisions, and their family’s health care decisions.
Appendix 1: Alternate terms for ‘online DNA testing’ and types of tests currently available.

<table>
<thead>
<tr>
<th>Commonly used Internet search terms</th>
<th>Types of tests available*</th>
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<tbody>
<tr>
<td>At-home genetic/genomic test*</td>
<td>Ancestry</td>
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<tr>
<td>Consumer-directed genetic/genomic test*</td>
<td>Cancer predisposition (e.g., breast cancer)</td>
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<tr>
<td>Consumer genetic/genomic test*</td>
<td>Carrier testing (including reproductive (preconception and early pregnancy) testing/screening)</td>
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<tr>
<td>Direct-to-consumer (DTC) genetic/genomic test*</td>
<td>Dating compatibility</td>
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<tr>
<td>DNA health test*</td>
<td>Drug response/ pharmacogenetics/ pharmacogenomics</td>
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<tr>
<td>DNA testing or gene test*</td>
<td>Ethnicity-based ancestry testing</td>
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<tr>
<td>Genetic/genomic wellness test*</td>
<td>Food intolerances/ preferences (including wine)</td>
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<tr>
<td>Health and wellbeing DNA test*</td>
<td>Health-related risk predictions (e.g., Alzheimer’s disease, blood conditions, heart conditions, other inherited/ genetic conditions)</td>
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<tr>
<td>Internet genetic/genomic test*</td>
<td>Health and wellbeing testing</td>
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<tr>
<td>Online DNA test*</td>
<td>Non-invasive prenatal testing</td>
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<tr>
<td>Online genetic/genomic test*</td>
<td>Nutrition and/or wellness</td>
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<tr>
<td>Personal genetic/genomic test*</td>
<td>Paternity</td>
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<td></td>
<td>Personality</td>
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<td></td>
<td>Skincare</td>
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<td></td>
<td>Sporting ability/fitness/aptitude in adults or children</td>
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<td></td>
<td>Talents</td>
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* This list of test types is likely to change as the field continues to develop.
* denotes a wildcard term, so searching for ‘test*’ would include test, tests and testing.

Related position statements
Pre-symptomatic and Predictive Testing for Children and Young Adults
Supplemental Online (Direct to Consumer) DNA Newborn Screening Tests

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