## IVD %

## IVD Australia Position Statement

## **Direct To Consumer Genetic Testing**

A number of companies are currently advertising and selling genetic tests using a model of provision called 'direct to consumer' (DtC), which sits outside the traditional healthcare system. Autonomy, empowerment, prevention, convenience and privacy are the principle keywords in the marketing of these DTC genetic tests. New genomic knowledge has shifted the focus from testing for specific and rare monogenic diseases to genetic and genomic testing to predict the risk of developing common complex diseases. The DtC model allows consumers to obtain information about disease risks, carrier status and other health-related traits, as well as non-health related information, such as ancestry and genealogy, and often occurs without medical supervision.

<u>Testing</u>: **IVD Australia** position on quality use of diagnostic services includes *selecting diagnostic and treatment options* wisely based on the best available evidence and the consumer's needs. Therefore, when used correctly, **IVD Australia** supports the right of consumers to access genetic testing via the direct-to-consumer channel provided the tests are (1) conducted by an accredited Australian laboratory under appropriate supervision; and (2) interpreted by a properly trained professional.

**IVD Australia** supports pathology testing products that are included on the Australian Register of Therapeutic Goods (ARTG) and/or are included in the Global Diagnostics Market Statistics survey. These pathology tests are scientifically validated.

<u>Interpretation</u>: Clinical geneticists play an important role in the provision of genetic testing, interpretation of test results and explanation of test results to families and doctors. This is because of the novelty and complexity of genetic testing and the associated ethical issues. In Australia, there are organisations that can help consumers to find an approved clinical geneticist (for example, <a href="http://www.hgsa.org.au/asgc/find-a-genetic-counsellor">http://www.hgsa.org.au/asgc/find-a-genetic-counsellor</a>).

## For more information on ...

the importance of pathology to your health, visit <u>Know Pathology Know Healthcare</u> marketing of pathology tests to consumers, visit <u>IVD Australia Code of Conduct</u> the Role of the Clinical Geneticist, visit <u>the Centre for Genetics Education</u> genetic testing, visit <u>Lab Tests Online<sup>AU</sup></u> genetic counselling and what is a clinical geneticist, read this <u>fact sheet</u>

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About IVD Australia: IVD Australia is the peak body representing the IVD Industry, including companies who manufacture and supply in vitro-diagnostics in Australia. In vitro, literally "in glass" diagnostics (IVDs) comprise the instruments and reagents that are used to perform pathology tests requested by General Practitioners, specialist Physicians and other healthcare practitioners. These tests are generally performed in accredited Public and Private pathology laboratories across Australia, but IVDs also include point-of-care tests such as HIV test kits, blood glucose meters for diabetes testing and home pregnancy test kits.

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