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| <p>Guidelines Referenced</p> | <ol style="list-style-type: none"> 1. https://ghr.nlm.nih.gov/primer/dtcgenetictesting/directtoconsumer 2. https://www.acmg.net/docs/ACMG%20Revised%20DTC%20Statement%20AOP%20Dec%202015.pdf 3. https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests 4. https://www.nature.com/articles/gim2012165.pdf?origin=ppub |
| <p>What is direct-to-consumer genetic testing?</p> | <p>Most of the time, genetic testing is done through healthcare providers such as physicians, nurse practitioners, and genetic counselors. Healthcare providers determine which test is needed, order the test from a laboratory, collect and send the DNA sample, interpret the test results, and share the results with the patient. Often, a health insurance company covers part or all of the cost of testing. (1)</p> <p>Direct-to-consumer genetic testing is marketed directly to customers via television, print advertisements, or the Internet, and the tests can be bought online or in stores. Customers send the company a sample (generally saliva) and receive their results directly from a secure website or in a written report. Dozens of companies currently offer direct-to-consumer genetic tests for a variety of purposes. The most popular tests use genetic variations to make predictions about health, provide information about common traits, and offer clues about a person's ancestry. The number of companies providing direct-to-consumer genetic testing is growing, along with the range of health conditions and traits covered by these tests. (1)</p> |
| <p>Major types of direct-to-consumer genetic tests</p> | <p>Disease risk and health The results of these tests estimate your genetic risk of developing several common diseases, such as celiac disease, Parkinson disease, and Alzheimer disease. Some companies also include a person's carrier status for less common conditions, including cystic fibrosis and sickle cell disease. A carrier is someone who has one copy of a gene mutation that, when present in two copies, causes a genetic disorder. The tests may also look for genetic variations related to other health-related traits, such as weight and metabolism (how a person's body converts the nutrients from food into energy). (1)</p> <p>Ancestry or genealogy The results of these tests provide clues about where a person's ancestors might have come from, their ethnicity, and genetic connections between families. (1)</p> <p>Kinship The results of these tests can indicate whether tested individuals are biologically related to one another. For example, kinship testing can establish whether one person is the biological father of another (paternity testing). The results of direct-to-consumer kinship tests, including paternity tests, are usually not admissible in a court of law. (1)</p> <p>Lifestyle The results of these tests claim to provide information about lifestyle factors, such as nutrition, fitness, weight loss, skincare, sleep, and even your wine preferences, based on variations in your DNA. Many of the companies that offer this kind of testing also sell services, products, or programs that they customize on the basis of your test results. (1)</p> |



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| Points to consider prior to performing direct-to-consumer genetic testing | <p>With many companies offering direct-to-consumer genetic testing, it can be challenging to determine which tests will be most informative and helpful to you. When considering testing, think about what you hope to get out of the test. Some direct-to-consumer genetic tests are very specific (such as paternity tests), while other services provide a broad range of health, ancestry, and lifestyle information.</p> <p>Because there is currently little regulation of direct-to-consumer genetic testing services, it is important to assess the quality of available services before pursuing any testing. In addition, before choosing a direct-to-consumer genetic test, find out what kinds of health, ancestry, or other information will be reported to you. Think about whether there is any information you would rather not know. In some cases, you can decline to find out specific information if you tell the company before it delivers your results.</p> <p>The American College of Medical Genetics recommends that patients consider these issues prior to having genetic testing performed:</p> <ul style="list-style-type: none"> • A knowledgeable healthcare professional should be involved in the process of ordering and interpreting a genetic test. • The consumer should be fully informed regarding what the test can and cannot say about his or her health. • The scientific evidence on which a test is based should be clearly stated. • The clinical testing laboratory must be accredited by CLIA, the State and/or other applicable accrediting agencies. • Privacy concerns must be addressed. (2) |
| Medical management following direct-to-consumer genetic testing | <p>From the FDA to those who have had direct-to-consumer testing:</p> <p>Do not change or stop taking any medicine based on a report from a genetic test you took on your own. Discuss the results of the genetic test with your health care provider, including whether the medication label includes information on how to use genetic information to determine dosage, and whether your health care provider recommends changes to your treatment. Medicine should always be taken as prescribed by your health care provider. (3)</p> |
| MTHFR | <ul style="list-style-type: none"> • The American College of Medical Genetics does not recommend that testing of the two common polymorphisms of this gene be performed (C677T, A1298G) • Many articles describing association with various conditions but causation not proven • Possible concern: homozygosity for the C677T variant may reduce enzyme levels <ul style="list-style-type: none"> ○ Check homocysteine level ○ If normal then no further testing or management ○ If elevated then consider taking vitamin B6, vitamin B12, and folate |
| When to Refer | <p>The Fullerton Genetics Center generally does not evaluate patients who have had direct-to-consumer testing. We would recommend that the patient initially contact the genetic testing company, who may have genetic counselors available to discuss the results. The lab may also direct you to a company that provides genetic counseling services.</p> |



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| Co-management Strategy (as appropriate) | Specialist scope of care Available as needed to answer questions regarding this testing. | Primary care scope of care Discussion of the above topics with the patients before and after testing as appropriate. |
| Return to Primary Care Endpoint | Following results of the testing. | |