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Oncologist-approved cancer information from the American Society of Clinical Oncology

PDF generated on June 21, 2016 from
http://www.cancer.net/navigating-cancer-care/cancer-basics/genetics/direct-consumer-genetic-testing

Direct-to-Consumer Genetic Testing [1]

This section has been reviewed and approved by the Cancer.Net Editorial Board [2], 01/2014

Key Messages:

- Direct-to-consumer (DTC) genetic tests, which can be bought online or without talking with a doctor, are used to estimate a person's risk of developing specific diseases, such as cancer.
- DTC genetic tests either look for specific inherited mutations (changes) linked to known hereditary cancer syndromes or common inherited genetic variations that are usually associated with only minor increases in cancer risk.
- Talking with your doctor or a genetic counselor can help you decide if genetic testing is right for you and help you understand the results.
- Because no at-home genetic test is currently approved by the U.S. Food and Drug Administration (FDA), these tests may not be accurate, and people should consider using quality-controlled genetic testing provided by a health care professional.

You may have seen at-home genetic tests advertised on the Internet, television, or elsewhere that can be used to check your risk for specific diseases, including cancer. These tests are called direct-to-consumer (DTC) genetic tests. DTC genetic test kits include instructions for collecting a saliva or blood sample that is mailed to a laboratory for testing. Test results are then provided to you by mail, online, or over the phone.

DTC genetic tests for cancer

Genetic tests [3] analyze a person's genes, chromosomes, or proteins to look for specific changes that may increase a person's risk of developing a disease, such as cancer. In general, inherited mutations (genetic changes passed down from parents to their children) cause about

5% to 10% of all cancers.

The most common type of genetic tests for cancer look for specific genetic mutations that are linked to known hereditary cancer syndromes [4], such as *BRCA1* and *BRCA2* mutations and hereditary breast and ovarian cancer [5] or *APC* mutations and familial adenomatous polyposis [6]. This type of genetic test is typically requested by a doctor; however, there are some DTC genetic tests for mutations of these genes. Knowing you have one of these mutations may lead to increased screening and even preventive surgery for some people.

Some DTC genetic tests for cancer look for common genetic changes known as variants. These variants are often associated with very minor increases in risk for particular types of cancer, such as prostate, colon, and breast cancer. In general, having one or more of these variants adds such a low risk that doctors do not use the information to make medical decisions. As a result, a doctor is unlikely to recommend this type of test.

Understanding the results

Genetic tests do not diagnose, cure, treat, or prevent cancer. They only help predict the likelihood that a person will develop a certain type of cancer during his or her lifetime. Therefore, if a mutation or gene variant is found, it does not mean cancer will definitely develop. Similarly, if your test is negative (no mutation or variant found), you can still develop the disease. Genetics are only one part of your health picture. Environmental factors, lifestyle choices, and your medical history also play a role in cancer development.

If you are considering using a DTC genetic test, it is important to talk with your doctor or a genetic counselor about what the results of the test can tell you about your cancer risk. The American Society of Clinical Oncology and many other reputable health organizations recommend that all genetic testing be accompanied by genetic counseling. Genetic counseling should occur before testing and address your risk for cancer, whether testing is right for you, and other options for determining your cancer risk. If you choose to have a genetic test, a genetic counselor can help you understand your results and what they mean for you and your family members. Learn more about what you can expect when meeting with a genetic counselor [7].

In 2011, the FDA recommended that certain types of DTC genetic tests, including those that predict whether a person is at risk for a disease, be made available only with the involvement of a physician or genetic specialist.

Advantages and disadvantages of DTC genetic testing

DTC genetic tests may provide greater access to genetic testing and enable some people to take a more proactive role in their health. However, many concerns about these tests have been raised, including:

Reliability. No DTC genetic test has currently been approved by the FDA, and state regulations

vary. That means there are often no independent checks on the quality or accuracy of these tests. Tests from different companies on samples from the same individual have given very different risk estimates for the same disease. Some companies' tests are not scientifically validated, and you could make health decisions based on inaccurate information.

Interpreting test results. The results of DTC genetic tests are sent directly to you. Unfortunately, it is not always easy to determine what these results mean for your future health, and the information may be incomplete. By not fully understanding the results, you may be unnecessarily worried or get a false sense of reassurance. Also, you may not know what steps to take next. Your doctor may be unable to provide guidance to you on the results of an unproven test.

Cost. DTC genetic tests range in cost from a few hundred dollars to over a thousand, and they are not covered by public or private health insurance plans.

Confidentiality. The confidentiality of genetic tests provided by a doctor is protected under a federal law called the Health Insurance Portability and Accountability Act (HIPAA). DTC genetic tests do not have this protection. Each company that sells them has its own privacy policy.

Choosing a DTC genetic test

If you are considering a DTC genetic test, find out as much about the company and its test procedures and policies as possible. Look for a company that:

Uses a laboratory that meets testing guidelines established by the state in which you live, as well as current federal regulations. Laboratories that perform genetic testing are subject to the federal Clinical Laboratory Improvement Amendments (CLIA) or even more rigorous state requirements. For example, in New York, DTC genetic testing is illegal if performed on a New York State resident by a laboratory not approved by the New York State Department of Public Health.

Has a clear policy related to the confidentiality, privacy, and security of your genetic information. Carefully review a company's policy on sharing the information it collects for commercial or research purposes. Also, confirm it has a security procedure in place that will protect any personal information shared via email or over the Internet.

Provides support and information from trained health care providers. Look for a company that offers genetic counseling and information about coping with psychological and emotional reactions you may experience after receiving your test results, plans for notifying family members, and plans for follow-up care after testing.

Does not make extreme or unproven claims. Some companies claim that once they analyze your risk, they can reduce it with products such as dietary supplements or customized meal plans. No valid research supports these claims.

Questions to ask

Before buying and using a DTC genetic test, talk with your doctor, nurse, genetic counselor, or another health care professional about your reasons for wanting the test and to make sure you understand the advantages and disadvantages of testing and how to interpret the results. You may want to ask:

- Will genetic testing provide me with any useful information about my risk of developing cancer?
- What type of genetic test do you recommend?
- What is the difference between a DTC genetic test and a test ordered by a doctor?
- Do you recommend testing for cancer variants that may have little effect on my cancer risk?
- Is DTC genetic testing reliable?
- Can you help me interpret the results of a DTC genetic test? If not, could you refer me to someone who can?
- How do I find a genetic counselor?

More Information

The Genetics of Cancer [8]

Understanding Cancer Risk [9]

Sharing Genetic Test Results With Your Family [10]

Podcast: ASCO's Policy Statement Update on Genetic Testing for Cancer Susceptibility, with Kenneth Offit, MD, MPH [11]

Additional Resources

National Human Genome Research Institute: Regulation of Genetic Tests [12]

Federal Trade Commission: Direct-to-Consumer Genetic Tests [13]

Links

[1] http://www.cancer.net/navigating-cancer-care/cancer-basics/genetics/direct-consumer-genetic-testing
[2] http://www.cancer.net/about-us
[3] http://www.cancer.net/node/24895
[4] http://www.cancer.net/node/24905
[5] http://www.cancer.net/node/18922
[6] http://www.cancer.net/node/18852
[7] http://www.cancer.net/node/24907
[8] http://www.cancer.net/node/24897
[9] http://www.cancer.net/node/25007

[10] http://www.cancer.net/node/24906
[11] http://www.cancer.net/sites/cancer.net/files/Genetic_Testing_for_Cancer_Susceptibility.mp3
[12] http://www.genome.gov/10002335
[13] http://www.consumer.ftc.gov/articles/0166-home-genetic-tests