

## At-Home Genetic Tests:

# A Healthy Dose of Skepticism May Be the Best Prescription

**C**ould a simple medical test tell you if you are likely to get a particular disease? Could it evaluate your health risks and even suggest a specific treatment? Could you take this test in the privacy of your home, without a doctor's prescription or guidance?

Some companies say genetic testing can do all this and more. They claim that at-home genetic testing can screen for diseases and provide a basis for choosing a particular diet, dietary supplement, lifestyle change, or medication. They sell their tests in supermarkets and drugstores, and they advertise their services in print, on television, and online.

The Federal Trade Commission (FTC) wants you to know the facts about the direct-to-consumers marketing of genetic tests. According to the Food and Drug Administration (FDA), which regulates the manufacturers of genetic tests; and the Centers for Disease Control and Prevention (CDC), which promotes health and quality of life, some of these tests lack scientific validity, and others provide medical results that are meaningful only in the context of a full medical evaluation. The FDA and CDC say that because of the complexities involved in both the testing and the interpretation of the results, genetic tests should be performed in a specialized laboratory, and the results should be interpreted by a doctor or trained counselor who understands the value of genetic testing for a particular situation.

# Facts for Consumers

## GENES AND GENETIC TESTS

Inside the cells of your body, chromosomes carry your genetic blueprint. Your chromosomes, which are passed to you by your parents, contain genes made of DNA (deoxyribonucleic acid). Your genes determine characteristics like eye color or height, and contribute to your chances of getting certain diseases.

Genetic tests examine genes and DNA to see if they indicate particular diseases or disorders. Several different types of tests are available. Some look at the number and shape of chromosomes to see if there are obvious abnormalities. Others look for small unusual portions of individual proteins or sections of DNA. Typically, these tests require a blood sample or a swab from inside the cheek. In “at-home” tests, the sample is collected at your home and then sent to a laboratory for analysis. Prices of at-home genetic tests range from \$295 to \$1200.

## INTERPRETING TEST RESULTS

The results of genetic tests are not always “black and white.” That makes interpretations and explanations difficult. In most cases, diseases occur as a result of interaction between our genes and the environment — for example, our lifestyle, foods we eat, elements we are exposed to such as sunlight, and tobacco. The interaction between these factors in contributing to health and disease can be very complicated. Even health care experts are just beginning to understand these issues. That’s why it is important to gather and analyze this information with a qualified healthcare provider so you can be sure genetic data is accurate and correctly used.

Most genetic tests look at only a small number of the more than 20,000 genes in the human body. A positive result means that the testing laboratory found unusual characteristics or changes in the genes it tested. Depending on the purpose of the test, a positive result may confirm a diagnosis, identify an increased risk of developing a disease, or indicate that a person is a carrier for a particular disease. It does not necessarily mean that a disease will develop, or if it does, that the disease will be progressive or severe.

A negative result means that the laboratory found no unusual characteristics or changes in the genes it tested. This could mean that a person doesn’t have a particular disease, doesn’t have an increased risk of developing the disease, or isn’t a carrier of the disease. Or it could mean that the test missed the specific genetic changes associated with a particular disease.

In short, the FDA and CDC say that genetic testing provides only one piece of information about a person’s susceptibility to disease. Other factors, like family background, medical history, and environment also contribute to the likelihood of getting a particular disease. In most cases, genetic testing makes the most sense when it is part of a physical exam that includes a patient’s family background and medical history.

## COMPANY CLAIMS

Be wary of claims about the benefits these products supposedly offer. Some companies claim that at-home genetic tests can measure the risk of developing a particular disease, like heart disease, diabetes, cancer, or Alzheimer’s. But the FDA and CDC say they

aren't aware of any valid studies that prove these tests give accurate results. Having a particular gene doesn't necessarily mean that a disease will develop; not having a particular gene doesn't necessarily mean that the disease will not.

Some companies also may claim that a person can protect against serious disease by choosing special foods and nutritional supplements. Consequently, the results of their at-home tests often include dietary advice and sales offers for "customized" dietary supplements. But the advice rarely goes beyond standard sensible dietary recommendations. The FDA and CDC say they know of no valid scientific studies showing that genetic tests can be used safely or effectively to recommend nutritional choices.

Be skeptical of claims that the tests can assess a person's ability to withstand certain environmental exposures, like particular toxins or cigarette smoke. The FDA and CDC aren't aware of any valid scientific studies that show that genetic tests can be used to predict whether a person can withstand environmental exposures.

Recently, some companies have claimed their at-home tests can give information about how a person's body will respond to a certain treatment, and how well people will respond to a particular drug. This claim is based on current medical research that shows differences in drug effectiveness based on genetic make-up. But, say federal experts, while these tests may provide some information your doctor needs or uses to make treatment decisions for a specific condition, they are not a substitute for a physician's judgment and clinical experience.

### IF YOU'RE CONSIDERING AN AT-HOME GENETIC TEST

According to the FDA and CDC, at-home genetic tests aren't a suitable substitute for a traditional healthcare evaluation. Medical exams that include conventional laboratory tests like blood chemistry and lipid profiles are a more appropriate starting point for diagnosing diseases and assessing preventive measures. Nevertheless, if you are considering using an at-home genetic test:

- Talk to your doctor or healthcare practitioner about whether it might provide useful information about your health, and if so, which test would be best. Make sure you understand the benefits and limits of any test before you buy it — or take it.
- Ask your doctor or a genetic counselor to help you understand your test results. Most companies that sell at-home genetic tests do not interpret the results.
- Discuss the results of your test with your doctor or healthcare practitioner before making dietary or other health-related decisions. Genetic test results can be complex and serious. You don't want to make any decisions based on incomplete, inaccurate, or misunderstood information.
- Protect your privacy. At-home test companies may post patient test results online. If the website is not secure, your information may be seen by others. Before you do business with any company online, check the privacy policy to see how they may use your personal information, and whether they share customer information with marketers.
- While most other home-use medical tests undergo FDA review to provide a reasonable assurance of their safety and

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effectiveness, no at-home genetic tests have been reviewed by the FDA, and the FDA has not evaluated the accuracy of their claims.

## FOR MORE INFORMATION

The **Federal Trade Commission** works for the consumer to prevent fraudulent, deceptive, and unfair business practices in the marketplace and to provide information to help consumers spot, stop, and avoid them. To file a complaint or to get free information on consumer issues, visit [ftc.gov](http://ftc.gov) or call toll-free, 1-877-FTC-HELP (1-877-382-4357); TTY: 1-866-653-4261.

The **Food and Drug Administration** is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA also is responsible

for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health. For more information from the FDA, call toll-free 1-800-INFO-FDA. Copies of press releases and consumer alerts are available from FDA's website at [www.fda.gov](http://www.fda.gov).

The **Centers for Disease Control and Prevention** is one of the 13 major operating components of the Department of Health and Human Services, which is the principal agency in the United States government for protecting the health and safety of all Americans and for providing essential human services, especially for those people who are least able to help themselves. For further information about CDC, call toll-free 1-800-CDC-INFO or e-mail [cdcinfo@cdc.gov](mailto:cdcinfo@cdc.gov).

*Produced in cooperation with the Food and Drug Administration (FDA)  
and the Centers for Disease Control and Prevention (CDC)*

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