

HEALTH

At-Home DNA Tests Are Here

Doctors Warn Amateurs of Undue Alarm, Risky False Assurance

By HELEN PEARSON

DAVID STEENE ORDERED a do-it-yourself home DNA test last year after reading about such kits on the Web. The results persuaded the 42-year-old London lawyer that he had a serious risk of getting cancer.

His solution? Regular exercise and daily portions of broccoli.

For years, genetic testing was available only at specialist clinics dealing with rare genetic diseases. Now, a growing number of small companies in the U.S. and Britain are pitching at-home gene tests to consumers. Some promise to reveal a person's susceptibility to cancer, heart disease or other maladies. Others provide advice on diet and lifestyle, tailored to the consumer's genetic profile.

Mr. Steene bought his DNA test for the equivalent of \$170 from Sciona Ltd. of Havant, England. Sciona says its test analyzes nine genes that break down toxins or help absorb vitamins, providing information on how well a person's body performs those functions.

GeneLink Inc., based in Margate, N.J., has a test that analyzes several genes that have been linked to eye disease, cancer and aging. "We can tell you where you are weak genetically," says John DePhillipo, chief executive of

Gene Science by Direct Mail

A sampling of at-home DNA tests that are on the market

COMPANY	ROLE OF GENES	ADVICE	COST
Sciona (U.K.)	Detoxification, alcohol metabolism, vitamin absorption	Diet, exercise, supplements	\$170
GeneLink (U.S.)	Aging and disease	Nutrition and skin-care regime	\$200
Myriad Genetics (U.S.)	Breast and ovarian cancer (by prescription)	Diagnosis of increased risk	\$300-\$2,680
Genelex (U.S.)	Drug metabolism	Adjust drugs and dosage	\$250
DNA Testing Place (U.S.)	Microbes involved in chronic disease	Left to doctor	\$350-\$400

Source: The companies

The panel has been asked to devise recommendations on regulations to protect both consumers and doctors who lack the time and expertise to judge the merits of new tests. And at the U.S. Department of Health and Human Services, an advisory committee on genetic testing two years ago recommended increased oversight over genetic tests.

Still, some people are eager to try out such tests. A Sciona spokeswoman says the company has sold more than 500 kits since launching the product in August 2001. Sciona is in talks with potential part-

Mr. Raees says that the company's sales of such tests are running at around \$250,000 a year and that it plans to launch new ones for serious genetic diseases, including sickle-cell anemia, this summer.

Myriad Genetics Inc. of Salt Lake City, another test maker, plan to try out a direct-advertising campaign in Denver and Atlanta in September to promote a test for breast and ovarian cancer, a spokesman says. Myriad, however, requires customers to visit to a physician to take the test.

Peter Dycke, a 49-year-old electrician in Palm Springs, Calif., says he consulted his doctor before using a kit from Genelex Corp. of Redmond, Wash. The \$250 test identifies people whose genes block metabolism of common drugs such as codeine, ibuprofen, Prozac and Viagra. Mr. Dycke takes a range of medications for a heart condition, asthma and acid reflux. He says he and his doctor used the results to adjust their doses and timing. "I could see how my body deals with the drugs I'm taking," he says. Genelex says it has sold several hundred tests in the past year.

Not all such companies are successful. Bioheart Inc., Fort Lauderdale, Fla., says it spent nearly \$3 million developing and marketing a genetic-risk test for heart disease, including Reader's Digest ads direct to consumers—but pulled out of the market after the campaign yielded only 30 sales in two years.

Risk assessments for complex diseases can be misleading, because many genes and lifestyle factors are involved, so do-it-yourself tests are 'more harmful than useful,' a researcher says.

GeneLink. NuGenix LLC, a direct-selling company based in Berwyn, Pa., has agreed to buy 15,000 tests from GeneLink, with plans to sell them for \$200. NuGenix will offer "genetically customized" nutritional supplements, such as personalized vitamin pills, alongside the results.

Not surprisingly, such tests are drawing fire from health experts. Doctors say the home-kit approach may fail to properly predict risk for diseases, leaving users falsely worried or falsely reassured. Risk assessments for complex diseases such as cancer or heart disease can be misleading, because many genes and lifestyle factors are involved, says Professor Paolo Vineis, a cancer researcher at the University of Torino, Italy. He thinks the tests are "more harmful than useful."

Consumers groups fret that results may fall into the hands of employers, insurers or marketers, posing a threat to users' privacy.

Partly due to such criticism, a dozen British retailers decided against stocking Sciona's tests in June after a campaign by GeneWatch UK, a group concerned with the risks of genetic engineering, and the Consumer's Association, another British group. Body Shop International PLC offered the kits at 11 British stores for six months but recently stopped stocking them because of weak sales, a spokeswoman says.

The British government recently called on the Human Genetics Commission, a panel of scientists, to launch an inquiry into the risks of such DNA tests.

ners to help it launch the tests in the U.S., she says.

Mr. Steene doesn't understand why the tests should cause a fuss and says he is eager to learn everything his genes can tell him. "I can't understand why anyone wouldn't want to know," he says. In his case, he says, that information spurred him to go on a serious high-fiber diet and lose more than 100 pounds.

Users of do-it-yourself test kits typically scrape a few cells from inside the cheek and mail the sample to a lab, or else attend a clinic for a blood sample. Within a few weeks, the kit maker responds with lifestyle or medical advice.

Helen Wallace of GeneWatch UK thinks such marketing is dangerous. "We're concerned there seems to be something of a marketing strategy to expand medication to people who are currently well," she says.

Trying to deflect criticism, Sciona and GeneLink are careful to distance themselves from making absolute estimates of disease risk. Others, such as DNA Testing Place of Atlanta, shy away from giving advice on the basis of their results. "We don't want to get involved in diagnosis," says Saeed Raees, chief executive officer of DNA Testing Place. The company's tests analyze blood samples for genetic traces of bacteria and viruses suspected of triggering chronic diseases such as asthma and chronic-fatigue syndrome. They leave consumers and their doctors to work out whether to diagnose the disease or alter existing treatment.