Why You Should Be Careful About 23andMe's Health Test

By **The Editorial Board**, www.nytimes.com
February 2nd, 2019

Last month, the DNA-testing company 23andMe secured Food and Drug Administration approval for a new screening for gene-based health risks. Along with celiac disease, Alzheimer's, Parkinson's, breast cancer and several other medical conditions, the company can now screen clients for two mutations that have been linked to colorectal cancer.

But "F.D.A.-approved" does not necessarily mean "clinically useful." 23andMe relies on much simpler technology than tests that you'd get at your doctor's office. As a result, the company's tests cannot tell you much about your actual risk of developing the diseases in question.

Here's how those tests work — and why you should interpret them with caution.

They read your gene.

You can think of your genes as long text documents. The words are your genetic code. Genetic mutations are like typos — imperfections that scientists can spot with some scrutiny.

They compare your gene against a reference gene to find problems.

DNA tests are scientists' way of proofreading your genes — which they accomplish by comparing them against a gene that's considered healthy.

23andMe's test reviews a handful of locations.

Genetic tests search for specific anomalies that have been linked to a higher risk for a given disease. Breast cancer, for example, is sometimes linked to errors in a gene known as BRCA. Some of these errors sharply increase a woman's risk of developing the disease. But other errors in the BRCA gene increase the risk of getting breast cancer by only a small amount.

Instead of examining the entire BRCA gene, 23andMe's breast cancer screen looks at just a handful of places in the gene where mutations are known to appear. That's like proofreading a document by looking at only a handful of letters.

The 23andMe test can miss other possible mutations.

The particular BRCA mutations that 23andMe tests for are rare: Just two out of 100 women with Ashkenazi Jewish heritage have them, and just one out of 1,000 women in the rest of the population have them.

Meanwhile, there are more than 1,000 other BRCA mutations that contribute to your breast cancer risk. The 23andMe test doesn't look for any of them.

That makes it difficult to draw conclusions from the 23andMe BRCA test. Just because you test negative for the few mutations that 23andMe screens for doesn't mean that you won't get breast cancer. It doesn't even mean that you won't get breast cancer caused by a BRCA mutation.

There are more comprehensive BRCA tests on the market. They require a doctor's prescription, but they are much more useful, because they look at the entire gene. That means they give you a much better picture of the role that this gene might play in your overall cancer risk.

23andMe's other genetic health risk tests have the same shortcomings as its BRCA test: They look for only a handful of errors that may or may not elevate your risk of developing the disease in question. And they don't factor into their final analysis other information, like family history. (Not everyone with a given mutation will go on to develop the disease.) So the results will not tell you much about your actual health risks.

The F.D.A. used to bar 23andMe from selling tests that purport to give health information because such tests were considered a flimsy predictor of health. Their results were also deemed too difficult for consumers to interpret on their own. The agency has since reversed that decision — in part because it has found the company's tests to be accurate and its disclaimers clear.

23andMe has said that its health tests can raise awareness about various medical conditions and empower consumers to take charge of their health information. But doctors and geneticists say that the tests are still more parlor trick than medicine. Most of the diseases 23andMe tests for, including breast and colorectal cancer, are not primarily genetic. If you're concerned about genetic susceptibility to cancer, Alzheimer's or other serious conditions, it's best to see a doctor.