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How to decipher direct-to-consumer genetic testing

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Jul 25, 2017


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For \$99 to several hundred dollars, patients can order a range of personalized health information about genetic health risks, without involving a doctor or insurance company. A recent U.S. Food and Drug Administration (FDA) reversal now makes direct to consumer (DTC) genetic testing possible on a larger scale.

In April, the FDA allowed 23andMe, the leader in the DTC genetic testing market, to sell tests for 10 diseases or conditions, providing consumers direct access to certain genetic risk information. This reversal of the FDA's previous position banning such consumer access paves the way for more companies to market genetic testing to consumers.

Consumers seek DTC genetic testing for a variety of reasons. "The easiest narrative is that you want to find out you're at risk for something and hopefully prevent it to improve your health," says Robert C. Green, MD, MPH, professor of medicine and director of the Genomes2People Research Program at the Broad Institute and Harvard Medical School.

But many patients also seek DTC testing out of curiosity and to explain, not predict, according to a 2017 study in *Public Health Genomics*, which surveyed 1,648 consumers from two leading genetic testing companies. “A lot of the customers had an illness already and hoped to explain it better to themselves,” says Green, a co-leader of this study. 

In a 2012 *Journal of Genetic Counseling* survey of 1,048 DTC genetic testing customers, 28% had discussed their results with a healthcare professional.

To date, 23andMe is the only genetics service available that includes genetic health risk reports that meet FDA standards. It has collected more than two million genotyped customers from around the world. But as the DTC genetic testing field becomes more crowded and the price goes down, consumer demand is expected to increase along with the value of the testing due to expected advances in sequencing technology. DTC genetic testing may provide some relief for patients about their health risks, but more stress for physicians.

Testing Limitations

DTC genetic tests measure specific markers along the genome. (Consumers can also have their entire genome sequenced—all three billion letters—for \$1,000 or more.) The testing process is easy for consumers. They spit into a test tube and mail it to a lab, where technicians purify and extract DNA from the saliva sample. It’s tested for more than 500,000 gene variants.

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