Consumer genetics first: 23andMe gets OK to sell limited DNA test for cancer risk

The U.S. Food and Drug Administration has cleared 23andMe to sell directly to customers a DNA test for gene mutations linked to breast cancer, making it the first consumer DNA testing company to win the agency's approval for a cancer risk screening.

The new test will analyze DNA for three specific BRCA1 and BRCA2 breast cancer gene mutations. Though there are more than 1,000 known BRCA mutations, the 23andMe test will focus on three mutations most common in people of Ashkenazi Jewish descent. The variants are far less common in other populations.

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Studies suggest that some 1 in 40 people of Ashkenazi descent has one of these three variants, [said Shirley Wu, 23andMe's director of product science], and women with one of the variants have a 45 percent to 85 percent chance of developing breast cancer by age 70…

Eric Topol, a geneticist at the Scripps Institute, was more tempered in his enthusiasm.

"This is very limited information on three mutations that are known to be pathogenic for BRCA," he told Gizmodo.

He said that more comprehensive but still inexpensive tests by companies like Color offer a more complete picture of risk. The difference, though, is that Color's tests must be ordered by a physician.

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The FDA, in its announcement of the news, also noted that most cases of cancer are not caused by hereditary gene mutations.

Read full, original post: 23andMe Gets FDA Green Light to Sell First Consumer DNA Test for Cancer Risk