

## Volledige reactie 23andme op Consumentenbond-onderzoek naar DNA-tests

Het Amerikaanse 23andme reageerde op onze kritiek dat DNA-gezondheidstesten niet betrouwbaar zijn. We geven de reactie per kritiekpunt weer. Omwille van de objectiviteit vertellen wij alle communicatie met dit DNA-lab niet.

**CONSUMENTENBOND:** *The direct to consumer tests only look at a fragment of the total DNA. For some diseases they test for changes in the DNA that mean a higher chance on getting that disease. All the other changes in the DNA are not being tested.*

**RESPONS 23ANDME:** “23andMe identifies variants that are well tested and have been proven to cause an increased risk of developing a disease. This is a more targeted approach than sequencing which looks at all variants on a certain gene, or the entire genome. Many of the variants uncovered by sequencing are classified as “of unknown significance,” meaning research has yet to uncover what these variants mean. Reporting variants that are not as well studied can have serious unintended negative consequences.”

“For people with a family history of disease or other clinical risk factors, sequencing in a medical setting is a much more appropriate approach - 23andMe is not indicated for these cases. 23andMe's test is a broad screen to give customers insight into their health, traits and ancestry. What we have learned is that many asymptomatic people learn of a risk they wouldn't have otherwise known. These are individuals who often don't know details of their ancestry or their family medical history.”

**CONSUMENTENBOND:** *They look at one or multiple changes in the DNA structure that mean a higher risk of getting ‘popular’ diseases. All these changes are summarized and then presented in a percentage: you have a .. % higher risk of getting this or that disease. That is not very accurate.*

**RESPONS 23ANDME:** “23andMe’s genetic risk assessment is scientifically sound and extremely accurate. Our testing process has proven to be over 99% accurate as compared to Sanger sequencing (the industry gold standard) and over 99% repeatable and reproducible, per the FDA review process. We look for demonstrated links between specific genetic variants and diseases by reviewing data from peer-reviewed, scientific literature. The published data originates from studies that compared genetic variants present in people with a specific condition to those without that condition. There must be multiple pieces of published research demonstrating a link between a variant and a disease before 23andMe can report on it. Links to these publications are available in each report. “

**CONSUMENTENBOND:** *What lacks is a good explanation. The average consumer does not understand the difference between the two mentioned tests and they do not understand what for instance a 23% higher risk means. When the chance of getting a disease is normally 1 for every 1000 persons 23% means 1,23 person instead of 1 person for every 1000. Nothing to worry about. The prediction of diseases is not that reliable. Diseases could be underestimated or overestimated.*

**RESPONS 23ANDME:** “The average consumer does understand 23andMe’s reports. 23andMe is the only direct-to-consumer genetic test to be reviewed by the Federal Drug Administration (FDA), the United States government agency responsible for ensuring medical devices are safe, effective and accurately represent their indications. The FDA has [published our user comprehension studies](#) as part of its review, which showed more than 90 percent understanding of the genetic concepts presented in our reports. “