

Top 5 Tips For Choosing A Genetic Testing Company



TOOLBOX
GENOMICS

Starting Check List

- ☐ Does the company use CLIA certified lab?
- ☐ How is your data is protected
- ☐ Are they working with the FDA?
- ☐ How does the company find their research?
Does the company use human-only research?
- ☐ Are there follow-up strategies to work with
your health-care professional?

****Disclaimer:** Before taking any new test, starting new supplements or changing your diet/exercise regimen, always double check with your health-care professional.**

Have you been thinking about genetic testing? Have you wondered if you inherited your grandmother's OCD method of cleaning the house? Have you wondered if you have an increased risk of diabetes because Uncle George developed diabetes in his early 40's? Have you wondered if you are a carrier for Cystic Fibrosis? These are just some of the many questions people ask when they are investigating the different information genetic testing provides. Genetic testing is a very personal decision and before you make that decision, there are some important things to keep in mind.

There are many companies that do genetic testing. Genetic testing involves three different options.

1. Diagnostic: a condition you currently have. Pre-natal screening is a great example of a diagnostic genetic test
2. Carrier: are you carrying a gene from either your mother and/or father that may lead to disease such as cystic fibrosis
3. Predictive: do you have the genes that might lead to the development of a condition or disease, such as Alzheimer's, Coronary Artery disease or folate deficiency.

In the predictive testing world, many people have become interested in SNPs. SNPs are single nucleotide polymorphisms. This is a change in of the base-pairs in your DNA. SNPs do not change your DNA; they simply change the coding for certain base pairs. These changes are what give you blue eyes, curly hair, may cause vitamin B12 deficiency or increase the chance of wrinkles. You may think that genes are your destiny, but they're really not. They provide little clues about who you are and how you interact with your environment.

It is important to remember that your genes are not your destiny; rather they are a blueprint to you. You may have 1000's of genes that will never be expressed or negatively affect you. While you cannot change your genes, YOU can change the environment that surrounds

your genes. The food you eat, the air you breathe, the amount you sleep, the way you exercise will all play different roles in how your genes are supported.

Now that you know your why, let's review some key components you want to investigate when selecting a company.

1. **Do they use a CLIA-capped or CLIA-certified lab?** CLIA (Clinical Laboratory Improvement Amendments) is a governing body that oversees laboratories. They make sure that the labs adhere to specific methods before they can analyze human samples. Some labs will take an additional step and obtain a CAP certification (College of American Pathologists) which has a 7 part check list that is renewed every 2 years. When you have your genetics tested at a CLIA-CAP lab, the lab has to create a specific protocol that lays out all the steps they take to obtain their results. Using a CLIA-CAP lab will ensure the lab has undergone the necessary scrutiny to ensure that the results they are providing are validated and accurate.
2. **Have you read through their Terms of Service to see how your data is protected?** While the Terms of Service section is a long, cumbersome document that can feel very overwhelming, this is the place where the company will tell you if they can sell your data if you choose to consent. Some companies will ask if you want to participate in research, which can include selling your data. Most companies are very good and will de-identify your data before selling it, but it is something you want to double check. If you are not comfortable with your data being sold, then look for the section that tells you how to opt out. Usually you will have to write a letter to the company and specify you do not want your data sold and opt out of all research.

3. **How are they working with the FDA?** Currently, the FDA views direct to consumer testing as a bit of a gray area. The FDA has acknowledged that genetic testing is here to stay, but they want to make sure that consumers are not going to be hurt by their results. At this point, if you are working with Company X and that company is utilizing someone else's data, such as 23andMe, then Company X does not have to be reviewed by the FDA.

If, however, you use a company that has created their own test kit, then two things will happen. If they market directly to the consumer (DTC), then the company cannot mention you are at a higher or lower risk for certain diseases or conditions, because the FDA feels that this needs to have practitioner oversight. Conversely, if they market to health-care practitioners, then as long as your healthcare provider orders the genetic test and it is within their scope of practice, then the FDA does not mind. The FDA is now starting to look into some more direct to consumer testing exemptions where companies would have to go in front of the FDA, have a one-time review, and then the FDA would give them their blessing.

4. **What kind of research do they use to back their claims or recommendations?** Humans are not rats. While rats make wonderful little substitutions for humans, and give us some fabulous insight into what may be going on in our bodies, oftentimes animal research does not translate into the same effect in humans. After all, rats can be confined in a cage where their food and environment are controlled. It would be unethical to subject humans to that type of environment. To ensure that you are getting information about associations or interventions that are going to be applicable to you, you want to find a company that utilizes human research only.

Additionally you want to make sure that the company utilizes a form of manual curation, meaning that the company has scientists reading the papers, not relying on computer programs.

Oftentimes there are fascinating tidbits about certain ethnicities/genders buried deep inside long research papers that are not readily apparent in the title.

5. **How does the company utilize further testing?** After all, just because you have the gene doesn't mean you're expressing it. There are several different types of blood tests, urine tests, saliva tests that you can do with your healthcare provider to see if you are expressing the gene. Some companies will provide follow up testing that you can do with your health-care provider to see if your gene is “on” or off. In this way, you will not jump to treat a particular condition or pathway that does not need supporting. This is always best done with your healthcare provider.

In conclusion, it appears that genetic testing is here to stay, and has the power to transform our health for good. Make sure that you choose a company or companies that are going to follow the best practice tenets outlined here to provide the best possible information for you with actionable recommendations.