Clinical Confirmation Testing

Jason Harris wrote a news column about a company located in Los Angeles known as Basepaws that was providing the services of an at-home preventative dental test that objectively looks at the microbes located in the mouth of the cat to find out if there are any signatures for the disease earlier before they become observable y a naked eye. They are mainly concerned about maintaining good dental hygiene for cats, as are the cat owners, therefore creating a market for testing that they roll out at 70 dollars.

The test itself is a first-of-a-kind and follows a previous test carried out by the same company that looked at the family tree for the cat since they believe that genetic testing is one of the most effective methods pet owners could use to aid them in understanding their pets better. In the research article, the scientists describe direct-to-consumer gene sequencing as processed data that are sold and advertised directly to the patients and provide the patients with information about their genes that may include transporter status for autosomal passive ailments, ancestry, predicted drug reactions, risk of developing certain conditions, and non-diseases phenotypic traits like eye color.

A surge in the number of people interested in personalized healthcare through human genetics has increased the demand for direct-to-consumer testing from ordinary citizens, meaning a growing market that leads to the emergence of various companies to offer the services such as, My Heritage and Family Tree DNA. This type of genetic testing aids individuals by providing them with information that they might never have come across due to various factors and circumstances such as unavailability of indifferent genetic testing, insufficient insurance coverage, bad family history of illnesses or prohibitive cost. It is essential to note that although clinical genetic tests may offer diagnostic information on a patient's genes, the direct-to-client test only offers risk knowledge for a specific set of situations but are not diagnostic.

According to the news article written by Jason, he admits that although pets are not capable of discussing issues with their owners, they find other ways to communicate with the humans who take care of them since they are both emotional and expressive. Consequently, when a pet is not feeling well or is feeling poorly, they might express this to their owners by ceaselessly losing their appetite for food. Moreover, the pets may sulk around the home and disappear from the view of humans by hiding in a closet or beneath a mattress, therefore, making it clear that something is wrong. Pet owners mostly feel skeptical about the test conducted by Basepaws due to the uncertainty of the significance of insights gotten from the study of over 600 microbes in the cat's mouth, especially since t involves swabbing the cat's mouth and sending the swab to the laboratory for testing.

However, an expert named Skaya believes genetic testing offers significant insights into the general health of cats since pet owners do not have the opportunity and mandate to brush the teeth of their pets daily. Therefore, according to Skaya, genetic testing acts as a door to aid pet owners on the way they talk to the vets about their cats, such that if they have test results for the microbes in the mouth of a certain cat, the owners are in a place to ask the vets what the data and knowledge level means therefore keeping the pet owners ahead of any medical problems that may arise. In the article, Jonas reached out to several specialists in veterinary dentistry to assure whether the genetics test produced worthwhile outcomes. Upon sharing Basepaws's news release

about the dental test package to the specialists, the specialists provided a unanimous response that the testing services were not worth the amount charged by the company.

One of the specialists, Peralta, who is an affiliate professor at Cornell University's College of Veterinary Medicine, believes that the claims made by Basepaws made very little or no medical and scientific sense since the information provided suggest the people behind the genetic testing of microbes in the mouths of cats do not fully comprehend the mechanical and clinical components of periodontal disease that frequently affects pets and other animals. Moreover, a medical practitioner and lecturer at the University of Wisconsin Madison's School of Veterinary Medicine named Jason Soukup stated that the genetic testing on cats should not be too heavily relied upon since the data and information gotten from the tests could be very easily misinterpreted and therefore lead to uncouth and unsupported recommendations for care due to lack of enough data to support the company's claims.

The research article notes that the recent rapid increase of gene testing corporations improves the general population's access to genetic testing, healthy or sick. The report notes that the tests conducted on someone's genes are not meant to affect the medical control of the individual's health. The information from the basic information could lead to improper suggestions to changes in their care. The company's providing the services of gene testing ensure to include disclaimers on the raw data to warn the individuals involved that the information has not been corroborated for accuracy and should therefore not be used for medical practice. However, this does not deter people from misinterpreting and misusing the information for medical purposes, especially consumers or medical providers with no schooling on the convolutions of genetics.

The article further states that the data presented may be subject to false-positive outcomes and miscalculation of alterations, resulting in dire consequences to the involved parties, such as unnecessary medical procedures, stress, and unnecessary testing of family members. The data may also prompt the involved people to partake in unwarranted financial burdens on the healthcare system and the individuals involved. The study conducted by the scientists reported two critical findings in the basic information DTC genetic sequencing. They recorded incidences of discrepant classifications of alterations arising from the genetic testing institutions or third-party interpretation corporations. They recorded a dangerously high false-positive rate of approximately 40 per cent. According to the research article, the high false positivity rate may be explained by the practical differences between the testing procedures used in the gene examination (Tandy-Connor et al., 2018).

The research also revealed that most genetic sequencing corporations use a single-nucleotide diverseness genotyping array analogous to spot-checking the DNA by concentrating only on specific preselected sites. Therefore, DTC genetic testing is not as comprehensive as practical diagnostic analysis. Due to the lack of next-generation progression and megaplex action-dependent probe inflation frameworks does not include full gene sequencing, duplication analyses, and gross deletion. Moreover, the scientist believed that motivating all gene sequencing companies and laboratories to share the generated data would reduce variant classification errors since there is a high variability when analyzing single-nucleotide heterogeneousness arrays between gene sequencing corporations. The research article also stated that gene sequencing corporations and third-party interpreting services should utilize reviewed information and data

from highly regarded and well-curated genetic databases to reduce the high number of false-positive rates.

Reference

Tandy-Connor, S., Guiltinan, J., Krempely, K., LaDuca, H., Reineke, P., Gutierrez, S., ... & Davis, B. T. (2018). False-positive results released by direct-to-consumer genetic tests highlight the importance of clinical confirmation testing for appropriate patient care. *Genetics in Medicine*, *20*(12), 1515-1521.