



TruDiagnostic



Company Profile

Founded in 2020, TruDiagnostic has already been making headway in the longevity industry with a mission to improve people's lives. TruDiagnostic wants to arm patients and physicians with information, enabling them to make the right decisions at the right times through insights found in the fluid epigenome. The company's core belief is that methylation is a biomarker with robust potential because it can be cross-trained to other biomarkers in a multi-omic framework. With a market currently made up of physicians in the integrative, cash-pay medicine space, TruDiagnostic have a clear pathway to profit, with immediate plans to offer direct to consumer kits and insights starting in 2022. Currently TruDiagnostic reporting is mostly for age-related diagnostics through their TruAge test, but this will be expanded as more data is collected for additional health verticals.

In addition to the clinical test offering, TruDiagnostic also provides laboratory services to research institutions. This includes proteomic analysis, RNA-Sequencing and genomic processing services. It has a robust bioinformatics department that can analyse large datasets for new predictive health algorithms. While TruDiagnostic aims to continue to produce the best aging algorithms to date, it is also expanding into other areas of epigenetic interpretation with an overall goal to become a leader in its clinical service.

TruDiagnostic's unique ability, making it stand out from the competition, is the ability to leverage the benefits of its large cash pay provider database. The physicians, nurses and other healthcare providers in this space are uniquely interested in aging and preventative medicine. This allows the company to use these to distribute testing, but more importantly, it also helps gather unique and in-depth covariates that can be obtained from direct-to-consumer testing.



These covariates are incredibly important, especially as the field of methylation continues to expand, as methylation data is useless without the outcomes and phenotypes of patients. Through TruDiagnostic's physician relationships, it are able to conduct low-cost clinical trials and gather health history and data such as blood chemistries, immune profiles, microbiome testing and more. This data allows investigation into the connections of these phenotypes to the methylome which then allows TruDiagnostic to be uniquely suited to create new algorithms, offering even more value.

TruDiagnostic will be updating its unique rate of aging algorithm every 5 years as the cohort ages enabling even more accurate rate of aging determinations. It also plans to create saliva conversion methods of all published aging clocks to make saliva collection a viable and accurate option. Further, the company plans to release a skin aging algorithm; this will provide the first epigenetic algorithm to quantify skin again based on phenotypic measurements. They believe this technology will be heavily adopted by skincare brands and medical spas in the future. Lastly, TruDiagnostic plans to release a custom research array to investigate the imprintome. With collaborators, TruDiagnostic has identified for the first time, all areas in the genome which are imprinted and inherited by a single patient. These areas have a large relationship to many diseases, and will be offered as an array of research investigations for private research groups and universities studying autism, Alzheimer's, schizophrenia and many other imprintome associated disease

TruDiagnostic's key performance objectives are:

- Developing new intellectual property through our testing and analysis programs
- Identifying new partnerships
- Increasing our testing volume with additional lower cost reports.
- Providing medical interventions based on these reports from supplements to telemed and EHR access

TruDiagnostic's additional opportunity for growth is the development of new IP through building out their phenotype and multi-omic database, enabled by partnerships with academia and an extensive provider network. It seeks to develop new IP that assess epigenetic changes and cellular senescence and other hallmarks of aging through methylation testing.



Flagship Product Deep Dive

TruAge Test

TruDiagnostic's flagship product is the TruAge test: an exclusively licensed phenotypic-trained age algorithm. This test provides a snapshot of an individual's intrinsic or biological age and can quantify age via advanced epigenetics using TruDiagnostic's exclusive, best-in-class algorithm. TruDiagnostic is the only company that has published algorithms, with their testing method, which assesses 850k CpGs, being the most advanced analysis currently available on the market. In addition, this test uses blood, which is the only validated method for biological age testing. TruDiagnostic is able to offer testing at a reduced price given the high volume of its lab, which currently serves three markets: direct to consumer, lab services and corporate health.

In its early experience the company has learned many useful lessons. One of the most important being the wish to be platform agnostic. As the technology for investigating methylation adapts, TruDiagnostic wants to be flexible to the best and least expensive method, all while prioritising not sacrificing the depth of the measurements. The private database has been a huge asset to research collaborations as TruDiagnostic now has more samples and phenotypic data than almost any database which is publicly available. It hopes to continue to build out a software and commercial platform which can use this data for drug discovery, health insights and the ability to publish papers

TruDiagnostic's product is an epigenetic change test that assesses 850k CpGs and so, directly assesses an individual's biologic age. However, the ability to analyse these samples goes way beyond age-related diagnostics. With custom deconvolution algorithms TruDiagnostic can report on:

- Environmental exposures
- The impact of early life and nutrition
- The mitotic clock history
- Telomere length
- Immune cell subsets
- Exposome features; smoking and drinking behaviours
- Epigenetic risk factors for obesity and diabetes

The company aims to continue to expand aging insights with the multi-omic dataset to build the best database of interventional epigenetic changes and how these changes relate to disease prevention. Using this epigenetic database, it is uniquely suited to continue to build out scientifically validated and well powered algorithms and reporting features beyond aging. TruDiagnostic is the only company to test above 120,000 CpGs (testing over 850,000) and is the only company to have their own published trials and interventional investigations.



Product Development

The company's technology is currently in its pre-clinical phase. The TruDiagnostic suite of proprietary algorithms have all been validated. Most studies have used TruDiagnostics' own DunedinPACE Rate of Aging, for which they have exclusive licence, this is the only 3rd-generation clock currently available. TruDiagnostic has several large, funded partnership studies with Yale, Harvard and UPenn which will establish the efficacy of their own novel aging, death predictor and immune cell subset deconvolution algorithms which are expected to be published in 2022.

Target market

While TruDiagnostic does have channels that directly target consumers, its biggest target markets are healthcare providers and antiaging therapy companies. Providers can offer TruAge testing, as well as their additional tests, to patients making changes (whether medication, lifestyle, or behavioural) in order to impact overall health and aging. TruAge tests can detect the impact of these changes on biological aging. TruDiagnostic has been approached by many antiaging therapeutic companies whose market products such as diet or nutritionals need to be validated through TruDiagnostic tests and algorithms.

If everyone in the world could reduce their epigenetic age by 7 years lower than their chronological age, prevalence of age-related disease would halve. TruDiagnostic has begun to find interventions which have objective data on reducing aging. It aims to help its consumers test, but also implement interventions to reduce their epigenetic aging. This would have a massive positive impact on reducing disease and helping our rapid growing aging populations. The company plans to expand to a direct-to-consumer market in niche areas such as pregnancy and fertility planning, neurocognitive diagnostics, nutrition and fitness recommendations and research services. These goals will become easier to obtain as a greater understanding of how to interpret the methylome data is gained, which currently is in its infancy.

Channels to market

TruDiagnostic plans to continue marketing tests through three markets: direct-to-consumer, lab services and corporate health. Currently, the focus is on keeping a deployment plan in the space of healthcare providers. This is due to the benefit of gaining very unique datasets in this space. In mid-2022 TruDiagnostic also plans to increase consumer reporting and advertising significantly in the direct-to-consumer space as they develop lower cost and more target testing such as exposome testing, fitness and nutritional testing and even aesthetically trained skin aging algorithms.

Additionally, through partnerships with academia, the company can continue to offer more 3rd party services and analytics. These include the creations of many custom methylation arrays to focus on research in certain areas such as the imprintome which will change the way we look at preconception and diseases such as autism and Alzheimer's. It also includes transcriptomic, genomic and proteomic processing services.



Success Factors

Team and Reputation

The company was founded by a group of investors with experience in the healthcare space. Prior to the founding of TruDiagnostic, members of mgmt. and the board had experience in the integrative space which had massive growth. The previous company and pharmacy was the 4th fastest growing healthcare business in the world in 2019. The vision for TruDiagnostic was created in late 2019. While epigenetic aging technology had previously been used, it had not been applied to interventional health studies. That changed in September of 2019 when the TRIIM trial was published. This trial was the first proof of concept that epigenetic age could be reversed with intervention. The team saw the opportunity to offer this testing to their network of cash-pay medicine providers to effectively quantify aging.

Beyond the goal to bring this testing to clinical practice, the TruDiagnostic team also decided to also use this as an opportunity to research connections of health and aging to larger portions of the epigenome. Since that time, TruDiagnostic has started Research collaborations with Harvard, Yale, Duke, Cornell, The Van Andel Institute, UCSF and more.

Intellectual Property

TruDiagnostic has multiple lines of investigation ongoing for development of new IP. Through academic partnerships, they are exploring development of tests to assess markers of Alzheimer's disease, development of cardiac disease and rejection of liver transplant. TruDiagnostic is expected to publish a highly accurate, multi-omic informed biological age clock and death predictor in the summer of 2022.

TruDiagnostic currently has 10 proprietary or exclusively licensed algorithms for aging, cellular deconvolution, rate of aging, telomere length and mitotic clocks and has over 39 research trials ongoing. Through its partnerships, it fosters publication of study findings and pursues federal grant funding opportunities. Both activities provide the company with a competitive edge, as it gains recognition as a leader in epigenetic methylation analysis. TruDiagnostic regularly seeks new partnerships. As a result of the company's fast growth and early success, it believes that it is well-positioned for an IPO within the next five to seven years.

Funding

In TruDiagnostic's first 18 months, over \$3 million had been invested. Amongst investors is the well-known Dustin Cappelletto who serves as Tru's Chairman; he is also the Founder and CEO of LIV Health. For the next 24 months, the company's goal is to raise \$8 million in capital. This capital will be used to improve the bioinformatics platform, research datasets and covariate data collection; it will also be put towards monetising the death prediction algorithm; monetising the skin age algorithm in the aesthetics market; continuing to publish results from interventional trials and increasing reporting and algorithm outputs, as well as the lab services business. TruDiagnostic is also intending to build out its C-Suite team.