

Chilean biotech GeneproDX can substantially increase the prediction accuracy of detecting thyroid cancer and dramatically reduce the need for surgery which is currently used to confirm cancer diagnosis in indeterminate nodules.

Thyroid nodules are widespread; particularly among people aged 60 years and older. In fact, it's estimated that up to 50% of people over the age of 60 will form these abnormal growths on their thyroid gland. And even though the nodules are relatively easy to identify, the diagnosis as to the type and also whether it is malignant or not is quite complicated. However, a patented new technology from Chilean **GeneproDX** called **ThyroidPrint®** and developed by [Hernan González, MD, Ph.D.](#), an associate professor of surgery with the **Pontificia Universidad Católica de Chile**, can now predict with 95% certainty the prevalence of cancer in indeterminate nodules, which saves patients money and unnecessary surgery.

Women are more prone to thyroid nodules than men. Although the reasons elude doctors and researchers, some think estrogen *may* play a role. In at least half of all cases, people may be completely unaware they even have these growths, which can be solid or filled with fluid. A combination of size and location of the nodule is what usually gets a person to raise concerns with their doctor.

For example, a nodule that is 1 cm may be benign, but if its location impedes swallowing or makes it challenging to take deep breaths, it needs to be removed. Conversely, if a 4.5 cm-nodule that's benign and presents no obstruction, then endocrinologists, as well as ear, nose and throat (ENT), and head & neck surgeons will often take a watch-and-wait approach because they might feel the [risk of surgery isn't worth it](#). It isn't uncommon for a nodule to grow, change in presentation, or become malignant.

There are [six known types of nodules](#). They vary in size, shape, composition, location, cause, and presentation, but for the most part, they are always benign. And then there's the one that, while much rarer, causes the most angst because it's cancerous.

Several types of nodules are usually malignant and turn into [thyroid cancer](#). The good news is that they account for only five percent of all thyroid nodules. The bad news is that they almost always present the same as benign nodules.

There are [a few other risk factors for thyroid nodules](#): [Hashimoto's Disease](#) (an autoimmune disease), inflammation of the thyroid gland, heredity, iodine deficiency, and [exposure to radiation](#) (be it intentional to fight illness or accidental). And because the cause or type of nodule doesn't preclude the presence of cancerous cells, doctors usually err on the side of caution and recommend a biopsy for nodules.

Determining the presence of nodules is easy, which is done by palpating the butterfly-shaped organ located just below the Adam's apple that runs along the front of the windpipe.

Once the doctor has confirmed the presence of nodules, they will order an [ultrasound](#) to determine the size and shape. The radiologist performing the ultrasound will provide recommendations that range from watch-and-wait to follow up with fine-needle aspiration (FNA) to rule out cancer.

And while the prevalence of thyroid cancer only occurs in approximately [five percent of those with nodules](#), there is this gray area that accounts for 25% of all nodule diagnoses known as the [indeterminate nodule](#). Of that 25%, it's estimated that 75% of those patients end up undergoing unnecessary surgery, called a thyroidectomy, to exclude malignancy.

Compounding the issue is that 83% of those unnecessary surgeries are done by [general surgeons](#) who perform fewer than ten thyroidectomies annually (as opposed to an ENT or head & neck surgeon who performs 300 or more a year). The inexperience of general surgeons significantly increases the risk of long-term problems, such as permanent airway obstruction and chronic hoarseness that never dissipates, and in extreme cases, complete and permanent loss of voice.

Secondarily, there's a 50/50 chance that a partial thyroidectomy (removal of one side of the thyroid gland) will require hormone supplements because the remaining thyroid fails to function on its own. If the FNA concluded indeterminate nodules exist in both halves of the thyroid, necessitating a full thyroidectomy, the need for hormone replacement becomes 100% necessary following removal.

Until recently, surgery was the only way to conclusively rule out thyroid cancer for those with indeterminate nodules. Given the risks associated with all surgeries, in 2006, a Chilean head and neck surgeon vowed to do something about this. Based in Santiago, Hernan González, MD, Ph.D., an associate professor of surgery with the Pontificia Universidad Católica de Chile, developed a test that will prevent thousands of people worldwide from needing to undergo this unnecessary surgery.

GeneproDX's thyroid cancer detection innovation is 95% accurate

A patented new [technology](#) from GeneproDX called ThyroidPrint® can now predict with 95% certainty the prevalence of cancer in indeterminate nodules, which saves patients money and unnecessary surgery.

There's another incentive for ThyroidPrint® that insurance companies like. [The cost of a thyroidectomy](#) can range from \$8,000 to \$25,000. The average cost for the procedure is about \$17,000. Factors that determine pricing fluctuation are the country where the surgery is being performed, whether it's a partial or complete removal of the thyroid, and whether the patient has healthcare insurance or not.

With a cost of just \$4,000, GeneproDX's ThyroidPrint® saves both insurance companies and patients a considerable amount of money. "With ThyroidPrint®, 67 out of 100 patients with indeterminate nodules won't require surgery," said Dr. González while explaining the math and how reimbursement works."



Image: Hernan González, MD, Ph.D. Photo: Courtesy.

"That's two-thirds, which is very significant," said Dr. Gonzalez. "Very importantly, it's cost-effective, so medical insurance will pay for it. Even though the net benefit for patients is clearly positive, there also has to be a health economics component. Basically, we prove that you calculate the price based on what's the actual savings that you will provide for insurance, and it's about 30%."

"In the U.S. today, the reimbursement rate for this [technology](#) is about \$3,600," said Dr. Gonzalez. "These are high-value tests because it's much cheaper to pay for the test for

everybody, and only operate on those who are confirmed to be suspicious for malignancy, or whose location and/or size present serious, long-term issues.”

ThyroidPrint® explained, in layperson’s terms

Consisting of a [gene signature](#), [ThyroidPrint®](#) is a test that determines the expression of a panel of 10 biomarkers found in the FNA sample of the node. Using a fairly complicated algorithm, this test can predict with 95% certainty whether a thyroid nodule is malignant or not.

As Dr. González explained it: “My mission was to develop a test that could address this question. We worked between 2006 and 2013. There was a lot of back and forth, a lot of failures. [Polymerase Chain Reaction](#) (PCR) as we know it today for COVID wasn’t as developed. It was just coming out. Ultimately fast-forward to 2012, we came up with a prototype for [ThyroidPrint®](#), which is a PCR-based test.”

From clinical trials and a global patent to anticipation of the FDA’s approval

In 2010, Dr. González founded [GeneproDX](#), a [startup](#) biotech, which as he phrased it, “spun out of the university.” The university allowed him to become the CEO while continuing his full-time job as an associate professor performing surgeries. The formation of the biotech allowed Dr. González and his research team to conduct clinical trials and seek funding to conduct further research for [ThyroidPrint®](#), which included additional, more robust clinical trials.

“In our first fundraising event in 2015, we raised \$2.2 million as seed money, which is very good for a Chilean biotech [startup](#). The university is happy because with the formation of the biotech; it doesn’t need to pay for anything associated with bringing [ThyroidPrint®](#) to market,” said Dr. González.

“We conducted our first clinical trials in [Chile](#) to determine if that prototype test in fact was able to predict benign nodules with that 95% threshold that we had set. Thankfully it worked out very nicely,” said Dr. González. “We performed a very large, multicenter trial. Then we said, ‘Well, so this is for a Chilean population, what happens if we have to look at a more diverse genetic background?’

Next, we raised another \$5 million, and performed a [second trial](#) in the U.S. We had [Stanford University](#) and other top-notch institutions working with us. We were able to prove that, in fact, the test works exactly the same, regardless of someone’s race or ethnicity.”

The trials included African Americans, Asians, Indians, Latinos, people of native descent, as well as people with two more races, according to Dr. González. The profile didn't change between the Chilean population and the U.S. population of more diverse backgrounds. The findings were published in 2020 in a very [high-profile scientific journal](#) which helped “greenlight” the test for final regulatory approvals.

In October 2020, the United States Patent and Trademark Office granted a [worldwide patent](#) to GeneproDX for ThyroidPrint®. The next step is to obtain FDA approval so it can be used in the United States and its territories, which Dr. González believes is now about eight months to one year away.

How competitors stand up to GeneproDX's ThyroidPrint®

GeneproDX's ThyroidPrint® isn't the only diagnostic tool that can change a nodule's diagnosis from indeterminate to benign or malignant. There are two other companies that offer other options, but there are some very distinct differences between them and ThyroidPrint®.

[Afirma](#) and [ThyroSeq](#) rely on similar [technology](#). Like ThyroidPrint®, their diagnostic tools both look for unique genetic markers on the thyroid nodule that help rule out a cancer diagnosis. Both use cells that were previously collected during the FNA procedure, which means patients don't need to go through a second FNA. Results using Afirma or ThyroSeq usually take about two weeks because they need to be sent to an outside lab.

There are two main differences that make ThyroidPrint® more desirable for the patient, doctor, and insurance companies: ThyroidPrint® can be tested in a hospital, with results turned around in just 24 hours, and the other main difference is in the type of artificial intelligence being used.

As Dr. González explained it, “ThyroidPrint® is a qRT-PCR5-based mRNA-expression classifier test that helps to determine whether a thyroid nodule with an indeterminate cytology result is benign or malignant. In other words, it relies on similar [technology](#) found in the [Covid 19 vaccines](#).”

Unicorn Hunters seems to think GeneproDX has legs

[Unicorn Hunters](#) is a simple, yet brilliant concept. Put eight entrepreneurs with diverse backgrounds together on one stage and allow them each to have a few minutes to pitch their company to the hosts and viewers for pre-initial public offering investment opportunities prior to an IPO. In their own words, “Unicorn Hunters is on a mission to democratize access to wealth so that it is no longer the privilege of a select group. With an audience of more than 14.5 million people around the world, Unicorn Hunters give founders a global platform to pitch millions of

investors simultaneously and provides viewers with the opportunity to invest in pre-IPO opportunities from their homes.”

The program’s hosts: **Steve Wozniak**, **Apple** co-founder; **Rosie Rios**, a former U.S. Treasurer during the Obama administration; [Silvina Moschini](#) and **Alex Konanykhin**, co-founders of **TransparentBusiness**; **Moe Vela**, a former senior advisor to both Vice Presidents **Al Gore** and **Joe Biden**; **Lance Bass**, the former *NSYNCEr (a boyband from the 1990s); **Christopher Diamantopoulos**, an actor and entrepreneur; and **John Bercow**, a former speaker of the House of Commons are as diverse in their current and former careers as they are in their personal lives, because like life itself, representation matters.

Now in its second season, on February 10, 2022, Dr. Hernan González pitched the hosts and viewers of Unicorn Hunters. GeneproDX’s ThyroidPrint® presentation impressed all the hosts with one exception. Steve Wozniak was the only one not to see the value in investing in GeneproDX. This is pretty impressive, given that Dr. González represents both innovation, and perhaps more importantly, [Latin America](#). If you missed the episode, you can see it [here](#).

Having received the funding needed, Dr. Gozález says, “We expect to launch the first version of this cartridge in about eight months from now. It will not be available in the U.S. immediately because we have to go through FDA clearance because it’s a medical device.” Based on this, it is expected to first be available in Asia, Europe, and [Latin America](#).

“People often ask me what our goal is for ThyroidPrint®. We intend to disrupt the current model and allow hospitals to say, ‘Well, we want to do our testing in-house and provide speedier results to patients with exactly the same level of clinical performance in terms of accuracy and precision,’” said Dr. González. “As a [startup](#), what we’re looking for is an M&A or IPO within 24 to 30 months. That’s our end game because we don’t have any other products. We do have some other options in the pipeline, but our focus is mainly on ThyroidPrint®, which we really need in order to be able to compete. We need to focus all our efforts on this test.”

And with investments that continue to roll in, thanks to Unicorn Hunters, GeneproDX has the funding it needs to enable patients worldwide with indeterminate thyroid nodules to avoid risky surgery. By knowing within 24 hours whether they have cancer, those patients can act more quickly, rather than taking a watch-and-wait approach.

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