

Moving Diagnostic Testing Out of the Lab and Into the Home

With the entire world closely watching the progress of COVID-19 testing, treatments, spread-prevention dynamics, and now vaccine development and distribution, we've all become arm-chair students of medical protocols 101.

We can discuss the pros and cons of swabs vs. throat cultures, Moderna vs. Pfizer, and at-home vs. clinical rapid tests. This instant clinical literacy is not uncommon when an individual or family member receives a sudden diagnosis or is even at risk for one. Because our lives have been centered on the whims of a communicable disease for the past year, health awareness has become part of our daily conversation.



Chief Science Officer Mahmoud Zubaidi, CEO Michael McNeely, Ph.D. and Director of Process Development Philip Luk

Medical innovation startup GattaCo Inc. has developed a method to simplify the way blood is diagnostically processed through a purification filter by creating a credit card-sized device that replaces the centrifuge to easily separate plasma from blood.

In the same way technology has allowed workplace and offices to become fully remote, many healthcare and medical industry experts believe that telemedicine is poised to explode in the years following the COVID-19 pandemic. Breakthrough innovations that allow patients to more independently test and monitor their conditions will facilitate this, which is where Murrieta, California-based startup GattaCo Inc. is ready to completely disrupt the space.

"I've been in the life science and medical industry for a couple of decades and am familiar with where we have pressing needs in the medical-diagnostics area – lab and blood tests in particular," says Dr. Michael McNeely, president and CEO of GattaCo. "There's been a lot of effort at moving diagnostic tests out of a lab so they can be done in more convenient places, such as in the home."

Most of us are familiar with diabetics doing home blood tests to monitor their blood glucose levels but what if the same process could be used

to self-test for liver, heart, kidney, or hormone function as well? Or what if we could confirm we have a virus without risking going to a crowded doctor's office or lab, but instead we can do a finger stick and get results for these conditions within minutes without ever leaving home?

"The reason we can do this for blood glucose but not other parameters is because, normally, it's actually the plasma that is tested and not the blood itself," McNeely says. "Glucose is one of the rare tests where it is the reverse, where blood can be used directly. In order to separate red blood cells from plasma, the sample needs to go through a purification step – usually centrifugation done in a lab – to get the plasma to test."

GattaCo Chief Science Officer Mahmoud Zubaidi has first-hand familiarity with the many attempts that have been made in the industry over the decades to replace the centrifuge.

"Other attempts haven't been very commercially viable until now," he says. "We have developed a



patented capillary pressure re-set – or Cap-Reset – technology. It's a new method that simplifies the way blood is processed through a purification filter. We have created a plastic, disposable, credit card-sized device that replaces a centrifuge. It easily separates the plasma from blood automatically and it can be run anywhere, with only a few drops of blood.”

If the name sounds familiar, GattaCo is derived from “Gattaca,” a 1997 film starring Ethan Hawke and Uma Thurman, set in a dystopian future society driven by eugenics. The tagline, “There is no gene for the human spirit,” resonated with the principals of Gatta Co.

“The need for purifying blood without a centrifuge is the motivation for how we got started and though we’re still very small, we’re growing, and we feel we can be very impactful with this technology,” McNeely says. “One of the areas where we’ve seen significant need is in pediatric testing. The reason for that is because doctors don’t like to order blood tests for children as it can be painful and traumatizing.”

The company announced in December 2020 it had been accepted into the West Coast Consortium for Technology & Innovation in Pediatrics (CTIP). The organization is an FDA-funded pediatric medical-technology accelerator centered at Children’s Hospital Los Angeles, with the goal of facilitating development, production and distribution of medical devices for pediatrics, supporting them on the journey to commercial release.

The benefits of GattaCo’s technology as it relates to pediatrics is not just about less stress and trauma for young patients – which is important – but it can also facilitate pediatric pharmaceutical clinical trials and there is tremendous research potential as well.

“There is a huge need – from a blood chemistry and blood biomarker perspective – for us to better understand what’s going on in children as they grow,” McNeely says. “And not only that, but it can help us more deeply understand how, when,

and where adult conditions may originate. To gain this insight, you have to do blood tests on children that are not done lightly. But we as a company are providing a new solution for collecting important data via plasma from a finger or a heel stick, or some other less invasive way, that is invaluable for research.”

GattaCo currently has its point-of-care or point-of-need A-PON™ Kit – the first of its kind -- on the market for research purposes. The A-PON is derived from its predecessor product, the Sipon (pictured). It is optimized for the detection of antibodies, including those for COVID-19, and the company announced its Early Access Program availability in April 2020. Currently, many potential partner companies are performing evaluations and validations.

The A-PON Kit includes everything needed to sterilize a finger, prick it with a lancet, do the draw, and separate the plasma from the blood. Step-by-step instructions are provided. Since the device is the size of a credit card, it’s easily and inexpensively mailed.

The company has a similar mini-PON™ product that is geared toward pediatric use. It requires only a single drop of blood and can separate enough plasma for many pediatric and neonatal testing needs. The plasma will still require a lab for analysis.

“We have pilot manufacturing already, and we are looking for solutions to scale up the number of units if we are able to sign a contract with a high-use partner,” McNeely says. “Since it can also be used for vaccine-efficacy testing, which our current level of production would not be able to support, so we’re looking for solutions to scale up to hundreds of thousands if not millions of units per month.”

McNeely recently signed an agreement for a new point-of-care product development -- the details are not yet public. “It will be a significant focus for the team in the coming months,” he says.

“We’re also about to enter Series A financing so we can continue to grow,” he adds. “We’re still quite small and we have a lot of work to do and are looking for more people to do it with, so that’s all very exciting. Since it’s substantially easier to manufacture a product with a simpler design and not a lot of material, we believe we can scale up quite quickly and have it at a price point that would be very attractive.” — By Susan Belknap, California Business Journal.

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