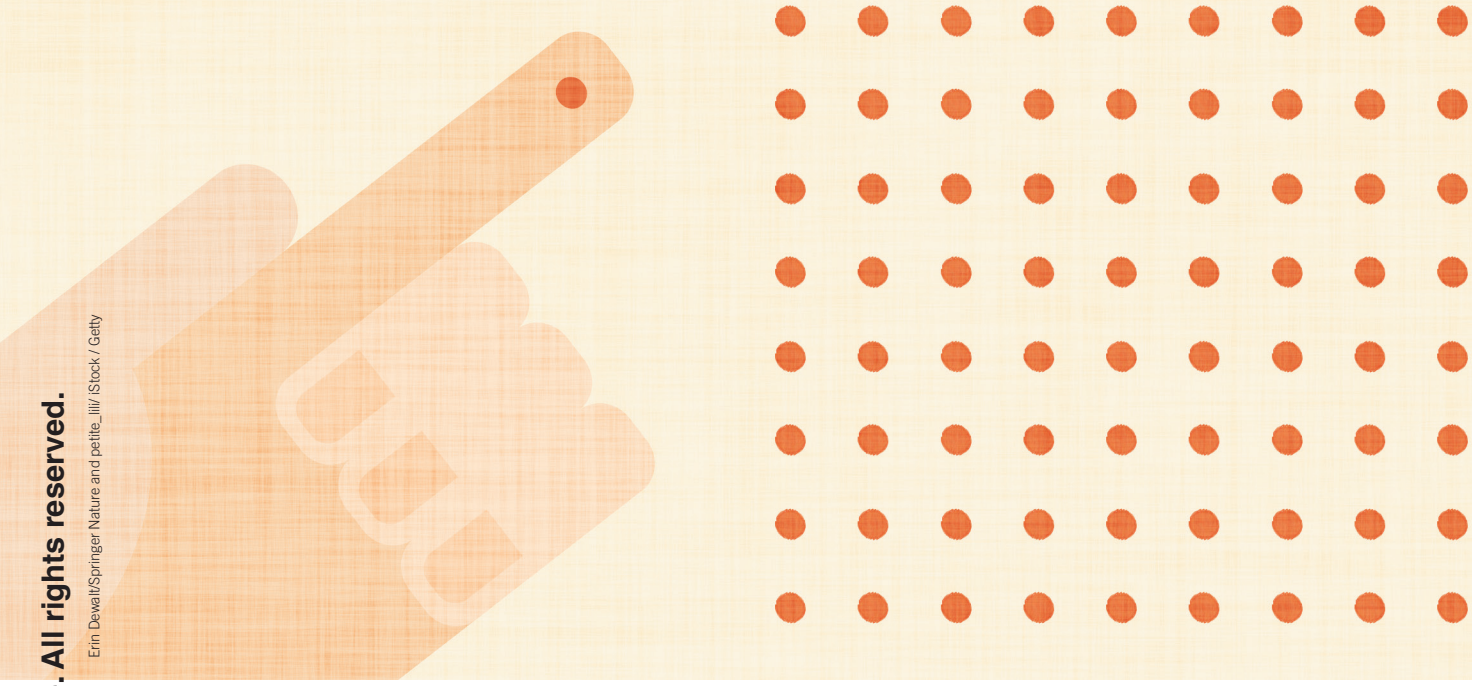

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After Theranos

The implosion of blood diagnostics developer Theranos has raised the question: What is feasibly detectible in a drop of blood? Emily Waltz reports.

Imagine doing a raft of diagnostic tests from a finger prick of blood. This was the dream sold by billion-dollar blood-testing startup Theranos. The company claimed it could run over 200 tests on a few drops of blood, while the rest of the field was plodding along on only a few dozen such tests. Unfortunately, Theranos' claim turned out to be just that—a pipe dream.

The debacle, which came to a head in late 2015 with the US Centers for Medicare and Medicaid Services (CMS) censuring Theranos, has heightened skepticism around the field of small-volume blood diagnostics, particularly products aimed at consumers. But the idea of recentering diagnostics on people, rather than using the widespread centralized diagnostic laboratory model, continues to gain traction. Investors are pumping money into startups chasing the holy grail of finger-prick diagnostics, and big players keep on acquiring innovators in the space. In November, San Diego–based Genalyte secured $36 million in financing for its blood-drop diagnostics; two months earlier, multinational Danaher announced the acquisition of Sunnyvale, California, diagnostics developer Cepheid. These are but the latest commercial players to chase the decades-long goal of measuring clinically relevant markers in a drop of blood.

Implosion

Theranos founder Elizabeth Holmes, a well-connected 19-year-old Stanford University drop-out, claimed her company, launched in 2003, could do practically any diagnostic test on a few drops of blood from a finger prick. Yet while the company grew to a valuation of $9 billion, courting breathless media coverage and TED talks, skepticism grew at the company's refusal to disclose details on how its platform worked. "They never shared their data with the scientific community," says Ralph Weissleder, director of the center for systems biology at Massachusetts General Hospital in Boston. "They were extremely evasive." Members of the research community grew increasingly suspicious, as did Theranos' own employees.

In October 2015, an investigative report in the *Wall Street Journal* dropped the bombshell that many of Theranos' tests were being run on commercial machines from other companies, rather than its own 'Edison' platform. The investigation revealed that blood samples were likely being diluted to meet the specs of those instruments, leading to errors, the newspaper reported. The next month, the CMS inspected Theranos' laboratory in Newark, California, and found numerous deficiencies, some of which posed "immediate jeopardy to patient health and safety," CMS said in a letter to the company (**Box 1**).

The agency banned Holmes from running a laboratory for two years. Walgreens, which was hosting dozens of Theranos blood-draw sites in Arizona, severed its relationship with the company, shuttered the sites, and in November sued the company. Theranos now faces multiple fraud lawsuits, along with investigations by federal prosecutors and the US Securities and Exchange Commission.

Reverberations

The debacle cast a shadow over the entire field of small-volume blood diagnostics. "[Now] when I talk to people there's always a great deal of skepticism," says Cary Gunn, CEO and founder of Genalyte. "I get asked the question, How are you different from Theranos?, at least daily."

The association with Theranos alone makes people nervous. In fact, the founders of one startup contacted by *Nature Biotechnology* asked to be left out of this article in part because they did not want to be linked to the disgraced company. "I refer to it as the 'Theranos crater' that you're trying not to fall into," says Paul Yager, a professor in the department of bioengineering at the University of Washington in Seattle. "It scared a lot of investors away from something that otherwise might have been a giddy rush into this general area."

Box 1 Squeezing through regulatory loopholes

Theranos tapped into the consumer market while largely bypassing regulatory scrutiny. And the company wasn't the first to attempt that—think 23andMe, the consumer genetic testing service. Both took advantage of a regulatory exemption called the laboratory-developed test, or LDT. The loophole allows laboratories to develop and use their own tests internally, provided that they don't sell the test to others.

They likely won't be the last to test the loophole. The FDA released in 2014 a draft guidance on LDTs, but the final guidance was never issued. With the change from the Obama to the Trump administration, it's unclear whether the loophole will be closed.

One of the values of the LDT exemption is that it allows researchers to create specialty or cutting-edge tests. "Say someone has a rare illness, and the person goes to see a specialist in an academic center. Those specialists [might] have tests available to them that they and other specialists in that field have developed," says Cary Gunn, CEO at diagnostic developer Genalyte in San Diego. "It's an incredibly valuable piece of [regulation] for specialty medicine and tests that just don't have the volume and economic driver to get FDA approved," he says.

As long as a laboratory operates at the federal standards set out by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the lab can do an LDT. And for the most part, such tests have been developed for low-volume, specialty purposes—for conditions that don't have the economics to justify the expense of a full FDA filing. But as both the numbers of such tests and their complexity have increased, and as some groups have started to take advantage of the exemption by doing routine, high-volume testing as LDTs, the FDA has been rethinking the policy.

In late 2015, armed with a set of case studies of LDTs that illustrated the dangers of unregulated testing, the FDA proposed to the Congressional Energy and Commerce's subcommittee on health stepping up regulatory review. The proposal was met with skepticism from some members of Congress as well as test developers, who feared it would stifle innovation.

But there's an upside. The debacle so captivated the attention of the public that it brought an otherwise dry area of science into the spotlight. "It's shocking the number of people who know the story of Theranos," says Gunn. "I ask Uber drivers for fun—because I'm in a lot of Ubers—and I'd say two out of three know the story. It's a common household name at this point."

That may be a good thing. Eugene Chan, of the DNA Medicine Institute (DMI), a medical technology incubator in Cambridge, Massachusetts, that is developing a blood-based diagnostic, says his early pitches were often met with questions about why small-volume blood analysis is important for healthcare. "I don't have to explain that as much anymore," he says, so "[Theranos] validated the space in some sort of twisted way." Adds Gunn at Genalyte, "We look at it as a healthy thing for the industry. Those who can withstand the additional scrutiny and the oversight end up producing better products."

Opportunity around portability

Genalyte, DMI and many others (**Table 1**) predicate their businesses on the idea that access to diagnostics should move closer to the patient. "It's a correction. Diagnostic testing has been centralizing very aggressively for 15 years and there's a belief in some care settings that the centralization has gone too far," says Gunn.

Most doctors don't maintain in-house laboratories any more, and instead send blood samples hundreds or even thousands of miles to a centralized laboratory. That distance can make it impossible to see a patient and prescribe treatment in one initial office visit, if laboratory tests are needed.

A portable or desktop blood analyzer could address that issue, say these companies. It could also be a boon in emergency situations and settings of limited resources—developing countries, war zones, places of infectious disease outbreaks, natural disaster areas, spaceships, boats and airplanes. In such situations as the West Africa Ebola outbreak, there may not be access to any kind of diagnostic service, and a low-cost blood analyzer would, arguably, save lives. "Where there's a real market possibility is in companies who can do these kinds of tests quickly in the field without the need for electricity, good water supply, temperature and humidity control," says David Koch, director of clinical chemistry at Grady Memorial Hospital in Atlanta, Georgia.

That's true for military uses as well. In fact, the US military's Defense Advanced Research Projects Agency (DARPA) is funding the development of such a device for deployed soldiers. "The concept of being able to test at the point of care is transformative for us," says Matthew Hepburn, a program manager at DARPA's Biological Technologies Office in Arlington, Virginia. For soldiers in the field, "the idea of obtaining a sample, sending that sample through a transport to a reference laboratory, having it tested and having it sent back to a soldier or medic—it's just untenable. It's not practical in so many situations we're in."

Theranos was trying to take the idea of decentralization further, empowering healthy people to order blood tests for themselves any time they want. The company is not alone in this business model. Seattle-based Arivale, a company co-founded by Lee Hood, provides a personal coach to walk customers through an analysis of more than 90 biomarkers from their blood and saliva samples. Customers can collect their saliva with the company's at-home kit.

But for blood, customers are told to go to one of the company's partnering laboratory sites to have it drawn from a vein by a professional. Arivale's arrangement illustrates the challenge of uniting blood diagnostics and the consumer—a gap that Theranos was trying to bridge.

Finger pricks and vein draws

The only realistic way to expect a person to collect his own blood is with a skin puncture, such as a finger prick, which accesses blood from capillaries. That kind of blood sample is different from blood drawn directly from a vein. Capillary blood from a finger prick flows across damaged tissue that is already working to heal itself. And if the capillary in the fingertip isn't hit just right—a common occurrence for the average, untrained person—interstitial fluid will flow out with the blood. Both scenarios change the composition of the sample and can affect the results of a test. Untrained people tend to squeeze the finger to get more blood, causing more interstitial fluid to flow out. And contaminants on the skin are bound to be problematic in some cases.

There's also a limit to how much blood can be collected from each finger prick. One drop of blood is about 25 μl, and eight to ten drops—up to 250 μl—is the most one can get from a typical finger prick. The high end of that is a decent-sized sample, if you can get it. And some groups such as Yager's are exploring the concept of using that much blood in a miniaturized or handheld device.

In general, whether of venous or capillary blood, small sample sizes make the most sense for portable blood analyzers. But not all markers are abundant enough in the blood to

Table 1 Selected companies with finger prick blood testing technologies

Company/location	Technology	Sample size/tests	Status
Abbott	Electrochemical detection	26 tests: chemistries, electrolytes, hematology, blood gasses, coagulation, cardiac markers, and a pregnancy test; 2–3 drops from a capillary, venous, or plasma sample, depending on the test; results in minutes	i-STAT on the market
Abionic/Lausanne, Switzerland	Nanofluidic biosensors, fluorescent anti-IgE antibodies, read with miniaturized fluorescent microscope	2 drops of blood: 10 allergens in 20 min	abioSCOPE (reader) and abioGuide (apps) has CE marking from EU
Archimej Technology/Évry, France	High sensitivity spectroscopy where the emission spectrum is dynamically controlled	Microvolumes of blood: multiple biomarkers for liver, kidney, heart status in real time	Beta-Bioled in development
Cepheid (now part of Danaher)	PCR on a cartridge	3–4 drops of capillary blood: quantitative and qualitative assays for HIV, hepatitis C and Ebola	Quantitative assays for HIV viral load and hepatitis C under development; qualitative assay for HIV has CE marking and WHO pre-qualification; qualitative assay for Ebola has CE marking and US and WHO emergency authorization
Cor	Vibrational spectroscopy	Drop of blood taken from the arm: HDL, LDL, total cholesterol, fasting glucose, triglycerides, fibrinogen	Cor Wellness System in development
DMI	Fluorescence and light scattering from multi-plexed nanostrips	5–10 μl of blood: hundreds of tests	rHealth under development
Eva Diagnostics/London	Multi-wavelength optical absorption	10 μl of capillary or venous blood: hemoglobin and hematocrit in 30 s	AnemiPoint: Undergoing evaluation
Genalyte	Photonic detectors lithographically printed on silicon chips	One drop of venous or capillary blood: 128 tests, starting with rheumatology	Maverick in development
Magarray/Milpitas, California	Magneto-nanosensing technology adapted from computer disc drive technology	Single drop of blood: modular with biomarkers in cancer, autoimmunity, heart diseases in minutes	In development for laboratory use or point of care
Pixcell Medical/Yokneam Illit, Israel	Viscoelastic focusing	Finger prick (capillary) or venous blood: 20 standard CBC parameters	Hemoscreen, CE mark in EU, going through 510K approval[a]
Philips	Antibody-coated magnetic nanoparticles and biosensor	Finger prick: troponin in 5 min	Minicare I-20: CE marking
Roche	Reflectance photometry	30 μl of blood: 17 tests in 2–3 min	Reflotron Plus (marketed in the EU)
Zepto Life Technology/ Minneapolis	Giant magneto-resistance sensing with magnetic nanoparticles	Small volumes of serum: multiple biomarkers in minutes	Under development

HDL, high-density lipoprotein; LDL, low-density lipoprotein; WHO, World Health Organization; CBC, complete blood count. [a]Premarket regulatory review of high risk medical devices.

reliably show up in small samples. "If you have a very small [blood] volume multiplied by very small [analyte] concentration, that means you have a very small number of molecules in the sample," says Shan Wang, an engineer at Stanford University, who is developing blood analyzer technology. The odds of finding an analyte in the sample go down as the sample gets smaller. And ultimately, "if there's nothing in your sample, there's nothing to amplify and detect," adds Yager.

Some tests, such as those that quantify viral loads, require a plasma sample—the liquid portion of blood that remains after the cellular components have been separated by centrifugation. That preparatory step may not be feasible in miniaturized devices or in decentralized business models. It also cuts an already small sample size roughly in half.

Given these hard limitations, one can imagine why researchers were highly skeptical of a company claiming to be able to detect over 200 markers in a few drops of finger-stick blood drawn by a customer at a drugstore. "It was too good to be true," says Weissleder.

What can be detected in a blood drop?

The number of analytes that can feasibly be detected in small volumes of blood is currently far fewer than what Theranos claimed. Of these, the glucose meter is probably the most successful consumer-based testing device. Available since the early 1980s, dozens of such instruments are on the market, enabling people with diabetes to track their blood sugar with a finger-prick blood sample on a pocket-sized device. Early models used test strips and measured colorimetric changes from enzymatically catalyzed glucose oxidation; more modern devices use electrochemical signals generated by similar reactions. Several continuous monitoring devices are now available that measure sugar in body tissues and transmit the data wirelessly to a monitoring device. (Devices that will transmit data via Bluetooth to an iPhone are under development.)

Drugs of abuse, toxins and many viruses are typically abundant in the bloodstream, making them relatively easy to detect in a few drops of blood, and several portable versions of devices that test for those analytes are in development. Tests that need only indicate the presence or absence of a marker, rather than quantify the level, are more straightforward and amenable to small samples. A drop of blood is also enough to isolate DNA and RNA for sequencing and analysis.

Blood chemistries, electrolytes, blood gases, coagulation tests, lipids and some hematology tests can also be performed on small blood volumes—some of them on finger-prick blood. Several companies, including multinationals such as Abbott (Abbott Park, Illinois), Roche (Basel, Switzerland) and Samsung (Seoul, S. Korea) have incorporated these tests into point-of-care devices. The instruments typically require electricity, a climate-controlled environment and someone with some kind of training, so they are marketed largely to hospital emergency departments, intensive-care units, veterinary offices and some doctors' offices. Healthcare professionals in those settings use the devices to get results immediately at the bedside, or point of care, without having to send the blood to a laboratory.

Immuno- and electrochemical assays

One of the first of these point-of-care devices, called the i-STAT, has been on the market since 1992, and was acquired, along with its developer, the i-STAT Corporation, by Abbott in 2003. The device can detect 26 analytes, some of which are cleared for detection in finger-prick samples. A technician puts the blood sample in one of 19 cartridges, pops it into the handheld analyzer and presses go.

The earliest uses of the i-STAT were in the neonatal unit, says Matt Bates, head of R&D for Abbott Point of Care in Princeton, New Jersey. "A premature baby has very low blood volume and you want to preserve that," he says. Early models of the device tested glucose and blood chemistries, including electrolytes such as sodium and potassium, and kidney function markers such as blood urea nitrogen and creatinine. The company later added blood gases—measurements of acidity, oxygen and carbon dioxide. "Then we found that we could do immunoassays," says Bates. Abbott has developed four immunoassays for i-STAT—one early pregnancy test and three cardiac tests.

The i-STAT's technology is based on electrochemical analyses, which measure the electrical potential or current in the sample. Algorithms then convert the electrical measurements into analyte levels. For many of the blood gas and electrolyte tests, ion-selective electrodes are used to convert the amount of the analyte to an electrical potential that can be measured. For hematology tests such as hematocrits, the number of cells in the sample are counted by measuring the electrical conductivity of the sample. The more cells, the less conductive the sample.

Immunoassays are more complicated. Those molecules are identified using ELISA (enzyme-linked immunosorbent assay) and an electrochemical sensor fabricated on a silicon chip. For example, to detect cardiac troponin, the silicon chip's sensor is coated with capture and detection antibodies that sandwich troponin molecules and hold them in place on the sensor surface. The detection antibodies are conjugated to an alkaline phosphatase enzyme, and when a substrate is washed over the molecules, the enzyme cleaves the substrate, causing a transfer of electrons. The chip's electrochemical sensor measures the flow of those electrons, which is proportional to the concentration of troponin within the sample.

Immunoassays are more challenging than clinical chemistry tests or nucleic acid tests because they require getting proteins to bind with each other and detecting those interactions. "That's more sophisticated and needs to be done in a more controlled fashion," says Gunn at Genalyte. "Proteins are tough because each one is unique and there is no general amplification technique," he says. One of the main challenges is the wash cycle, adds Bates at Abbott. "We have developed a way of removing excess detection antibodies that have not formed a sandwich with troponin and the capture antibody, with a limited volume of fluid," he says. That can be applied to other assays, but "the limiting step is then prioritizing which immunoassay we work on next."

Gunn says that since immunoassays are an unsolved problem, they are the "sweet spot" of the market, and the focus of his company. Genalyte pitches itself as being able to run 128 immunoassays on a desktop device on less than a drop of blood from a finger prick, although it hasn't identified a need to run that many at once, Gunn says. The company is focusing first on an autoimmune panel of 12 tests geared for rheumatologists' offices. In that instrument, antibody molecules that bind the target analyte are printed onto a tiny ring-shaped biosensor on a silicon chip. The captured analytes are detected by measuring the shift in infrared light in the ring concomitant with analyte binding[1].

The key to getting a good sample from a finger prick, Gunn says, is to collect plenty of blood—not just a drop or two. "By the time you've collected eight to ten drops from a finger prick, the variability is reduced and you end up with a result that you would get out of a venous draw," he says.

In November, the company presented the results of a study at the American College of Rheumatology/Association of Rheumatology Health Professionals annual meeting in which it ran tiny (10 μl) samples of finger-prick whole blood though its instrument and compared with traditional tests its ability to detect autoantibodies associated with connective tissue disease. Genalyte conducted the tests on its instrument in five doctors' offices in San Diego and again in its laboratory, and repeated the entire experiment at a hospital in France. The results from the finger-prick samples on Genalyte's instrument were on par with those from larger volumes of venous whole blood tested with traditional equipment, Genalyte reported. "We wanted to be able to compare it scientifically every which way," to establish credibility amidst the clinical community's heightened skepticism, Gunn says.

Genalyte's autoimmune panel will indicate whether a biomarker is above or below a particular threshold—a semiquantitative test. Gunn says Genalyte's technology is capable of quantitative analysis, but because semiquantitative tests are the standard in rheumatology diagnostics, there is no need to offer a fully quantitative test. The company has not yet submitted its device to the US Food and Drug Administration (FDA) for approval.

Sticking with magnetism

To expand the range of analytes that can be detected in small volumes of blood, some groups are pulling technologies from other industries. Dutch electronics giant Royal Philips joined the point-of-care diagnostics field in 2003, and has developed a handheld device based on magnetic nanotechnology. The device, called the Minicare I-20, manipulates the movement of analytes in a blood sample using magnetic nanoparticles, and measures the analyte's abundance using an optical detection technique[2].

In that strategy, proprietary magnetic nanoparticles coated with an antibody or other affinity reagent bind with the target molecule in the blood sample. A magnetic field then attracts all the nanoparticles to an active biosensor surface that is also coated in antibodies. Those bind to a second site on the target, creating a sandwich structure. Another magnetic field pulls the unbound nanoparticles away from the active surface, leaving only the nanoparticles of interest bound to the biosensor surface. A light is shined on the active surface and the intensity of the reflection determines the quantity of biomarker in the sample.

Philips in May received Europe's CE mark to use its device to detect troponin—a marker of myocardial infarction—in blood. Unlike other devices that measure troponin, Philips' test works reliably with blood from a finger prick, says Michel Simmons, senior marketing director of Philips' handheld diagnostics business unit in Eindhoven, the Netherlands. Philips markets the device to hospital emergency departments in Europe, Simmons says.

Similar technologies caught the attention of reviewers for the Nokia Sensing XChallenge, a $2.25-million prize intended to spur innovation in sensors for health metrics. Among the winners announced in November 2014 were two employing magnetic nanotechnologies, led by Shan Wang at Stanford[3] and Jian-Ping Wang at the University of Minnesota[4].

Toward a 'tricorder'

The grand prize of that competition went to Eugene Chan's DMI, which is developing a device, targeted at consumers, which can do a range of tests and a complete blood count, including red blood cells, white blood cells, hemoglobin, hematocrit and platelets. Devices currently on the market can analyze only some of those features, Chan says. To accomplish this, DMI has miniaturized traditional flow

cytometry in a handheld device that can mix thousands of tiny test strips, each about the size of a few blood cells, and reactive chemicals in a small blood sample. When laser light is shined through the mixture, the output—fluorescence and light scattering—created by the cells and nanostrips indicates the cell type and biomarker levels. One fluorescence wavelength is utilized to uniquely identify the nano strips; another is used to measure the amount of analyte present. With uniquely coded nanostrips, multiplexing is attained. DMI is funded by the US National Institutes of Health (NIH) and the US National Aeronautics and Space Administration (NASA) and has even demonstrated the device in zero gravity[5].

DMI is also a finalist in the $10-million Qualcomm Tricorder XPrize (a competition named after the fictional handheld detection device in the *Star Trek* television series). Entrants are expected to develop a mobile device capable of diagnosing more than a dozen conditions and five vital signs. Winners will be announced in early 2017, according to the XPrize Foundation.

But a true tricorder-like device—something that fits in a pocket and can be used in space, in disaster areas or at home by someone with no training—has to perform all the steps of blood analysis start to finish, with blood from the body going directly into the device. That means miniaturizing or finding an alternative to typical sample prep steps that are required before analysis, such as pipetting, mixing, spinning or incubating. "For most of these microfluidic applications, that's the ultimate question," says Chan. "I can make these cool small chips but I've got this big box that goes with the small chip because I have to do sample prep."

Tackling that is DMI's next challenge. It's also an area that other groups, including Cepheid in Sunnyvale, California, have been confronting. The company has developed a self-contained PCR laboratory on a portable cartridge with 11 chambers that carry out different functions. Lab-on-a-chip-type technologies have been around for years and can be used to detect infectious diseases in blood by amplifying the pathogen's DNA or RNA. But challenges remain, particularly with sample processing.

For example, Cepheid is developing instrumentation for early and quantitative detection of HIV viral loads using whole blood from a finger prick[6]. But whole blood samples contain both viral RNA and proviral DNA—the latter of which is not a good indicator of viral load. To get an accurate count, the two must be separated so that only viral RNA is measured. In traditional instrumentation, the issue is resolved by spinning the blood in a centrifuge and separating the plasma from the cellular components, which contain the DNA. But that processing step isn't ideal for point-of-care applications or a miniaturized device, says David Persing, chief medical officer at Cepheid.

With support from the Bill and Melinda Gates Foundation, Cepheid is developing novel ways to selectively detect HIV RNA in whole blood inside the cartridge. The company is exploring several different approaches. One is to do a reverse transcription step under conditions that keep DNA intact. "If it stays double-stranded, it doesn't get reverse transcribed along with the RNA, which is single-stranded," says Persing. Another approach the company is trying is to use RNA-selective extraction protocols. A third option is to design a filtration technology inside the cartridge to stop up the cellular components of the blood so that only the plasma continues through the assay, he says.

It's an ambitious goal. The sensitivity of such a device has to be high. Conventional assays typically use about 1 ml of plasma. In a sample that size, there may be only a few hundred copies of HIV RNA in the early weeks of infection. Cepheid's device must work with a sample that's about a tenth of that size.

Circling back to the consumer

Still, Cepheid markets its products to professionals. Companies marketing to consumers have, in a way, even greater challenges. DARPA, for example, wants a device that is intuitive enough that anyone—and DARPA emphasizes 'anyone'—can use it. "That makes people nervous," says Hepburn at DARPA. "They say you need to be a lab technician." The device must also be able to detect multiple pathogens with laboratory-grade accuracy in a portable device using finger-stick blood, urine or a nose swab.

The agency chose Abbott's Ibis Biosciences to do the job and has since awarded the company about $18.5 million. Ibis is developing a miniaturized PCR technology, but like other groups across the industry, it is finding specimen preparation aspects "particularly challenging" says David Ecker, head of R&D for Ibis. "The aspiration here is to put any kind of specimen on the device, and have it run end-to-end specimen preparation, high-yield, high-purity extraction of nucleic acids in a hands-off fashion. That's very hard, but we have an advanced strategy in place to tackle this issue," he says.

It's hard, but only if the goal is to achieve laboratory-quality results. If the goal is to provide a consumer gadget for people who don't have a particular health condition they need to track, the bar may not need to be so high. Take, for example, San Francisco-based Cor, which is developing a home-based finger-prick device aimed at tracking such markers as cholesterol, glucose and triglycerides. The company says its instrument provides a "similar level of accuracy" to laboratory tests. The test results are then translated into "insights" and "action plans" for the user's health. Since the company is only making general wellness claims, Cor projects that its regulatory path will be compressed.

But consumer-oriented devices also raise bioethical questions. "There's what can be done with a drop of blood, and what should be done," says Eleftherios Diamandis, head of clinical biochemistry at Mount Sinai Hospital in Toronto. A healthy person who decides to run a bunch of tests on himself runs the risk of receiving false positives or frightening information that he doesn't know what to do with.

Tests are generally assigned a reference interval for what is normal—usually the 95th percentile. That means that 5% of tests will come back outside of the reference interval, or abnormal. Figuring out whether that's a true positive or a false positive is where a professional comes in. A doctor should be able to determine the significance of an abnormal test result by putting it into context with other laboratory results and the patient's overall health.

The average person probably won't know how to do that. And it means the true positives can get lost in the mix, adds Diamandis. "If you look for a disease in a mostly normal population, it's next to impossible to find the diseased persons without intermixing them with the false positives," he says.

Koch at Grady Memorial Hospital says that conceptually, he likes the idea of the public being able to monitor themselves. But he, too, fears that will translate into a lot of false positives. "If people start doing that, my fear is there will be a lot of angst, people will be running to their doctors, asking for scans and spending a lot money," he says. "I'm not sure our medical system, even in the United States, can manage that."

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