

▶ DNA Analysis at the Site of Care

Max Perelman, Co-founder of Biomeme, wants to turn your smartphone into a lab for quick DNA diagnostics and on-site disease tracking.



We want to empower anyone to do the entire qPCR process from start to finish, and to do this we've dramatically simplified the whole process and made the platform fit in the palm of your hand.

**Max Perelman
Biomeme**

The polymerase chain reaction (PCR) has become a standard tool in many disciplines, including drug development, forensics, and in healthcare for diagnosing diseases and identifying bacteria and viruses. It was developed in the 1980s as a way to focus on a segment of DNA and copy it. Because significant amounts of a sample of DNA are necessary for molecular and genetic analyses, studies of isolated pieces of DNA are nearly impossible without PCR amplification.

Over time, PCR analysis has become cheaper and more mobile. Still, PCR analysis is complicated and expensive and is usually done through a centralized process in labs.

But, according to Max Perelman, co-founder of Biomeme, currently there are no systems for doing truly mobile real-time PCR. Now a system developed by Biomeme, used with a smartphone, could change all this. Biomeme is a start-up company that so far has raised \$165 million in funding.



The Biomeme system includes a docking station for real-time qPCR, a mobile app to control the system and analyze results, and targeted test kits for preparing samples and identifying pathogens or diseases by their specific DNA or RNA signatures.

"We want people to be able to do the entire process from start to finish," he says. "We want a system that is affordable, doesn't require a molecular biologist or pipetting expertise, and is an out-of-the box system."

What Mr. Perelman and his co-founders — Marc DeJohn and Jesse vanWestrienen — developed is a system that is about the size of a soda can that docks with a smartphone, which in total weighs about 15 oz. In addition to the docking station, the system includes a mobile app to control the system and analyze results and targeted test kits for preparing samples.

"We've taken advantage of every sensor that is available on a smart device, from the camera, to the touch interface, to the barcode scanning ability to the GPS, WiFi, and Bluetooth," he says.

Additionally, the company has created a sample preparation process that even Mr. Perelman's 7-year-old daughter has been able to master.

"People forget that PCR analysis is just one piece of the puzzle," he says. "There is a specific process for preparing samples."

Biomeme's current prep works with water, urine, or swab samples, Mr. Perelman says. The sample prep involves four color-coded vials. One is a lysis buffer, two wash buffers, and an elution buffer. A metered pipette is used to transfer the sample from the vials into the PCR tubes with lyophilized reagents. Those tubes are then put into the Biomeme device.

The test takes less than an hour and the result shows on the smartphone. The results can also be transmitted to the cloud, where results can then be transferred to an EMR, laboratory system, or epidemiological database. Additionally, doctors can receive a notice through email or text when the results are available.

The Biomeme system has potential to enable mobile testing at the point-of-need for healthcare (mobile clinics, disease tracking, home use), agriculture (plant disease tracking, food safety), vector surveillance (malaria, West Nile, Lyme disease), vet-

erinary medicine, and environmental monitoring (soil and water safety).

Mr. Perelman says there is a place for this device in clinical trials, particularly in pharmacogenomics, to rapidly screen potential participants. It can also be used to screen for a potential drug interaction.

When it becomes available, Mr. Perelman says he hopes to sell the system in the \$1,000 to \$2,000 range, with a consumer version for even less. The product will first be introduced next year in Central America with help from partner The Gorgas Institute, the World Bank Pan American Health Organization reference laboratory for Central America, with a system for testing for chlamydia, gonorrhea, and trichomoniasis. This year, Biomeme is also working with partners Drexel University and the University of Pennsylvania to test clinical samples with the goal of conducting field trials in Panama to be certified for use in that region.

"Our sweet spot for human diagnostics right now is in markets that might not have a central lab model," Mr. Perelman says.

The global PCR market is projected to reach around \$27.4 billion by 2015, with a CAGR of 13.9% for the analysis period 2009 to 2015, according to a June 2013 report from Axis Research Mind. North America is estimated as the largest market with a market share of 40% of global market.

But, Mr. Perelman says it may be a few years before the system is ready for the U.S. human diagnostic market.

"The U.S. healthcare market isn't quite ready yet," he says. "We have a very complicated care provider model. Our intention is to come to the U.S. market in a few years."

Mr. Perelman says a diagnostic at the point of care is important because gonorrhea is becoming more challenging to treat. In fact, surveillance data from the Centers for Disease Control suggest that the antibiotic cefixime is becoming less effective in treating gonorrhea, and CDC officials say it is only a matter of time before gonorrhea becomes resistant to the class, including cefixime. **PV**

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