

New lab-on-a-chip can detect heart and gum disease instantly

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Someday in the not-too-distant future patients may visit a doctor's office, provide a sample of saliva or blood, and know in minutes if they are prone to heart disease, gum disease, or cancer. There would be no sending samples to off-site labs for analysis and waiting days to obtain the vital information.

A five-pound, hand-held medical diagnostic device being developed at the National Nuclear Security Administration's Sandia National Laboratories promises to be this ticket to better health for millions of Americans.

"We have taken technology that we've worked on for several years — Sandia's lab-on-a-chip devices — and are adapting them for use in medical diagnostics," says Anup Singh, project lead. "We've tested saliva samples from healthy patients for gum disease, and within the next few months we will begin using the diagnostic tool to test diseased samples."

Much of the research is being done at Sandia/California.

The research is funded by the National Institutes of Health (NIH).

Lab-on-a-chip technologies were developed in the mid-1990s for detecting biotoxins and chemical agents. In new incarnations they are used in the analysis of bodily fluids, such as saliva and blood, for detecting certain diseases. Expanding on established microchip-based separation technologies, the research team adapted a method known as immunoassay to a chip. The combination of the lab-on-a-chip and the

immunoassay technique allows for fast and sensitive analysis of biomarkers specific to certain diseases.

As part of the immunoassay process, antibodies specific for biomarkers of interest, such as gum or heart disease, are tagged with a fluorescent dye and then mixed with a patient's saliva or blood. Biomarkers present in the sample attach themselves to the fluorescent antibody. The mixture is injected into a microchip using a syringe. An applied electric field forces the sample to flow through a microchannel that is two to five centimeters long, tens of microns deep, and a few hundred microns wide.

As the sample moves through the channel, cast-in-place porous polymers in the microchannel sort molecules based on their sizes and electrical charges. If biomarkers for the disease are present in the patient's sample, the lab-on-a-chip analysis will separate fluorescent antibodies bound to the biomarker from unbound antibodies.

A photomultiplier tube then detects the fluorescence emission with extreme sensitivity. After quantifying the relative fluorescence of the two species — bound and unbound antibodies — researchers can determine the amount of biomarker present in the patient's sample. If the sample contains significant fluorescence emission from a bound antibody, indicating that biomarkers are present above a certain level, a doctor could conclude that the patient has or will eventually get the disease for which he or she is being tested. At the conclusion of the test, while the patient is still in the doctor's office, preventive or therapeutic care could begin.

The entire device, including the channeled glass chips, photomultiplier, and electronics, will fit into a hand-held package that weighs less than five pounds.

“The beauty of this device is that it has everything required to make it useful — sensitivity, portability, and the ability to run tests quickly,” Singh says. “It is small and can be carried with ease almost everywhere. It’s also very sensitive and works fast. Within a few minutes you can tell if you have a diseased sample.”

Terry Michalske, director of Sandia’s Biological and Energy Sciences Center, originally alerted the research team to a call for proposals by the National Institute of Dental and Craniofacial Research, a division of the NIH, to develop a new way of approaching oral diagnostics.

He says of the resulting research, “The results that Singh and his team have accomplished are truly world-class. They have succeeded in combining cutting edge science and engineering to achieve something that has the potential to revolutionize medial diagnostics.”

The Sandia researchers are partnering with Will Giannobile, an associate professor at the University of Michigan School of Dentistry who is an expert in gum disease. The team also includes Harold Craighead, a professor at Cornell University’s School of Applied and Engineering Physics, and Mark Burns and Charlie Hasselbrink, professors at the University of Michigan’s School of Engineering.

Much of the research is centered on detection of gum disease from a patient’s saliva and gingival crevicular fluid, the fluid between the tooth and gum. Early detection of gum disease is of significant interest to the medical community. Some 20-45 million Americans suffer from gum disease and more than \$2 billion a year is spent to diagnose and treat the disease.

“It is postulated that saliva is a mirror of blood,” Singh says. “Everything in saliva exists in blood but at concentrations 100 to 1,000 times lower than blood.”

Saliva is already being used for detecting HIV and drugs-of-abuse in commercial instruments. Saliva makes sense as a patient sample; obtaining saliva is a noninvasive process that requires no needles and is much more tolerable than traditional blood taking. Singh anticipates that in the future, saliva will be used to detect everything from gum disease to heart disease to cancer.

In addition to biomarkers for gum disease, Sandia researchers are also developing assays for cardiovascular disease markers such as C-Reactive protein. Singh says that although the primary goal is to analyze saliva, “we have shown that our device can work with blood as well.” Having the ability to analyze multiple bodily fluids makes the device useful for a wide variety of clinical applications.

Having already studied saliva samples from healthy people, the Sandia researchers will begin studying samples from 50 to 100 diseased patients in January. The patients are being recruited by Giannobile at the University of Michigan.

“Working with samples from actual patients will give us the opportunity to see how accurate our immunoassay method works,” Singh says.

Source: Sandia National Laboratories

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