

Paper as a Versatile Platform for Low-Cost Diagnostics

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Abstract

Novel technologies are needed to address the urgent healthcare requirements of patients in the developing world and other resource-limited settings. Diagnostic devices that provide critical patient information at the point of need play a key role in the treatment and monitoring of disease. Such devices must be robust, simple to use, actionable, and extremely low in cost. Paper and other porous media provide an attractive platform from which to build devices that are able to address these needs. In an effort to expand the capabilities of porous media in diagnostics, we present a novel platform based on patterned paper microfluidic devices. In particular, 3-dimensional devices formed by stacking multiple layers of patterned paper provide the ability to perform many fluidic handling operations including: filtration; splitting; mixing; incubation; capture; and separations. Diagnostics For All (DFA) is developing tests based on this platform, in order to provide highly-functional diagnostic devices at unprecedented low cost. In this presentation, we will describe some specific examples of paper-based tests designed specifically for use in resource-poor areas.

Liver function test

In recent years, considerable effort has been given to providing universal access to medications for diseases afflicting the developing world. Increased access to anti-retroviral (ARV) therapies to treat HIV has been particularly successful, with millions of patients now receiving desperately needed medicines. Additionally, access to therapies for tuberculosis (TB), malaria, and other treatable diseases is increasing at an impressive rate. While increased access to therapies is encouraging, a number of these medications are known to exhibit substantial liver toxicity in patients, resulting in debilitating symptoms and even death in the most severe cases. In the developed world, routine monitoring of liver function for patients on ARVs and many other medicines is the standard of care. Monitoring for liver toxicity in the developing world, however, is severely limited by expense and access to modern instrumentation. Because of these obstacles, many developing world patients receive minimal or no monitoring during treatment. DFA is addressing this need by developing a

low-cost, patterned paper-based, liver enzyme diagnostic test that can provide an assessment of liver health from a single drop of fingerstick blood in about 15 minutes. We will present some of our recent results from field testing of this device.

Multi-plexed Immunoassay

Immunoassays which make use of antigen-antibody or antibody-antibody interactions are an important class of diagnostic tools. While such assays are routinely performed on lateral flow platforms, it is difficult to multiplex more than one target onto a single device. Simultaneous analysis of multiple targets increases the amount of information provided to the caregiver in a point-of-care scenario and greatly enhances the quality of care available to the patient. We present a multi-layer immunoassay platform that is capable of splitting a single sample multiple times in order to simultaneously perform different assays. Additionally, these devices are low in cost, require very small sample volumes, and are easily reconfigured for other assays. We will present some of our work toward a multiplexed device for detection of Dengue and Malaria.

Molecular Diagnostics

Devices capable of isolating, amplifying, and detecting target DNA and RNA sequences are at the forefront of modern diagnostics medicine. Such technologies offer unprecedented sensitivity and specificity in the detection of biomarkers for infectious disease, cancer, and other chronic illnesses. These devices are typically very expensive, large, and require a modern laboratory and trained technicians to operate. These limitations severely restrict the use of molecular diagnostic tools in the developing world. DFA is exploiting our ability to perform autonomous fluid operations such as filtration, mixing, splitting, capture, and washing on patterned paper-based microfluidic devices to enable access to molecular diagnostic technology on an extremely inexpensive, disposable device platform. We believe our approach represents a fundamental shift in the field of nucleic acid detection and will significantly increase diagnostic capability in the developing world.