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Paper-based Microfluidic Point-of-care Diagnostic Devices for Monitoring Drug Metabolism

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Modern day health care systems face many challenges due to the growing aging population, rising costs, and limited resources in developing countries. Infrequent and time-consuming medical examinations at local hospitals are insufficient to meet the challenge of growing health-diagnostic needs in the patient population. Accurate, compact, and inexpensive Point-of-Care (POC) diagnostic devices that can detect biochemical changes in the body, and indicate to the user in a simple format the results so that necessary medical attention can be sought before serious complications arise is one solution to solving the world's health care needs [1,2]. The global market for POC diagnostics, valued at $13.8 billion in 2011, is expected to increase to $16.5 billion in 2016, according to a new report Point-of-Care Diagnostics from BCC Research [3]. The ease of use of POC devices has allowed patients to personally monitor their own health quantitatively at home. There is no requirement for samples to travel to a laboratory outside their home and no need for results to be transmitted and collected. Rather, the patient or caregiver, in the clinical setting doctor or nurse, initiates the test and receives the results on the spot, thereby, saving time by providing results rapidly. Furthermore, information pertaining to the onset of disease or monitoring of a drug's effectiveness during treatment can be more easily assessed when using a POC device.

Improper dosage of prescription drugs may be insufficient to be effective or in larger amounts can lead to increased toxicity in the blood that may be lethal in severe cases. The current system of analysis for drugs prescribed for treatment or for diagnostic purposes, Therapeutic Drug Monitoring (TDM), aims to enhance drug efficacy, reduce toxicity or assist with diagnosis but has inherent limitations that include its high cost and accessibility only in some large hospitals [4]. A regular test for drug concentration is warranted to effectively monitor the health care of a patient. The development of a quantitative POC detection device to determine the concentration of drug in the minimal sample of blood, that is both easy to use and which does not interfere with the normal patient's routine is desired.

The optimal POC device would be minimally invasive, accurate, have great selectivity, sensitive, would be transparent, have a long battery life, would be stable to both aqueous and organic media, could be stored between −55°C and 55°C for years, could be used in both a hospital setting and at home by patients, and would cost less than one dollar to fabricate and manufacture [5,6].

A novel direction for POC diagnostics, that presents a more practical approach, is the implementation of paper that utilizes its natural capillary action to move sample instead of a plastic substrate and pumps. Paper is the ideal platform for a POC device for clinical and analytical chemistry because it is light weight, biocompatible, easily disposed of, easy to use, store, transport, modify and is compatible with various biological assays. A major advantage of paper is that it is amenable to colorimetric tests which can be detected by the naked eye or a cellular phone.

In a preferred embodiment, a paper-based POC microfluidic chip for the detection of drug concentration can quantify the analytes of interest in a simple procedure that requires low volumes of blood sample [7-11]. With one drop of blood, the device can filter the plasma from the whole blood and allow it to flow to the test zone through hydrophilic channels, where a simple colorimetric or chemiluminescent assay utilizing an inexpensive hand held black light or LED can be performed with specific markers and dyes that have been prefabricated into the paper channels and capture or respond to analyte at the test zone. In this way the patients will be able to easily analyze the concentration of the drug at home and clinicians can accurately test the effectiveness of the drug dosage for the patient by remote reporting via the internet or wireless application.

The anticipated success of a paper-based microfluidic chip has already been confirmed with the recent development of a device by the non-profit organization Diagnostics for All, in which a POC device measured markers of liver function [2,12]. This test, on a piece of paper the size of a small postage stamp, utilized a colorimetric assay with two enzymatic markers of liver function, and worked with just a drop of blood from a finger stick. It is currently undergoing field tests in developing countries where the test for liver function is critical for patients receiving medication for TB and AIDS [2]. This tested and proven paper-based microfluidic device represents an opportunity to revolutionize health care by providing a more universally attainable diagnostic for the detection of drug, analyte, and metabolite concentration in blood for patients on specific medications at reasonable costs. Microfluidic paper-based POC devices have the potential to support decentralized testing thereby allowing patients to test and monitor themselves in the safety of their own home making the reality of personalized medicine not too far in the distant future.

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