Low-Cost Disposable Device for Point-of-Care Nucleic Acid Testing of HIV: Sample-to-Answer in 60 Minutes for Less than $5.00

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A rapid, electricity-free cartridge for nucleic acid testing (NAT) from finger-prick blood is proposed to combat the high rate of undiagnosed HIV infection in low-resource settings. The low estimated cost per test cartridge ($3.00-$5.00), coupled with the rapid turn-around time of 60 minutes, is expected to enhance early infant diagnosis and treatment, decrease the risk of transmission by undiagnosed individuals with acute infection, and increase drug regimen adherence. This technology is designed to meet the growing need for acute viral diagnosis and to provide the benefits of rapid point-of-care (POC) results. The isothermal sample-to-answer NAT approach is composed of front-end sample preparation, one-step transcription and amplification, and endpoint immunochromatographic detection. The assay successfully detected 2,000 copies of HIV RNA from a panel of patient-derived isolates, thus demonstrating primer immunity to sequence variability. The system has further displayed high sensitivity and specificity when analyzing crude patient samples. For use in POC conditions, the assay was simplified, streamlined, and integrated into a self-contained microfluidic cartridge. An iterative approach to design and prototyping guided the development of a multilayered PMMA bio-electromechanical system and PDMS large-scale-integrated chip. In response to observed limitations, a novel paper microfluidic cartridge operated solely by mechanical forces on reagent blister packs, coupled with a spring-loaded mechanism for automatic reagent release, was subsequently designed. As the first proposed NAT platform for on-location identification of viral diseases and genotypic drug resistance patterns, this system will revolutionize the POC testing paradigm.

Awards Won:

First Award of $5,000

Intel ISEF Best of Category Award of $5,000

Intel Foundation Cultural and Scientific Visit to China Award

U.S. Agency for International Development: First Award of $2,000