Isothermal Nucleic Acid Amplification System for Point-of-Care HIV Diagnosis

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Approximately 34 million people worldwide are infected with HIV, including 2.3 million children. To date, there is no accurate point-of-care HIV test for neonates or acutely infected adults. Prompt diagnosis is vital for early initiation of anti-retroviral therapy, which can significantly suppress infection and improve survival rates. This project presents a rapid isothermal nucleic acid amplification system capable of performing point-of-care HIV diagnosis from crude samples. Elements of thermal lysis, recombinase polymerase amplification (RPA), and immunochromatographic strip (ICS) detection were combined to create a self-contained assay possessing the sensitivity necessary to diagnose the disease in its acute stage. This project outlines a strategy that is: (1) capable of performing isothermal amplification and detection of HIV DNA and RNA; (2) equipped to diagnose viral nucleic acids using raw, unprepared samples; and (3) readily adaptable for integration into a micro-device format. The RPA-ICS assay was able to amplify and detect HIV sequences, producing a robust endpoint signal. The system was shown to successfully detect HIV DNA in samples containing a 4% concentration of HIV genome-encoded cells, non-infected cells, proteins, and other whole blood constituents with minimal front-end sample preparation. For use in a point-of-care setting, a micro-device incorporating all steps of the assay was conceived using computer-assisted-design software. This device is capable of analyzing samples without external manipulation or access to specialized equipment. Through virtue of its rapid, isothermal, and self-contained nature, the system described here provides proof-of-concept results to support the development of a successful point-of-care HIV nucleic acid-based test.

Awards Won:
Second Award of $2,000