Affordable Rapid Diagnostic Tests for Malaria

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Executive Summary

- Malaria constitutes a major global health problem that is endemic in 100 countries globally.
- This tropical disease poses a heavy financial burden, not only in third-world countries of Africa but also on the United States.
- Rapid Diagnostic Tests (RDTs) are currently used because they are accurate and require little training to administer.
- However, they are unable to detect parasite levels when below 100 per µL of blood, at early stages of malaria.
- Our microfluidic device takes advantage of the unique magnetic properties of parasitic cells to concentrate malaria cells for better diagnostic capabilities.
- High sensitivity than traditional RDTs.
- Yields a rapid diagnostic result within minutes.
- Bypass necessity of skilled technician or a central laboratory.
- Inexpensive and effective method of detection suitable for global distribution.
- Allows for possibility of distinguishing malarial infection, particularly Plasmodium falciparum.

Problem and Clinical Need

- Malaria is one of the greatest global health problems.
- Tropical disease, predominantly common in children.
- Africa contains 44 out of the 100 malaria-endemic countries.
- Accounts for the majority of the global malaria cases (86%) and deaths (91%).
- 300-500 million cases of malaria occur per year globally, with 500,000 deaths.
- A child dies of malaria every 45 seconds in Africa.
- Problem: Lack of affordable devices that can diagnose malaria at its early stages.
- Poor availability and processing time of microscopy labs.
- Low parasite sensitivity in early stages.

Description of Design

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What is Novel About the Device?

- Incorporates the known magnetic properties of malarial red blood cells in order to concentrate parasites in a way that has not been done before.
- Earlier diagnosis of malaria over traditional RDTs.
- Minimal blood contacting components provides for a safer handling of devices.
- Cost-effective, easily mass produced, and robust for global distribution.
- Improved ergonomics for ease of use.
- Combines several systems into one all-inclusive diagnostic device.
- Lancet facilitates the withdrawal of an appropriate amount of blood.
- Microfluidics: blood flows through device via capillary action.
- Nickel grid concentrates malarial blood.
- Fiberglass: absorbs waste blood to concentrate antigens.
- Buffer Release: lysed concentrated antigens.
- Immunochromatographic Test Strip: detects malarial antigen with greater sensitivity.

Estimation of Product Costs

- Costs are extremely important in developing medical devices for third-world countries and developing nations.
- Microwave Ceramic: Electricity, Shipping Costs, Employee Costs.
- Early estimates for main raw materials suggest cost flexibility: PETG Plastic per device: $0.10.
- PLGA Plastic per device: $0.10.
- Lancet per device: $0.08.
- External Casing Plastics: $0.25.
- Ni Grid: $0.10.
- Permanent Magnet: $0.10.
- Immunochromatographic test strip: $ 1.20.

Areas to save costs and optimize design: External Casing with enclosed magnet that acts as a semi-permanent piece. Lowering area of nickel grid, packaging efficiency, potentially will be able to use less antibodies in the test strip due to concentration (the greatest cost of the device).

Anticipated Regulatory Pathway

- Focus on the fastest method to move product to market while still proving safety and effectiveness of device.
- Class II Medical Device (non-critical, diagnostic).
- 510(k) Submission Due to Parts of Previous TGA Registered Devices.
- Regulatory Division of Immunology and Hematology Devices.
- Office of In-Vitro Diagnostic Device Evaluation and Safety.
- Center for Devices and Radiological Health.
- Planned post-market analysis and surveillance.