

Title: Microfluidic Diagnostic Device for Ethiopia

Team: Micro-fluidic Assessment for Malaria (MAM)

Members:

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Client: Tim Kwa

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Function: To create a microfluidic device to screen for malaria at the point of care in developing countries possibly via the use of blood chemistry analysis.

Client Requirements:

- 95% accuracy
- Result within one hour
- Battery powered with a battery life of up to 3 hours
- Device needs to be approximately the size of a laptop or smaller
- No more than \$5 per test

Design Requirements:

1. Physical and Operational Characteristics

- Performance requirements:* The device should accurately diagnose Malaria in remote conditions without the use of electricity or advanced laboratory equipment. The device needs to be disposable, ideally give results within an hour and can be used with minimal training.
- Safety:* The device should put the user at a minimal risk for accidental malaria infection via puncture and blood-borne infection.
- Accuracy and Reliability:* Greater than 95% accuracy in detecting malaria in a blood sample.
- Life in Service:* The epoxy device mold should withstand 300 uses and the PDMS device should be discarded after use due to the nature of blood-related infectious diseases.
- Shelf Life:* The epoxy device mold should be able to be stored at room temperature for up to 1 year. The PDMS mold should be used within 6 months of construction and be able to be stored at room temperature.
- Operating Environment:* The device needs to be able to function in outdoor environments experiencing a temperature range from approximately 48°F to 78°F, depending on the time of year. Since most of the use of this device would be on site in rural areas, it should be able to withstand elements such water and

dust. The device should come with a simple set of instructions to follow while using.

- G. *Ergonomics*: The PDMS device and epoxy mold should be easy to recreate without advanced technical knowledge with minimal laboratory facility requirements.
- H. *Size*: The size of the entire device should be approximately the size of a laptop, or smaller, ideally.
- I. *Weight*: The weight should be minimal as to increase the ease of which it can be transported to onsite point of care locations.
- J. *Materials*: Mold made of epoxy, and PDMS microfluidic device. No other known material restrictions.
- K. *Aesthetics, Appearance, and Finish*: Device should be durable and resistant to normal use by the lab in Ethiopia, also it should be able to be shipped in a ready to use form.

2. Production Characteristics

- A. *Quantity*: The creation of at least one functioning mold to replicate the final product with ease via PDMS molding. The design team should create at least 10 functioning PDMS molds to ensure reproducibility.
- B. *Target Product Cost*: Maximum of \$5 for one unit

3. Miscellaneous

- A. *Standards and Specifications*: The device should be accurate to > 95%, cost less than \$5 per unit, be battery powered and smaller than a laptop. We need to make it easy to follow disposal protocols for possibly infectious bodily fluids. Our method should be repeatable, and the devices should perform consistently.
- B. *Customer*: This product will be used by technicians in rural areas of Ethiopia in order to diagnose the inhabitants of those rural areas for malaria. The time it takes from the diagnosis beginning to ending should be relatively quick, approximately five minutes, in order to maximize time to begin treatments. The faster that the disease is diagnosed and treated, the less fatal the disease becomes.
- C. *Patient-related concerns*: After usage, the device should be able to be easily disposed of in order to not further contaminate other patients.
- D. *Competition*:
 - a. Binax Now- only brand of malaria rapid diagnostic test approved for use in the United States. Pack of 12 tests sells for \$396.20.
 - b. 86 different malaria rapid diagnostic tests are available from 28 different manufacturers. Cost is \$0.50 to \$1.50 per test, these have no quality control standards and are the currently available method for testing