Low-cost fluorescence cell imager

Country of origin | United States of America

Health problem addressed
CD4+ T-cell count monitoring is crucial in ART administration. While expensive, laboratory-based platforms for CD4 testing are available, there is still a need for good and cost-effective POC CD4 testing options, in order to improve access to accurate testing, especially for rural patients, and to reduce loss to follow-up of patients.

Product description
A low-cost, two-color fluorescence cell-imager for CD4+ T-cell counting at point-of-care.

Product functionality
Based on a novel, multi-mode planar waveguide configuration, the system capitalizes on advances in volume-manufactured consumer electronic components to deliver an imaging system with minimal moving parts and low power requirements.

Developer’s claims of product benefits
Implementation of fluorescence microscopy for near-patient diagnostics has been limited by cost and complexity associated with traditional fluorescence microscopy. There is an acute need for robust, low-cost imaging in high disease burden areas in low-resource settings, where access to central laboratory facilities and trained staff is difficult. This novel system provides a point-of-care cell counting solution at low cost and from a whole blood sample. The disposable cartridge safely contains the sample for biohazard waste disposal. The imaging reader is simple enough to be used at point-of-care. In other words, the system provides advantages of accurate results, comparable to that from an expensive laboratory instrument, with a simple protocol and a disposable cartridge, at the point-of-care.

Operating steps
A sample is loaded onto a disposable cartridge. The cartridge is inserted into the imaging reader, attached to and controlled by a laptop. The assay results are calculated and displayed on the laptop. The cartridge is disposed as biohazard.

Development stage
The system is currently being evaluated with patient samples at the Antiviral Research Center in San Diego, California, USA. An additional field study in Mozambique is expected to launch in mid-2012.

Future work and challenges
The aim is for simpler protocol, more indications, and no laptop. Foreseen challenges: complications with clinical trials and regulatory approvals at individual countries targeted for distribution; meeting pricing demands in low-resource settings; resistance of hospitals to modify their diagnosis/treatment protocols.

User and environment

User: Physician, technician, nurse
Training: Provided by a trained user; proficiency testing samples provided with kit; ~8 hours
Maintenance: None

Environment of use
Settings: Rural, urban, primary (health post, health center), secondary (general hospital), tertiary (specialists hospital)
Requirements: While stable continuous power supply is preferable, power supply for recharging the laptop battery is fine (the imaging reader runs as a USB peripheral off of the laptop); a trained operator; biohazard waste disposal; refrigeration system for the reagents, cartridges, and samples; a freezer for storing QC samples; pipettes; mixing device; timer.

Product specifications
Dimensions (mm): 200 x 180 x 380
Weight (kg): 5
Consumables: Disposable Cartridges; Proprietary Assay Mix Tubes; Proprietary fixative solution
Life time: N/A
Shelf life: N/A
Retail Price (USD): N/A
List price (USD): N/A
Other features: Mobile, reusable
Year of commercialization: N/A
Currently sold in: N/A
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