Combination HIV/T. pallidum Ab test

Country of origin | United States of America

Health problem addressed
There is an unmet need to diagnose the diverse co-infections that account for a significant fraction of HIV morbidity. However, co-infection testing is costly and too complex for most regions with high HIV prevalence. Multianalyte testing at point of care should enable improved therapeutic decision making, particularly in low-resource settings.

Product description
This device is a rapid diagnostic system that delivers a panel of serologic immunoassay results using a single drop of blood, serum, or plasma.

Product functionality
The system consists of disposable cartridges and a simple reader instrument, based on an innovative implementation of planar waveguide imaging technology. The cartridge incorporates a microarray of recombinant antigens and antibody controls in a fluidic channel, providing multiple parallel fluorescence immunoassay results for a single sample.

Developer’s claims of product benefits
HIV and co-infections are diagnosed using separate tests. Existing point-of-care tests generally yield qualitative results, and more complex laboratory tests are expensive and logistically difficult, requiring storage and transportation of samples to central labs and causing delays between sample collection and diagnosis. This system provides parallel, quantitative fluorescence immunoassay results for multiple disease markers from a single 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 MBio system provides advantages of multiple rapid tests in a single-protocol, disposable cartridge with automatic quality control features, as well as qualitative results.

Operating steps
A sample is loaded onto a disposable cartridge. The cartridge is inserted into the imaging reader. The assay results are calculated and displayed on a Laptop. The cartridge is disposed as biohazard.

Development stage
The system is currently being evaluated with patient samples at clinics in San Diego, California, USA, Salvador, Bahia, Brazil, and Kisumu, Kenya. A portion of the results obtained in collaboration with University of California, San Diego, has been published in the Journal of Clinical Microbiology.

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): 165 x 115 x 245
Weight (kg): 3
Consumables: Disposable Cartridges; Proprietary Sample Diluent, Wash Buffer & Detect Reagent; snap cap microtubes
Life time: N/A
Shelf life: N/A
Retail Price (USD): N/A
List price (USD): N/A
Other features: Portable, reusable
Year of commercialization: N/A
Currently sold in: N/A

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Innovative health technologies under development for low-resource settings
Not yet commercialized
Please see disclaimer on following page
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