Ultrasensitive p24 antigen test

Country of origin | United States of America

Health problem addressed
Approximately 1.5 million infants are born to HIV infected women each year, the majority of whom live in developing countries and are not tested for HIV until it is too late for optimal antiretroviral therapy (ART).

Product description
A point of care test that detects HIV p24 antigen in HIV exposed infants using a lateral flow assay and pre-analytical devices that separate plasma from heel-stick blood and disrupt immune complexes.

Product functionality
The US p24 test detects p24 antigen in HIV-exposed infants using a lateral flow test strip as well as pre-analytical devices for separating plasma from heel-stick blood and disrupting immune complexes that would normally interfere with other p24 immunoassays.

Developer’s claims of product benefits
Central lab-based DNA PCR is the most common method for detection of HIV-1 infection in infants but it is expensive, requires reliable electricity, refrigeration, highly skilled laboratory technicians and a robust sample transport network. The US p24 test is a low cost alternative to the central-lab based PCR, providing competitive sensitivity and specificity. The US p24 test is low cost, portable and easy-to-use. The test can be run while the patient waits (40 minutes total; 5 minutes operator time) by the health care worker collecting the infant sample. The device is portable and runs on rechargeable batteries capable of running several weeks worth of tests on one charge.

Operating steps
To run the US p24 test, (i) Prick infant’s heel and collect blood; (ii) Place blood on plasma separator (iii) Add p24 buffer to the separated plasma sample; (iv) Heat plasma sample solution in small, battery-powered processor; (v) Insert test strip into the plasma solution in the processor and wait 30 minutes; (vi) Read test results.

Development stage

Future work and challenges
Independent evaluations on the US p24 test will begin in 10 African and Asian countries in 2012. This will help inform the suitability, ease-of-use and regulatory approvals.

User and environment
User: Physician, technician, nurse
Training: Ministries of health
Maintenance: None

Environment of use
Settings: Rural, urban, primary (health post, health center), secondary (general hospital), tertiary (specialists hospital)
Requirements: The sample processor requires a periodic charge after several weeks worth of testing

Product specifications
| Dimensions (mm): 202 x 156 x 134 |
| Weight (kg): 1.7 |
| Consumables: Blood collection tube, a plasma separator, buffer, test strip |
| Life time: 3-5 years |
| Shelf life: 3-5 years |
| Retail Price (USD): 7-15 |
| List price (USD): 400-700 |
| Other features: Reusable, portable, mobile |
| Year of commercialization: N/A |
| Currently sold in: N/A |

Contact details
David Kelso  | Email k-palamountain@kellogg.northwestern.edu  | Telephone +1 847 491-4971  | Fax N/A

http://www.who.int/medical_devices
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