Isothermal nucleic acid amplification system for POC diagnosis

Country of origin | China

Health problem addressed

One major limitation of effective tuberculosis control is the lack of a suitable diagnostic technology. Current technologies, such as sputum smear microscopy, are insensitive; immuno tests are indirect, and the available molecular tests are complex and expensive. It is the responsibility of scientific and business communities to provide rapid, simple, accurate and affordable technologies and products.

Product description

This TB diagnostic is based on 5 core technologies: 1. Glass transition of reagents for ambient temperature transport/storage; 2. Instrument free sample preparation; 3. Isothermal Nucleic-acid amplification; 4. Visual read-out: a DNA lateral-flow device (LFD); 5. Cross-contamination control device. The TB DNA test with these integrated technologies can be delivered and performed at almost any location.

Product functionality

Sample preparation: using syringe and a membrane unit, no centrifugation; Amplification: proprietary Cross Priming Amplification (CPA) technology, water bath is the only instrument needed; Lateral-flow strip detection: visual readout in an enclosed device, cross contamination proof; Glass transition of reagents: the entire kit can be transported/stored at ambient temperature.

Developer's claims of product benefits

The amplification method (CPA) and cross-contamination proof detection device are the primary inventions. The glass transition method and sample preparation device are improvements on existing technology: Cost effectiveness: No setup cost, almost no instrument cost; Ease of use and Maintenance: Single test package, simple operation; Reduced training Requirements: No highly trained personnel required; Labour and time saving: Sample to result in 2 hours; Reduced resource Requirements: The only equipment needed is a water bath maintaining a temperature around 63°C; Technical superiority: Detected 10 or less pathogens with high specificity; Better accessibility: Shipped and stored at ambient temperatures; Cross-contamination control: Sealed cartridge ensuring amplicon is never exposed.

Operating steps

Step 1: Sample preparation - Use our instrument-free nucleic acid extraction device. The process takes 15 minutes after sputum specimen liquefied and boiled; Step 2: Amplification - Amplification can be accomplished with any incubator that keeps a constant temperature. CPA takes 60 minutes at 63°C. Step 3: Detection and read-out - Place the CPA reaction tube into the cartridge and lock. Read result in 10 minutes.

Development stage

The Isothermal Amplification Diagnostic Kit was approved by TUV for CE marking. Our manufacturing facilities are EN ISO 9001:2000 and EN ISO 13485+AC:2007 approved. One example of product trials conducted was at Taipei Medical University, Municipal Wan Fang hospital - sensitivity: 99%, specificity: 94%, PPV: 97%, and NPV: 97%.

Future work and challenges

Market education: The technologies are new and little known. It requires significant effort to educate users, promote products and gain acceptance. Regulatory approval: The CE mark has been obtained for the TB tests. Entry approval from individual governments is still needed requiring time and resources. Network: A network for distribution and demonstration, covering health centers in developing countries, needs to be established.

User and environment

User: Nurse, physician, technician

Training: Product brochure, instruction for use, actual testing kits. Training takes about 3 hours.

Maintenance: Nurse, physician

Environment of use

Setting: Rural and urban health care facilities.

Requirements: The assays can be used at community health centers with minimal or no lab infrastructure, and can be performed by personnel with minimal training; water and method to boil for bacteria decontamination, water-bath to maintain temperature between 58 to 65°C, and temporary electricity (battery/solar) are required. Long-term storage at larger clinics would need to transport the devices to hard-to-reach areas.

Product specifications

Weight: 500g/20 tests

Shelf time: 1 year

Consumables: Pipette tips

Retail Price (USD): $6 (including sample preparation, amplification and detection)

Other features: The diagnostic test is portable and single-use.

Year of commercialization: 2009

Currently sold in: China, Thailand, Singapore, Taiwan, Canada and USA (research only)

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