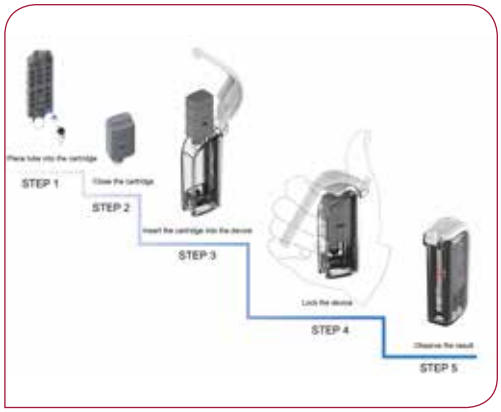
Tuberculosis detection kit based on isothermal amplification



Country of origin | China

Primary function | Diagnosis

Health problem addressed

Tuberculosis (TB) is a major global health problem, affecting millions of people each year and is a leading cause of death worldwide. In 2014, an estimated 9.6 million new TB cases and 1.5 million deaths occurred. The South-East Asia, Western Pacific and African Regions collectively account for 86% of the world's TB cases. With a timely diagnosis and correct treatment, almost all patients can be cured.

Disease addressed

Certain infectious and parasitic diseases such as TB.

Technical descriptions

Cross priming amplification (CPA) is a class of isothermal amplification reactions that is carried out by a strand displacement DNA polymerase. Strand displacement is encouraged by the annealing of cross primers with 5' ends that are not complementary to the template strand and the binding of a displacement primer upstream of the crossing primer. The resulting exponential amplification of target DNA is highly specific and highly sensitive, producing amplicons from as few as four bacterial cells.

Developer's claims of products benefits

Current state-of-the-art technology for TB detection are chest X-rays and computer-aided detection; smear diagnosis; culture-based tools and nucleic acid amplification-based tests. These tests either require well-trained staffs to interpret results or expensive equipment, which are usually not suitable for low-resource settings. Often, transportation is difficult or rapid testing and detection of TB on the same day might not be possible. This technology is affordable, sensitive, specific, user-friendly, resistant to ambient temperature transport, shows rapid result and consists in an instrument-free device.

Operating steps

Extract TB DNA is from a sample using boiling and chemical reagents from specimens. Add the extracted DNA into a reaction solution containing specific primers and probes, amplification reagent and glassified Bst DNA polymerase. In the reaction solution, amplification and hybridization are carried out in one step. Subsequently, any presence of amplified TB DNA in the end product is detected by a disposable detection device. Appearance of a control line and a test line indicates a positive reaction.

Regulatory status and standards compliance

European Community (CE-mark), China, Philippines, Indonesia. ISO 13485:2012.

Use and maintenance

User: Technician, nurse.

Maintenance/Calibration required: No

Environment of use

Setting: Rural settings, urban settings, indoors, primary level (health post, health centre), secondary level (general hospital), tertiary level (specialists hospital).

Facility requirements: Clean water supply, healthcare waste disposal facilities (pathological waste, sharps, chemicals, etc.).

Product specifications

Weight (kg): 0.05

Dimensions: 25mm x 53.6mm x 91.5mm

Consumables: Micropipette and disposable tips, sutum collection container, liquefying bottle or leak-proof 5-10 ml centrifuge tube, 1.5 ml centrifuge tubes with safe-lock feature.

General product: Any isothermal heating device (eg heating block, water bath, etc.), centrifuge (10 000 rpm), Vortex, timer

In UN catalog: No

Commercial information

Reference price (USD): $15.00

Year of commercialization: 2014

Currently sold in: China, Indonesia, Philippines, South Africa

Number of units distributed: 1 001-10 000

Other features: Portable

Contact Lin Hu | Telephone +86 571 88939355 | Web https://bit.ly/2L5boek