

A Functional Blister-Pack LabDisk System for Point of Care Testing

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Introduction

Urgent diagnostic questions related to severe medical conditions, such as MRSA sepsis, or to a bioterrorism attack, e.g. by release of pathogenic bacteria or toxins, require integrated and automated devices for rapid point of care testing.

Methods

We present one candidate for a mobile nucleic acid and immunoassay based detection unit. Centrepiece of the detection system is a disposable LabDisk, fabricated as functional blister package, in which reagents are pre-stored and fluidic structures are integrated to perform all required liquid handling operations automatically in a centrifugal processing device (Fig. 1).

Results

Based on this system, assays for the detection of bacterial pathogens such as methicillin resistant *Staphylococcus aureus*, and *Bacillus anthracis* and toxins such as ricin and botulinum toxin are being developed and field-tested. In a first embodiment of the Blister-Pack LabDisk system complete sample to answer analysis, including DNA-extraction from a diluted bacterial culture and isothermal amplification by RPA (Recombinase Polymerase Amplification) can be performed within 35 minutes. The sensitivity of the amplification method is below 10 copies (Fig. 2). In another embodiment of the Blister-Pack LabDisk system PCR based genotyping of 22 clinical MRSA isolates has been performed. Results were identical to those obtained by a reference PCR in standard reaction tubes.

Discussion

Feasibility of the Blister-Pack LabDisk system, enabling rapid and fully automated sample to answer analysis has been demonstrated. The portable system is meant for time critical analysis of a few samples at the point of need. It is of relevance for the use in the doctors' office, intensive care units, remote areas, and for mobile environmental or food analysis.

References

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Fig. 1 Blister technology used for functional packaging of diagnostic reagent kits.

Fig. 2 Isothermal amplification of *Staphylococcus aureus mecA* gene in a Blister-Pack LabDisk.

Anhang 1



Blister technology

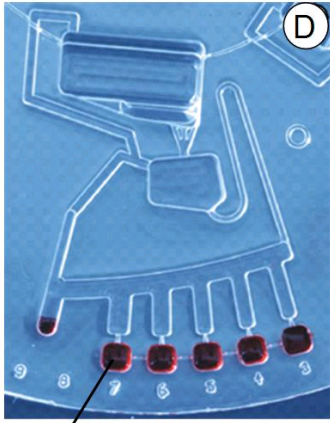


Reagent kit & protocol



Functional reagent package with microfluidically imprinted protocol

Anhang 2



Reaction cavities

