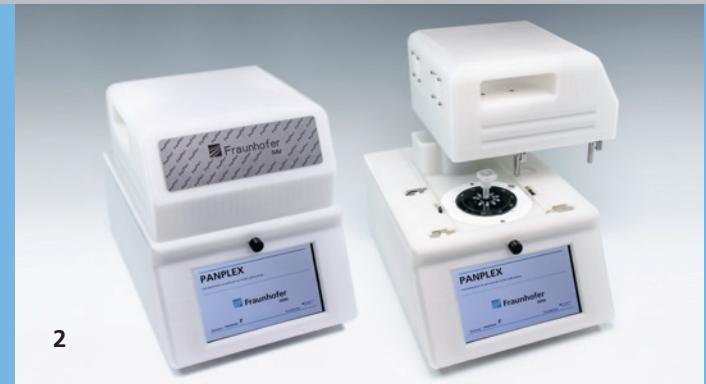


FRAUNHOFER INSTITUTE FOR MICROENGINEERING AND MICROSYSTEMS IMM



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1 *Microscopic image of a virus*

2 *PanPlex device including the microfluidic cartridge*

MICROFLUIDIC PLATFORM FOR FAST DETECTION OF VIROLOGICAL INFECTION STATUS

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Motivation

Influenza pandemics are a persistent threat all over the world. Point-of-care testing approaches have the potential to revolutionize medicine as they offer immediate access to diagnostic parameters facilitating and accelerating treatment. To keep the manufacturing costs for the consumable low, most systems rely on microfluidic technologies.

Today, almost all parameters are acquired by sending patient's samples to core lab facilities. The related sample logistics causes diagnostic delays of at least several hours. Obviously, the consequent delay in therapy may reduce the possibility of recovery and prolongs the patients suffering.

Pilot implementation

The underlying technology platform has initially been developed to detect various

Quick facts

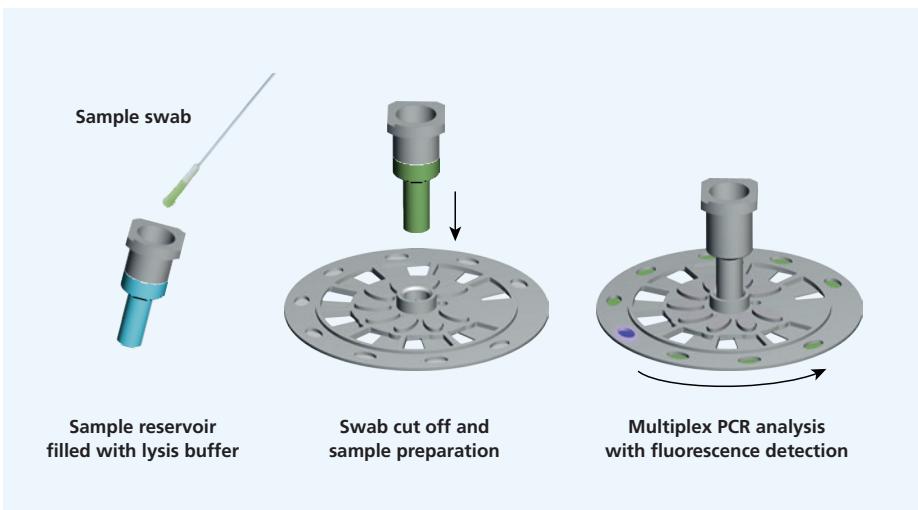
Status: portable prototype instrument

Purpose: detecting various serotypes of influenza and several coronaviruses

Features:

- Fast and significant results by multiplex panel testing (up to 18 reactions)
- Low sample-to-answer time (below 30 minutes)
- Cost effective design and compatibility to mass production
- Usage by non-trained operators
- Multichannel fluorescent detection
- Ambient storage due to dried reagents
- Innovative heating concept for microfluidic cartridges
- Simple nasopharyngeal swab sampling
- Fully automated sample preparation, detection and display of results
- Nucleic acid based testing

Keywords: POCT, lab-on-chip, diagnostics, influenza, pandemics, PCR, RT PCR, microfluidic, nucleic acid based testing.



serotypes of influenza and several coronaviruses. The infection status of a patient can be carried out directly in the practice of a general practitioner or on admission to a hospital. The basic prerequisite for this is the speed and complete automation of pathogen detection. The innovative heating concept ensures a low sample-to-answer time below 30 minutes. Assay reagents are stored in 9 trays of the processing cartridge, which allows up to 18 different detection reactions. To analyze the infection status, only a nasopharyngeal swab is necessary which is transferred in the sample container. After the container has been placed on the microfluidic cartridge, the sample processing can be started. This step as well as the subsequent measurements are carried out completely automatically in the system developed for this purpose. The processed data are made available to the attending physician for diagnosis.

The basic platform technology

The POCT-technology platform for nucleic acid based testing consists of a low-cost

microfluidic cartridge which is designed as a disposable and includes an automated analyzer that controls the cartridge, reads out and processes the data. The platform is equipped with a flexible, user-friendly sampling and sample processing system. The sample may range from swabs to body fluids. The assay is based on a single processing liquid, pre-stored in the sampling container. This multipurpose liquid serves for sample release and homogenization, and is compatible with dried assay reagents for amplification without prior nucleic acids purification. Assay specificity is provided by lyophilized nucleic acids amplification reagents for PCR or isothermal amplification. Customized assays can be realized in an easy manner just by clipping on assay-specific reagent trays.

The platform enables instant testing of entire disease panels (e.g., respiratory viruses, sexually transmitted diseases, MRSA and related resistance markers). However, the platform is open to adapt to a variety of sampling and sample processing. However, if required for special sample materials, the POCT platform can provide various

technological add-ons for sample lysis and extraction. This reflects the flexibility of the entire platform.

Application examples

We so far have several realized pilot implementations for molecular diagnostics based on the underlying technology platform, e.g. for MRSA or rapid STD (sexual transmitted diseases) detection and the SimPlex system for nasal pathogens.

Future potential

The platform is readily available to develop your application or product for decentralized testing and is not limited to molecular diagnostics. As it is capable to handle various sample input materials and provides an easy to follow operational procedure the potential comprises:

- Personalized medicine
- Companion diagnostics
- Genotyping

Further fields of application:

- Civil safety
- Veterinary testing
- Detection of pathogens or microbes in food, cosmetics or industrial raw materials
- Environmental testing

3 Microfluidic cartridge

4 The Graphic User Interface of the PanPlex system