

- 1 Processing device
- 2 Disposable assay cartridge

“SIMPLEX” – A LAB-ON-A-CHIP TECHNOLOGY PLATFORM FOR MOLECULAR POCT DIAGNOSTICS

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Point-of-care testing for innovation in medicine

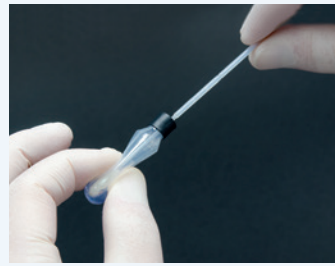
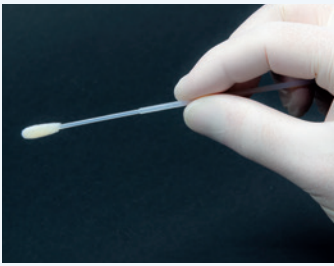
Immediate access to diagnostic parameters is believed to be a key enabler for innovative medical methods and new treatment plans. Today, almost all parameters are acquired by sending patient's samples to core lab facilities. The associated sample logistics inevitably introduces a diagnostic delay of at least several hours and medical doctors have to revisit the patient upon availability of results. Obviously, a delay in therapy comes along with the diagnostic delay and healing may be deteriorated and patients suffering prolonged. Moreover, revisiting the patient is costly. To circumvent this shortcoming, diagnostic testing will be more and more decentralized. A trend commonly termed point-of-care testing (POCT) or near patient testing (NPT). This requires technologies, which

provide full automation, can be used by non-trained personnel and deliver immediate test results.

At present, a manageable number of POCT product developments are under way, both in huge diagnostics companies and in small start-ups. Generally, a POCT system comprises specific test consumables and a dedicated instrument. To keep the manufacturing costs for the consumable low, most systems rely on microfluidic technologies.

SIMPLEX, the POCT technology platform – the basis for your product

Based on our long-standing experience in microfluidic systems, Fraunhofer IMM has developed the SIMPLEX technology platform for nucleic acid based POCT. The SIMPLEX platform is not limited to molecular diagnostics.



COLLECT

TRANSFER/RELEASE

LOAD

RUN TEST

3

Fields of application can also be:

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

The platform is readily available to develop your application or product within its framework.

SIMPLEX pilot implementation

The SIMPLEX pilot implementation is equipped with a flexible sampling and sample processing system, which is compatible to swab-derived sample material or liquid samples.

The assay is based on a single processing liquid, pre-stored in the bulge of the SIMPLEX sampling tube. 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. The reagents are allocated in eight amplification cavities of the processing cartridge, providing access to up to 16 parameters. Production of (customized) assays can be done in an easy manner just by clipping on assay-specific reagent trays. The SIMPLEX pilot implementation enables instant testing of entire disease panels (e.g., respiratory viruses, sexually transmitted diseases, MRSA, and related resistance markers).

Specifications

The SIMPLEX pilot implementation demonstrates Fraunhofer IMM's expertise to develop a fluidic cartridge design in conjunction with the assay.

SIMPLEX provides:

- Compatibility to mass production (injection moulding)
- Cost-effective production due to smart assembly concepts and simplicity in design
- Multiplex panel testing
- High Resolution Melting (HRM) analysis
- Ambient storage (dried reagents)
- Usage by non-trained operators

However, the platform is open to a variety of sampling and sample processing technologies (e.g., Snap-Valve system from Medical Packaging Inc.). The sample may range from swabs to body fluids and considers user-friendly handling steps.

In order to enable simple and cost-effective cartridge design for the pilot implementation, the sample lysis was omitted. However, if required for special sample materials, the SIMPLEX platform can provide various technological add-ons for sample lysis and extraction. Also measures for elimination of inhibitors of nucleic acids amplification can be considered. This reflects the flexibility of the entire platform.

In the SIMPLEX processing device a number of platform technologies are embedded:

- Powerful heating and cooling technology
- Multichannel fluorescent detection

- Integrated Linux operated ARM Cortex-A8 microcontroller with touchscreen panel for stand alone operation
- Portability
- Battery powered operation feasible
- Integrated analysis software and connectivity (WLAN, email)

Summary

SIMPLEX represents a technology platform for versatile point-of-care testing and enables advanced molecular diagnostics (MDx) at decentralized settings. The platform is capable to handle various sample input materials and provides an easy to follow operational procedure. This enables a broad range of applications:

- MDx of Infectious diseases
- Personalized medicine and
- Companion diagnostics
- Genotyping