

1 *Image of a microarray: Specific disease markers in urine or blood can be detected in each of the fluorescent spots. Each spot can be referenced and analyzed.*

2 *The compact biochip system is suitable for use in any physician's office or outpatient clinic.*

DIAGNOSIS BY RAPID TEST NEW BIOCHIP READERS ANALYZE BLOOD FULLY AUTOMATICALLY RIGHT IN THE PHYSICIAN'S OFFICE

On-site diagnosis

Speed can save lives – for example in the case of blood poisoning. The more quickly and directly doctors recognize and treat sepsis, the greater the patient's chances of survival. With the aid of a new biochip, physicians will now be able to analyze blood right in their own office.

Generally, the doctor draws a blood sample and sends it to a central laboratory for testing. This takes up valuable time, which, under some circumstances, could cost the patient his or her life. The new fully automatic biochip system allows immediate blood testing, right on site, and the results are ready in less than 25 minutes.

200 Spots on one microarray

The biochip developed by Fraunhofer IPM uses microarrays as the basis for protein

fluorescence immunoassays. The microarray spots are one nanoliter in volume and contain catcher molecules to detect proteins that indicate sepsis. This way, a hundred of these types of spots are placed on a surface just 5 mm × 5 mm in size.

The microarray is located on an inexpensive, injection-molded polymer substrate into which small prisms are ingrained. The design enables total internal reflection fluorescence (TIRF) to be used as the detection method. With this effective technique, a laser beam is coupled into the substrate and guided inside it in order to excite the fluorescence. The substrate with the microarray is capped with an additional injection-molded part with integrated channels and fluidic structures for the reagents. The two substrates form a closed cartridge in which the patient's sample is analyzed.

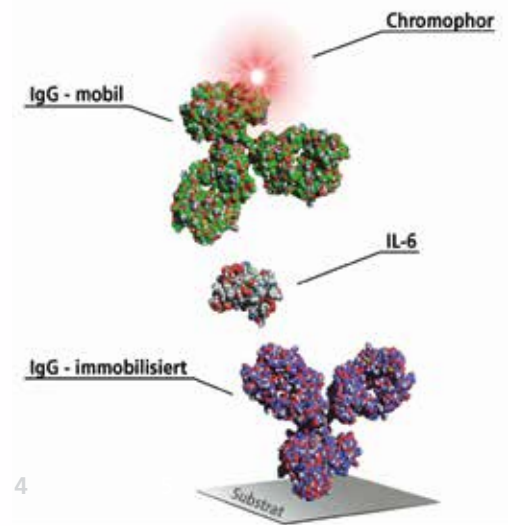
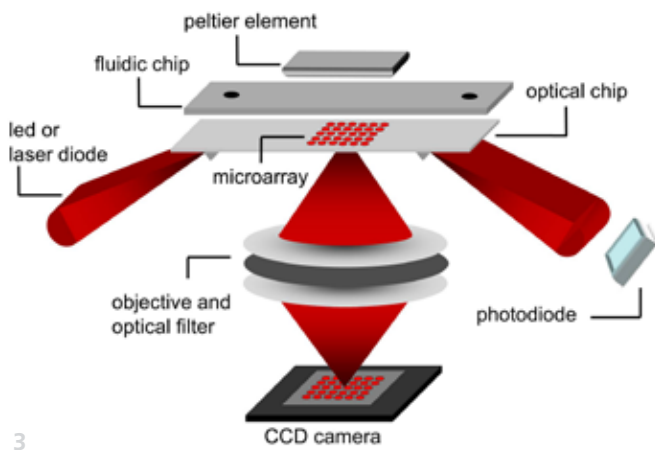
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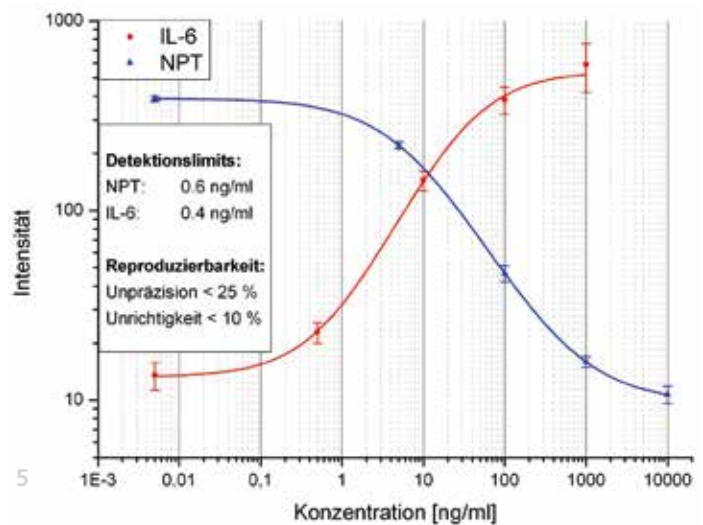


Detection of fluorescent antibodies

The fully automatic compact system evaluates the sample in the cartridge in a multi-step process, including fluidics, visual and software-based analysis. While in the cartridge, the blood sample is separated into blood cells and plasma in order to guide the plasma, which is easier to analyze, onto the biochip. The sepsis-induced proteins bind specifically to these spots. Fluorescent labeled antibodies illuminate the proteins and allow them to be quantified. According to requirements, the system simultaneously processes binding inhibition, direct, indirect, competitive, and sandwich immunoassays, which enables parallel detection of the interleukin 6 (IL-6), neopterin (NPT), C-reactive protein (CRP) and procalcitonin (PCT) parameters. These parameters provide important information for the diagnosis, such as the severity and cause of the illness or disease.

Other applications

The system can detect concentrations of less than 100 pg/ml of sepsis-relevant proteins in the plasma. In the effective measuring range, the level of imprecision and inaccuracies is below 25 percent. The biochip can be utilized for a broad array of applications: Different catcher molecules may also be used to diagnose coronary diseases or cancer. Furthermore, the chip facilitates doping and urine testing as well as quality assessments of food products.



Technical Specifications

Assay time: < 25 minutes

Multiparameter detection using microarrays

Simultaneous execution of various immunoassay methods

Detection of: IL-6, NPT, CRP, PCT

Array size: up to 200 spots

Integrated separation of blood and plasma

Detection limits comparable to high-end commercial laser scanners

Inaccuracy and imprecision: < 25%

- 3 A laser beam excites the bound, fluorescent dye on the microarray.
- 4 Fluorophore or fluorochrome labeled antibodies fluoresce and reveal the pathogen in the blood.
- 5 Parallel detection of the neopterin and interleukin 6 sepsis parameters.