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## IN VITRO DIAGNOSTIC DEVICE FOR PARTICLE BASED MULTIPLEX TESTS

### Task

In particle-based multiplex testing, different types of particles are used simultaneously, with each type having immobilized a specific binding partner for a specific molecule species on the surface of its particles. In a solution, the analyte molecules to be detected are bound to their binding partners on the corresponding particle type. The bonds are then detected optically through the addition of a secondary marker that marks all particle-bound analyte molecules of the multiplex assay. In a flow cytometer, the binding of analyte fractions can be detected through the fluorescence of the secondary marker. In addition, the particles have an intrinsic fluorescence, which is spectrally distinct from the fluorescence of the secondary marker. Each type of particle is encoded via the intensity of its intrinsic fluorescence.

### Method

To read out such particle-based multiplex assays, however, there is currently no standardized diagnostic equipment available which, in addition, can be integrated into an automated process. This absence strongly limits the expansion of particle-based multiplex assays, which are superior to conventional microtiter plate-based tests in terms of sensitivity

- 1 *Fiber-based multi-beam arrangement for the excitation of different fluorescent markers.*
- 2 *Demonstrator for an in-vitro diagnostic device to read out particle-based multiplex assays.*

and material usage. To fill this technological gap, Fraunhofer ILT has developed device technology that provides different excitation wavelengths in the visible and near-infrared spectral range and the corresponding detection channels.

### Result

The technology has been implemented as a compact desktop unit for multiplex diagnostics and can be used in combination with a microfluidic system for the measurement of particle-based assays. The system can be used both as a stand-alone solution and as OEM module for fully automated sample analysis.

### Applications

The device technology developed for reading out particle-based multiplex assays can be applied in clinical as well as in food and environmental diagnostics.

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