#### The Division Diagnostics: Microengineering to enable POCT PCR

Polymerase chain reaction (PCR) technique, as a molecular detection method, has been widely used and commercialized in the field of medical point-of-care-testing (POCT) in the past decade. A key enabler have been significant advances in microfluidic technologies. Today, POCT PCR for diagnostic applications can be considered as a mature technology and the industrial learning curve steadily delivers cost-savings and improvements in performance and robustness.

In more than 15 years of R&D in the field, the Division Diagnostics at Fraunhofer IMM has developed a wide range of microfluidic POCT PCR modules and solutions. Our team Bioanalytics for Industrial Media, is actively exploring new industrial applications for POCT PCR and provides respective R&D to develop industrial solutions.



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**Bioanalytics for industrial applications** 

# PCR as a powerful POCT method beyond medicine



# Pathogen detection at the point-of-need

Polymerase Chain Reaction (PCR) is a commonly used and recognized molecular technique for medical diagnostics. Its application for industrial samples at the point-of-need imposes challenges that are addressed by Fraunhofer IMM's work.

#### The ideal point-of-care-testing (POCT) device

### The main requirements to be met for an ideal POCT device are:

- fast from sample to result
- easy to operate / fully automated
- mobile and sufficiently miniaturized
- sensitive and specific
- cost-efficient

#### The technology gaps for industrial applications

PCR has been well-established based on microfluidic technology and protocols. Automated sample preparation is available with good performance and robustness. Being matured in medical applications, PCR starts to be accepted as standard in addition to culture methods in industrial applications, especially when dealing with pathogens in water and food samples. The main technology gaps existing so far are the need to

concentrate the sample from a large volume to microfluidic compatibility and the requirement to distinguish between live and dead pathogens in order to avoid false positive results from dead microorganisms.





#### Our unique approach

#### 1. Pathogen concentration

In IMM, we have developed an automatic concentration device to concentrate pathogens from 1 L into 200  $\mu$ L. The whole process takes less than 10 minutes and enables the limit of detection to be <1,000 CFU/L.

#### 2. Live/Dead discrimination prior to PCR analysis

In IMM, we have validated a non-toxic pretreatment method in order to remove false positive PCR results solely from dead bacteria. The elimination efficiency is higher than 99%.

#### Benefits for our customers

We have more than 25 years of experience in microfluidic technologies and about 15 years on PCR-POCT testing. Holding a wide IP portfolio we rely on well established technologies and a range of experience in nucleic acid extraction and amplification from almost any type of human or industrial sample.

## Our technology can be readily adapted for pathogen detection for instance in:

- industrial water
- environmental water
- drinking water
- bioreactors and bioprocessing industry
- food and beverage industry
- in-door air quality monitoring industry
- agriculture industry
- cosmetics industry
- pharmaceutical industry
- painting and coating industry
- clothing industry