Deliverable 11.1

ML² – Multi Layer Micro Lab

Demonstration of “Pathogen diagnostic lab-on-a-chip demonstrator”

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1. Authors and Affiliation

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[a] Fraunhofer CMI, a division of Fraunhofer IPT, as part of the ML^2 consortium to create low-cost pathogen diagnostics by combining microfluidic and electronic layers into a single device.

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2. A rising threat to human health

Bacterial resistance to antibiotics is escalating and represents a significant health threat to the human population. These alarming circumstances have largely resulted from the current clinical practice of prescribing broad-spectrum antibiotics first and identifying whether or not they are needed or even useful later-after the standard 18 - 48h culture. When it is critical to know whether or not a particular pathogen is causing disease, as is the case for outbreaks or epidemics, clinicians and laboratories turn to a rapid nucleic acid test (NAT) that can identify a pathogen within hours. However, NATs require specialized lab space, expensive reagents, and extensively trained technicians to appropriately conduct the assays. To reduce costs, labs process samples in batch once-per-day making the effective turn-around-time 24h, by which time patients have left the clinic, often with broad-spectrum antibiotics in hand. In order to stem the tide of antibiotic resistance and preserve this critical resource for the correct patient, rapid point-of-care diagnostics are essential.

3. Our solution

At Fraunhofer CMI/ IPT, we are developing a NAT demonstrator chip that can identify pathogens within 20 minutes and can be produced at low-cost thus eliminating batch processing altogether. Our demonstrator chip works by introducing the pathogen sample with NAT reagents into the microfluidic channel of a small 3 cm x 5 cm thermoplastic chip. The genetic content of the sample is amplified as it moves through the microfluidic channel that traverses two heating zones. Within 20 minutes, the presence of the pathogen is detected on-chip by fluorescence. The final chip itself will incorporate the heating elements and microfluidics into separate layers and will be laminated *en masse* by ML^2 industrial scale roll-to-roll manufacturing methods.

We have demonstrated detection for two bacterial pathogens and a viral pathogen highlighting our device's broad utility. We are currently optimizing the chip material as well as embossing methods to be compatible with the manufacturing processes.