

## Analytical tools in diagnostics: Quo vadis?

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Physicians rely to a significant degree on *in vitro* diagnostic (IVD) tests and imaging modalities for diagnosis and therapeutic decision-making. An increasing number of accidents, infectious and particularly chronic diseases as well as other health problems have in recent decades given rise to sophisticated clinical laboratory automation solutions with high-throughput analyzers processing hundreds or even thousands of samples per day with high reliability and accuracy. Yet, the dynamic and magnitude of the Covid-19 pandemic brought even the larger laboratories to capacity limits. Throughout the world *drive-in* test centers were set up to primarily deal with the sample collection and a plethora of Point-Of-Care (POC) diagnostic devices – with to some extent questionable analytical performances – flooded the market in response to that extraordinary need for diagnostic testing. The pandemic has, no doubt, accelerated the roll-out of telemedicine and decentralization of diagnostic testing that was already occurring due to the progress being made for instance in information and communications technology (ICT), device miniaturization and integration as well as in molecular and engineering biology.

In this presentation, we will give an overview of the global market, of technological developments and milestones in IVD and more specifically in POC diagnostics. We will showcase examples how diagnostic testing is getting closer to patients and consumers, for instance with wearable sensors and at-home diagnostic instruments. To conclude, we will present a POC diagnostic system, aimed for the detection of mild traumatic brain injury (mTBI), that is currently in development [1], the challenges and the opportunities associated with increasing the technological readiness level (TRL) from a proof-of-concept demonstrator conceived in a research laboratory environment towards clinical evaluations and the possible future product development and regulatory approval.

[1] M. Jović, D. Prim, E. Saini, M. Pfeifer, *Biosensors*, **2022**, *12*, 172.