

Nano and Bio-structured Systems as a New Frontier of Diagnostic Devices

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The molecular analysis of Nucleic Acids (NAs -DNA, RNA) created a disruptive innovation in many fields of medicine allowing early diagnosis, target-therapy and new markers discovering. This analysis is based on PCR (Polymerase Chain Reaction) methodology (discovered by Kary B. Mullis, awarded the Nobel Prize in Chemistry in 1993) that, however, is quite complex including multiple laboratory procedures and high cost, limiting, *de facto*, its massive use. This limitation wildly emerged during the COVID outbreak since the molecular test, although the most sensitive and selective for the SARS-CoV-2 diagnosis, could not be massively used for the infection monitoring and control.

New biotechnologies allowing fast, ultrasensitive, low cost and easy to use molecular detection of NAs are, therefore, the new frontiers of genetic analysis to be used in the future for decentralised and massive diagnoses and prevention. This is particularly relevant in the field of the infectious diseases that can catastrophically affect the health of population, as it is the case of the current pandemics due to the SARS-CoV-2 virus that – up to now – infected up to 613 millions of people causing 6 millions of deaths worldwide.

In this contribution we present two innovative PCR- and label-free approaches to detect genetic targets without any amplification step based on the combination of new surface molecular recognition strategies integrated into micro/nano-technologies. These methods involve the capture of whole genome at inorganic surface (silicon or electrode surface) that transduces the recognition event through ultrasensitive advanced micro-/nano-sensors via electro-chemical, electrochemiluminescence (ECL) and photoluminescence signals. The examples here presented show the ultrasensitive detection of viral whole genomes (Hepatitis B and COVID-19) without any amplification step reaching Limit of Detection (LoD) of few copies, below the LoD of the PCR gold standard method.

These devices match the vision of future home-made molecular diagnosis by microchips integrated into smart mobile devices (i.e smartphones or smart watches) and therefore represent the new frontier of the molecular analysis (Molecular “Point-of-Care” (M-PoC).

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