

Can Point of Care devices performing Nucleic Acid Testing (POC NAT) replace Real time PCR or not?

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Point-of-care testing (POCT) refers to analytical tests performed near to the patient's site, away from the central laboratory and operated primarily by non-laboratory staff. The aim of using a POCT device is to reduce the testing turnaround time (TAT) and thus improving the clinical care outcome. The most common settings that use such devices are the critical care units, surgical theatres and physicians' offices.

Moving laboratory testing of some analytes away from the central lab, not only increases the cost by losing the economy of scale, it also jeopardizes the quality of the test result and hence questioning the medical decision taken based on such result.

In order to rely on the results of a POCT device, certain conditions must be taken into consideration like the pre-analytical variables, the safety of the patients and the personnel using the device, the "fit for purpose", the analytical performance of the method used and its in-house verification, the traceability of the calibrating material to a primary reference material, the interfacing of the device with the laboratory / hospital information system and the chain of responsibility for medico-legal purposes regarding the released results.

Nucleic acid testing (NAT) for infectious diseases, is usually done in the main lab setting. In developing countries, where endemic diseases are present (specially TB and HIV), and where financial resources are limited, the availability of a rapid cost effective POC NAT would solve a lot of problems, if it is subjected to proper control. NAT involves three main steps: sample preparation, amplification, and detection. The real challenge when replacing the commercially available real time PCR analyzers with a POC NAT device is to incorporate the three steps together in an accurate way to produce a comparable result to that produced by the real time PCR machine present in the central lab, in a rapid cost effective way. There are a lot of analyzers available in the market for nucleic acid testing of infectious diseases using either a polymerase chain reaction amplification with a real time fluorescence detection (Such as GeneXpert of Cepheid, Liat of IQum, MDx of Biocartis and FL/ML of Enigma), or using an isothermal amplification accompanied with a real time fluorescence or bioluminescence detection (Such as Razor of Idaho, LA-200 of Eiken, Twista of TwistDX and BART of Lumora). Some of the previously mentioned analyzers are FDA cleared for some or all of their assays, others are not.

With the advance in POC NAT technology and with the development of new analyzers / assays every day, the question remains there: Can such point of care devices performing Nucleic acid testing at the patient's side, replace the regular, complex, highly controlled bench top real time PCR analyzers present in central labs or not.