Letter to the Editor

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Molecular diagnostics at the times of SARS-CoV-2 outbreak

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To the Editor,

We read with interest the Points/Counterpoints recently published in *Clinical Chemistry* by Longshore [1] and Nolte [2], discussing different models of delivering molecular diagnostics. Although we recognize the increased pressure to control costs in delivering services to patients, and in particular laboratory tests, the trend toward consolidation and volume-based models can be seriously questioned, especially considering how the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) outbreak has so deeply deranged our laboratory practice and almost dismantled our routine "comfort zone".

The postulated advantages of core molecular laboratory and consolidated model advocated by Longshore, and based on "operating efficiency" and better utilization of testing platforms, have become almost obsolete, overwhelmed by the need for an effective, rapid and accurate etiological diagnosis of SARS-CoV-2 infection using real-time reverse transcription polymerase chain reaction (rRT-PCR) on respiratory tract specimens, which shall be performed in almost every hospital and healthcare facility, for enabling timely identification and isolation of positive cases.

Owing to potential preanalytical and analytical vulnerabilities of rRT-PCR assays [3], together with the huge number of patients' samples that need to be analyzed in many different settings, the centralized model not only generates bottlenecks for effective diagnosis and treatment of patients, but may also contribute to foster an explosive spreading of this pandemic. Most countries

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have so far demonstrated their capacity to test a modest, virtually insufficient, number of suspected coronavirus disease 2019 (COVID-19) cases, whereby molecular testing has only been reserved to severely ill patients or to highrisk patient groups (e.g. heavily symptomatic patients or contacts of positive cases). This limitation has been clearly perceived by many patients, physicians and politicians worldwide as soon as the SARS-CoV-2 has become pandemic. It has hence been soon realized that insufficient capacity to enable accurate and timely results of molecular diagnostics was due, at least in part, to consolidation, downsizing and general underfunding that clinical laboratories have experienced in the last decades, a process orchestrated for fulfilling the vision that laboratory tests are commodities, as a consequence of the scarce appreciation of their value in guiding patient management and favorably influencing clinical outcomes.

The compelling need of very rapid turn-around time (TAT) for diagnosing SARS-CoV-2 with RT-PCR, sample vulnerability during transportation, as well as the possibility that respiratory specimens of patients with negative test results but high clinical suspicion/probability of infection shall be recollected and re-tested, must now discourage further suggestion of adopting consolidated models. A more widely distributed organization based on integrated molecular technologies and professional expertise available in departments of laboratory medicine is now unavoidable for providing rapid, accurate and effective laboratory services in every hospital and healthcare facility, thus aiming for a "zero-kilometer" laboratory service [4].

The SARS-CoV-2 pandemic has contributed to emphasize the centrality of public clinical laboratories in accurate diagnosis, prognostication and therapeutic monitoring of COVID-19, as well as its vital role within projects of epidemiological surveillance [5]. This, in turn, should lead laboratory professionals, physicians and politicians to open a debate on the dangerous effects when consolidation models have been applied to laboratory medicine in the last decades.

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