

ABSTRACT

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The total testing process harmonization: the case study of SARS-CoV-2 serological tests

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Abstract: The total testing process harmonization is central to laboratory medicine, leading to the laboratory test's effectiveness. In this opinion paper the five phases of the TTP are analyzed, describing, and summarizing the critical issues that emerged in each phase of the TTP with the SARS-CoV-2 serological tests that have affected their effectiveness. Testing and screening the population was essential for defining seropositivity and, thus, driving public health policies in the management of the COVID-19 pandemic. However, the many differences in terminology, the unit of measurement, reference ranges and parameters for interpreting results make analytical results difficult to compare, leading to the general confusion that affects or completely precludes the comparability of data. Starting from these considerations related to SARS-CoV-2 serological tests, through interdisciplinary work, the authors have highlighted the most critical points and formulated proposals to make total testing process harmonization effective, positively impacting the diagnostic effectiveness of laboratory tests.

Keywords: harmonization; SARS-CoV-2 serological tests; total testing process

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