

Ignoring SARS-CoV-2 testing performance during COVID-19

The *Lancet* Commission on lessons for the future from the COVID-19 pandemic¹ discusses a series of failures during this challenging time, and we acknowledge the authors' comprehensive and important work. However, the authors refrained from discussing the urgent need to closely monitor the performance of SARS-CoV-2 testing, and to act when underperforming testing facilities and test systems were identified.

Epidemiological measures during a pandemic are mainly based on indicators aggregated from laboratory-confirmed cases of infection. Performance of testing facilities and their assays directly affects the correctness of test results, the consequent accuracy of epidemiological indicators, and, therefore, the effectiveness of measures on which the indicators are based. During the COVID-19 pandemic, an unprecedented number of testing facilities were set up, and an astonishing number of different assays were used for pathogen genome and antigen detection and for antibody determination. Because legal procedures for approval of assays and qualification of test facilities and their personnel were suspended during the pandemic, the reliability of test results became questionable, especially when reported differences in

the performance of SARS-CoV-2 assays suggested considerable rates of false-negative and sometimes also false-positive results.²⁻⁴ SARS-CoV-2 testing, therefore, does not necessarily mean obtaining reliable results. Although total counts of erroneous results will remain unknown, they could have affected epidemiological indicators. By not acknowledging this failure, the authors¹ contribute to the continuation by governments and political decision makers of ignoring that SARS-CoV-2 testing was not always done under controlled conditions.

External quality assessment (EQA) schemes are one of the most important and effective tools for monitoring the performance of testing.⁵ They not only report the analytical performance of individual laboratories, but as recurring snapshot experiments accompanying the pandemic, they also provide information on the performance of different types of testing facilities and assays and procedures used by them. At times when official surveillance is suspended, such schemes are the only way to recognise the performance of testing facilities and test systems. EQA schemes have proven suitable with regard to the detection of pathogens by antigen² and nucleic acid amplification tests,³ but also with regard to the effects of pooling of samples.⁴

We refer to recommendations on the design of EQA schemes and the roles of their providers in future epidemics.⁶ They offer best practices for monitoring the performance of

pandemic-associated analytics to provide relevant information to public health authorities.

HZ is majority owner of Gesellschaft für Biotechnologische Diagnostik; and owner and managing director of Institut für Qualitätssicherung in der Virusdiagnostik. All other authors declare no competing interests.

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- 1 Sachs JD, Karim SSA, Akinin L, et al. The *Lancet* Commission on lessons for the future from the COVID-19 pandemic. *Lancet* 2022; **400**: 1224–80.
- 2 Donoso Mantke O, Corman VM, et al. Importance of external quality assessment for SARS-CoV-2 antigen detection during the COVID-19 pandemic. *J Clin Virol* 2022; **154**: 105222.
- 3 Mercer T, Almond N, Crone MA, et al. The Coronavirus Standards Working Group's roadmap for improved population testing. *Nat Biotechnol* 2022; **40**: 1563–68.
- 4 Buchta C, Camp JW, Jovanovic J, et al. Results of a SARS-CoV-2 virus genome detection external quality assessment round focusing on sensitivity of assays and pooling of samples. *Clin Chem Lab Med* 2022; **60**: 1308–12.
- 5 Buchta C, Müller MM, Griesmacher A. The importance of external quality assessment data in evaluating SARS-CoV-2 virus genome detection assays. *Lancet Microbe* 2022; **3**: e168.
- 6 Buchta C, Zeichhardt H, Aberle SW, et al. Design of external quality assessment (EQA) schemes and definition of the roles of their providers in future epidemics. *Research Square* <https://doi.org/10.21203/rs.3.rs-2072782/v1> (preprint).



Lancet Microbe 2023

Published Online
February 3, 2023
[https://doi.org/10.1016/S2666-5247\(23\)00030-7](https://doi.org/10.1016/S2666-5247(23)00030-7)