



Published in final edited form as:

Lab Med. 2023 March 07; 54(2): 126–129. doi:10.1093/labmed/lmac154.

Increases in CLIA-Waived Testing Sites Since the Start of the COVID-19 Pandemic

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Abstract

The number of testing sites receiving their first Certificate of Waiver (CoW) under Clinical Laboratory Improvement Amendments of 1988 (CLIA) increased significantly since the start of the COVID-19 pandemic. We compared the first-time CoWs in 2020–2021 to those in 2018–2019. The total number of first-time CoWs during 2020–2021 was more than twice what it had been in 2018–2019, corresponding to the population testing needs during the COVID-19 pandemic, especially in assisted living facility, pharmacy, physician office, and school/student health service settings. This study highlighted the need to strengthen clinical testing strategies in order to be better prepared for future public health emergencies.

METHODS

Data on CLIA-certified laboratories were obtained from the Quality Improvement and Evaluation System (QIES), which is maintained by the Centers for Medicare & Medicaid Services. Each laboratory has a unique identification number and certificate effective date, which were used to identify the first CoW issued during the period of investigation. Pre-COVID CoW data from January 2018 to December 2019 were compared to January 2020 to December 2021, during COVID. Facility types in QIES include assisted living facility, pharmacy, school/student health service, physician office and others. First-time CoW issued monthly (including CLIA-exempt states New York and Washington) were analyzed for each selected facility type. All computational work was conducted in SAS (version 9.4, SAS Institute, Cary, NC).

RESULTS

The number of first-time CoWs increased 73% from 2019 to 2020 (12,796 vs. 22,105) and 39% from 2020 to 2021 (22,105 vs. 30,599) (Figure 1A). The total number of first-time CoWs during 2020–2021 was more than twice what it had been in 2018–2019 (52,704 vs. 25,872, Figure 2). Figure 2 demonstrates a dramatic rise of first-time CoWs in each facility category for 2020–2021, compared with 2018–2019. The increases ranged from

20% in physician offices (12,215 vs. 10,128) to more than a tenfold increase in assisted living facility/home health agency/intermediate care facility (5,352 vs. 446). Assisted living facility, pharmacy, physician office, and school/student health service categories had a pronounced increase during 2020–2021, compared with 2018–2019 (Figure 3). Pharmacies responded to the pandemic early with first-time CoWs rising significantly from April to June 2020. First-time CoWs held by assisted living facilities and school/student health services peaked in October 2020 and November 2020 respectively. The total test volume (not limited to COVID testing) reported by all first-time CoWs increased from 29 million in 2019 to 94 million in 2020, and to 204 million in 2021 (216% and 118% increase respectively, Figure 1B).

DISCUSSION

We found that first-time CoWs in nearly all types of testing sites had increased during the first two years of the COVID-19 pandemic, compared to the two-year period prior to the pandemic. By contrast, the pattern of incremental increase of first-time CoWs by month varied among several selected facility types. Pharmacy not only had the largest increase in first-time testing sites, but also responded the soonest at the onset of the pandemic in 2020 and performed the majority of COVID-19 testing for local communities (1). After an elevated percentage of COVID-19 associated mortality occurred in long-term care facilities during March – May 2020 (2), assisted living facilities reached the highest number of first-time CoWs by October 2020. School/student health services had increased numbers of first-time CoWs from November 2020 - January 2021 and an even higher rise in the Fall of 2021, correlating with efforts to sustain in-person instruction and extracurricular activities (3). Early COVID-19 testing was associated with reduced mortality and improved pandemic control (4). Our results demonstrated that increased numbers of first-time CoWs correlated with the population testing needs during the COVID-19 pandemic. To improve the current CLIA laboratory infrastructure so that it can better handle the urgent need for increased testing, strategies that enable existing laboratories to ramp up testing capacity when needed will be essential. This could potentially decrease instances of falsified or inaccurate testing, as reportedly occurred in some pop-up COVID-19 testing locations (5). This study helps shed light on the need to strengthen clinical testing strategies in order to be better prepared for future public health emergencies.

Acknowledgments

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention. Use of trade names and commercial sources is for identification only and does not constitute endorsement by the UNITED STATES Department of Health and Human Services or the Centers for Disease Control and Prevention.

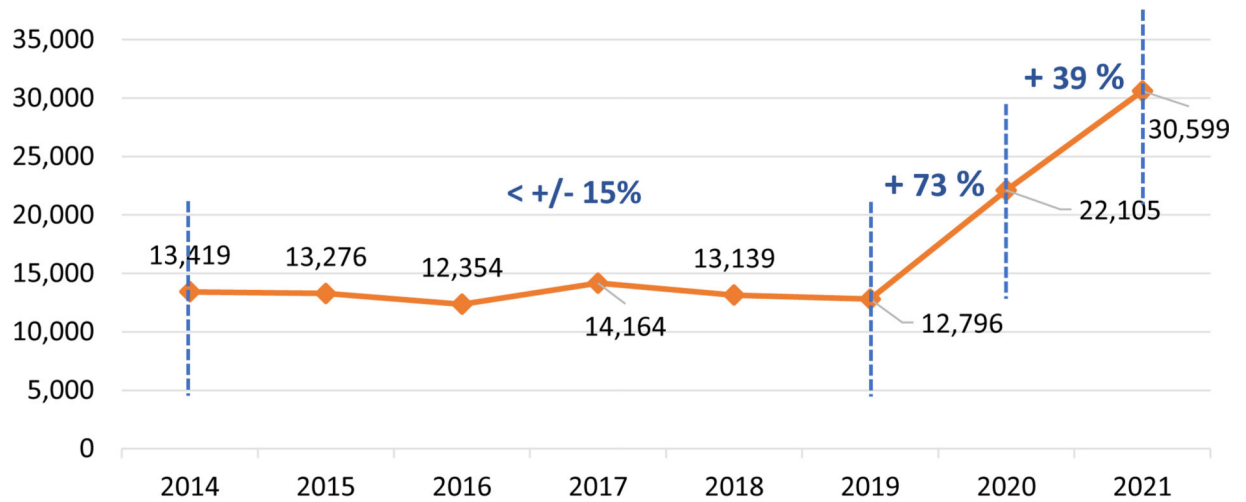
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A. Number of First-time Certificate of Waiver Testing Sites 2014-2021



B. Test Volume in First-Time Certificate of Waiver Testing Sites 2014-2021

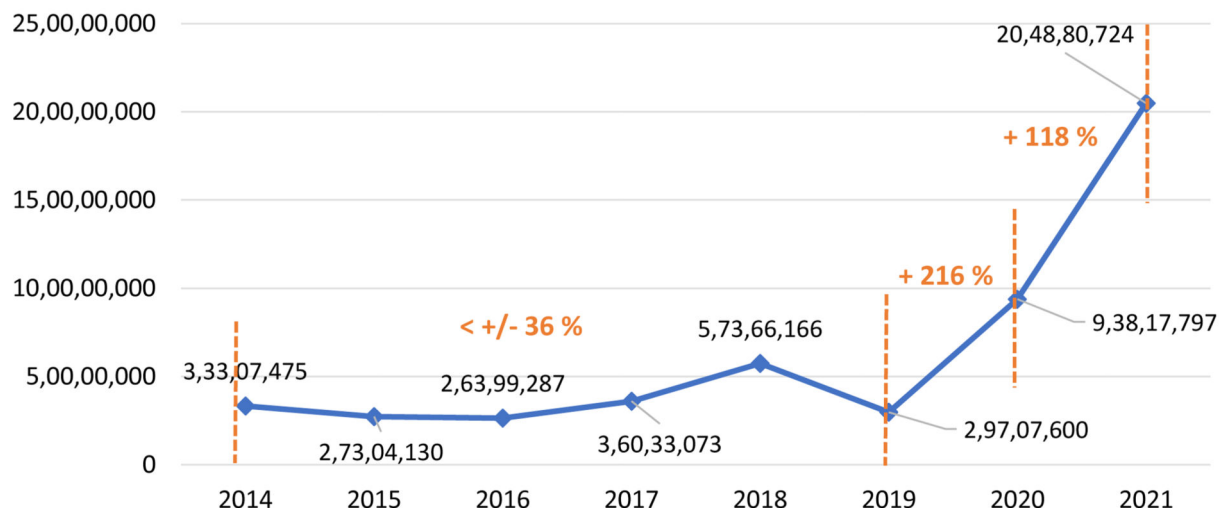


Figure 1.

Number of first-time CoW testing sites (A) and test volume (B) 2014–2021

Distribution of First-Time Certificate of Waiver Testing Sites Before and During the COVID-19 Pandemic

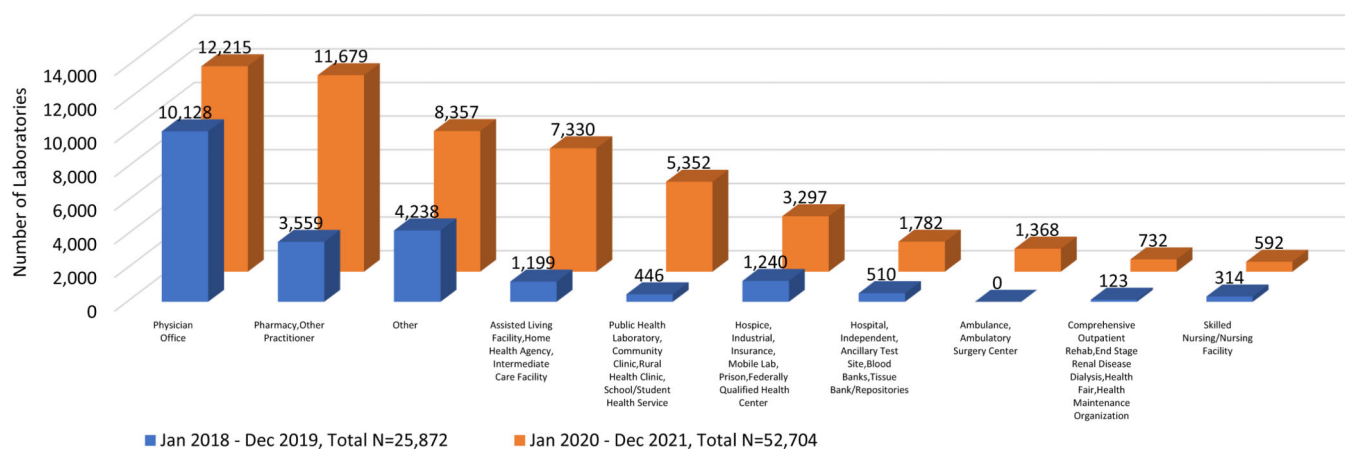


Figure 2.
Distribution of first-time CoW facilities before (2018–2019) and during (2020–2021) the COVID-19 Pandemic

Number of First-Time Certificate of Waiver Testing Sites by Selected Facility Types Before and During the COVID-19 Pandemic

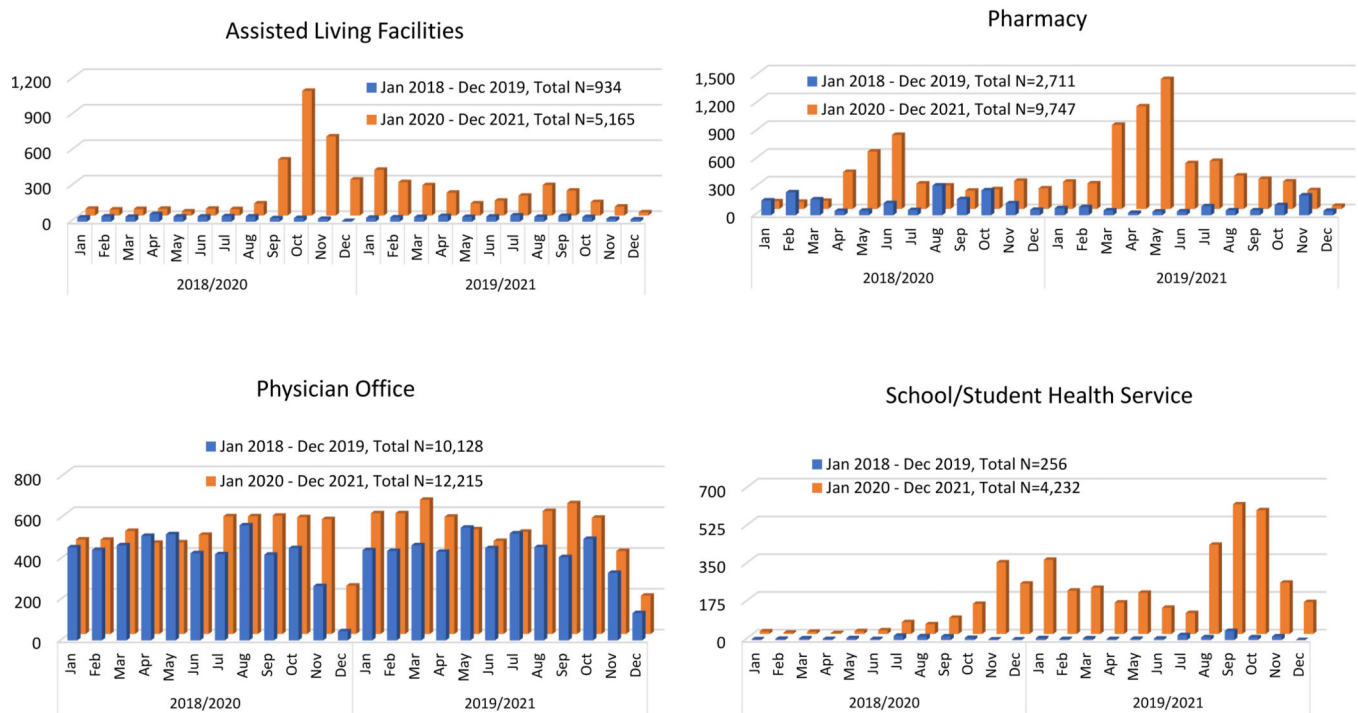


Figure 3.

Number of first-time CoW testing sites by selected facility type before (2018–2019) and during (2020–2021) the COVID-19 Pandemic