

## The Clinical Laboratory Workforce in the U.S.: Supply, Distribution, Education Pathways, and State Responses to the COVID-19 Emergency

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### PRACTICE SCOPE AND SETTINGS

The primary role of the clinical laboratory workforce is to collect and analyze biological specimens to provide patients and medical providers information for preventing, diagnosing, treating, and managing disease. Clinical laboratories perform an estimated 13 billion tests in the United States each year, and approximately two-thirds of clinical decisions are made on the basis of laboratory test results.<sup>1-4</sup> The COVID-19 pandemic has further highlighted the critical role that the clinical laboratory workforce plays in the U.S. healthcare system. Managing the pandemic and interrupting the spread of coronavirus requires large-scale laboratory testing.<sup>5,6</sup> As of May 2021, 450 million COVID-19 tests had been performed, with approximately 1.5 million tests performed each day.<sup>7,8</sup>

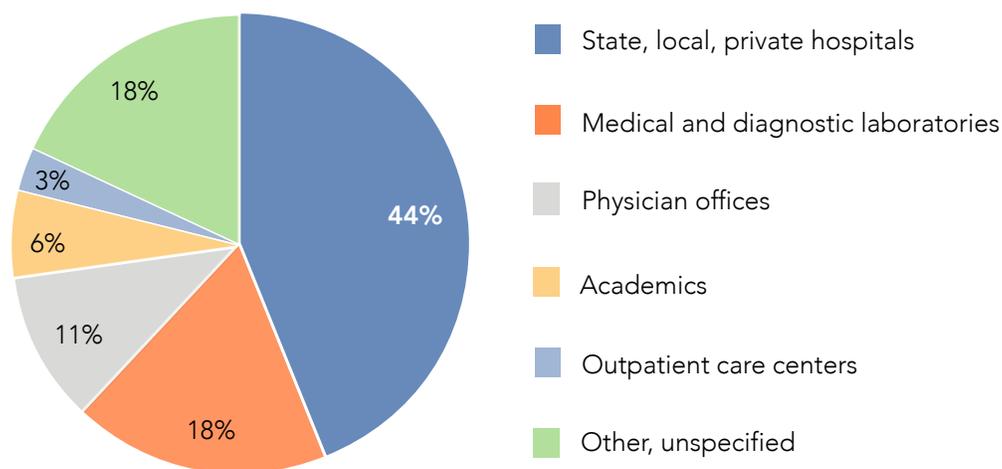
Multiple clinical lab occupations are often placed into a single broad workforce category. Yet, this workforce encompasses occupations ranging from medical laboratory assistants and phlebotomists to medical laboratory scientists, which vary greatly in educational requirements, scope of practice, and roles and responsibilities in the lab setting.<sup>9</sup> For the purposes of this policy brief, we focus on six clinical lab occupations to provide a sense of the breadth and depth of the field: medical laboratory assistants, phlebotomists, histotechnicians, histotechnologists, medical laboratory technicians, and medical laboratory scientists.

Available data to track emerging trends within the clinical laboratory workforce are sparse, making it challenging to get a comprehensive picture of key issues for this workforce.<sup>9-11</sup> For example, some states do not require licensure or certification for some laboratory occupations, which could otherwise be used to track the available supply of this workforce.<sup>9,10</sup> Partial workforce estimates, however, are available. U.S. Bureau of Labor Statistics (BLS) regularly reports on the size and characteristics of “clinical lab technicians and technologists” as defined by Standard Occupational Classification codes, which groups multiple occupations. In 2019, approximately 470,400 people worked as clinical lab technicians and technologists (n=337,800) and phlebotomists (n=132,600).<sup>12,13</sup> Of these, 44% worked in general medical and surgical hospitals, 18% in medical and diagnostic laboratories, 11% in physician offices, 6% in academics, 3% in outpatient care facilities, and 18% worked in other, unspecified locations (**Figure 1**).

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Figure 1. Work locations of clinical laboratory technicians and technologists and phlebotomists, 2019<sup>a</sup>



a. Percentages are based on combined data from U.S. Bureau of Labor Statistics (BLS) data for clinical laboratory technicians and technologists and phlebotomists. Data Source: BLS Occupational Outlook Handbooks for Laboratory Technologists and Technicians; BLS Occupational Outlook Handbooks for Phlebotomists.

## DEMOGRAPHICS

In 2019, the American Society for Clinical Pathology (ASCP) conducted a national survey of the clinical laboratory workforce (including the professions of interest in this report).<sup>14</sup> Respondents were an average of 42.4 years old and 80.9% were female.

Race and ethnicity data on individual clinical laboratory occupations are sparse. A study using American Community Survey data examined changes in race and ethnicity among allied health occupations, including clinical laboratory technologists and technicians, in the U.S. from 2005 to 2014.<sup>15</sup> This study found that the clinical lab workforce was slightly more racially and ethnically diverse compared to the overall health workforce and had increased in diversity over time. Specifically, 68.5% of clinical laboratory technologists and technicians were White in 2014, 4.2 percentage points less than in 2005, and 9.7% were Hispanic, an increase of 2.1 percentage points since 2015. Black/African American clinical laboratory technologists and technicians in 2015 were estimated to comprise 15.3% of this field, which is higher than the 12.7% Black/African American representation in the overall U.S. population.<sup>15</sup>

## EDUCATION, TRAINING, AND ROLES

Education, training, and roles vary widely among clinical laboratory occupations (**Table 1**). Phlebotomists and medical laboratory assistants complete 12 or fewer months of post-secondary training while medical laboratory scientists may have a combination of bachelors, master's or doctoral degrees in the field (**Figure 2**). Some career pathways build upon prior clinical laboratory training or education, while others allow for more direct pathways without prior experience.

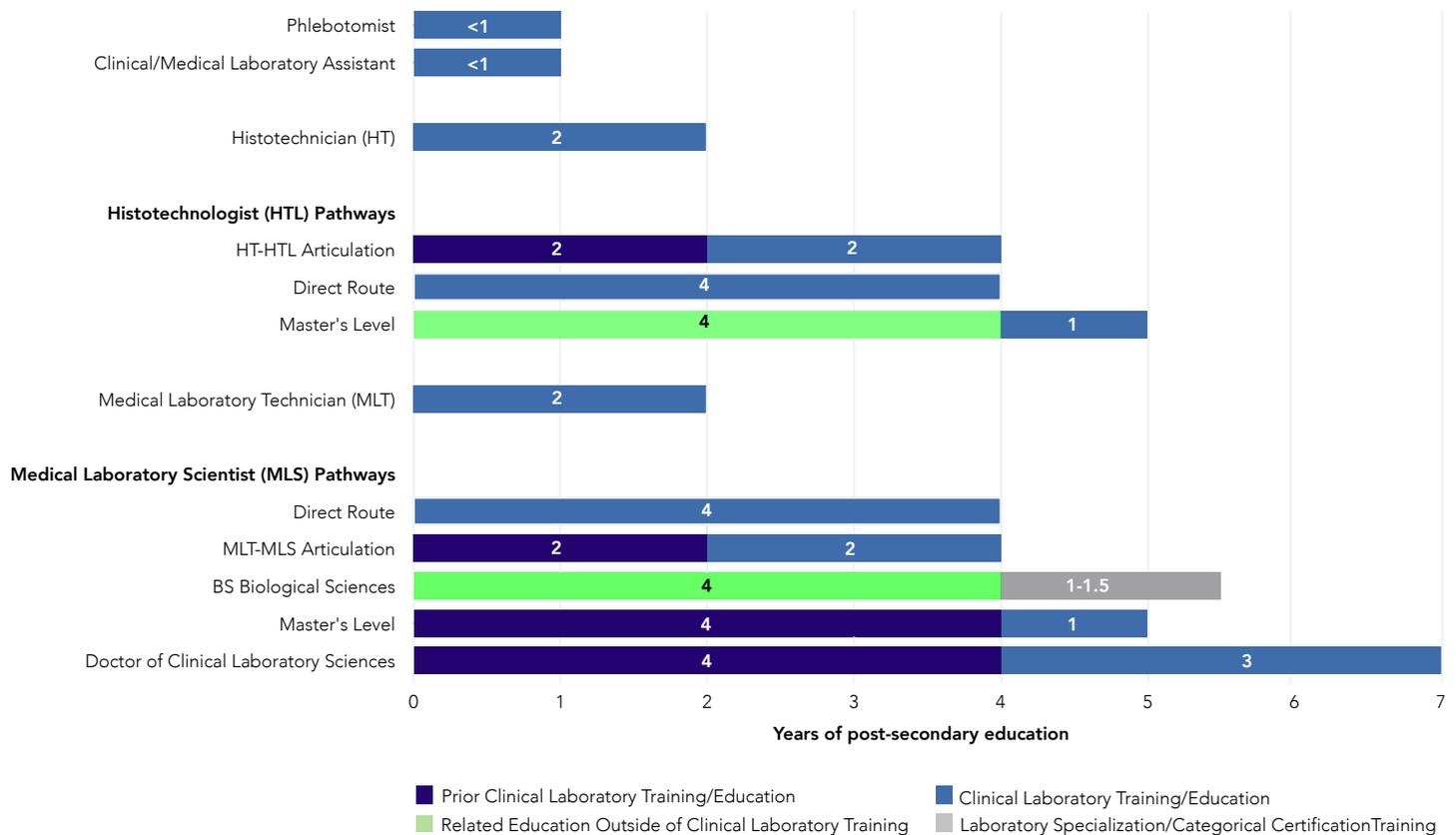
**Table 1: Education and Scope of Practice for Select Clinical Laboratory Professionals**

Occupation	Education	Roles
Phlebotomist	<ul style="list-style-type: none"> <li>• May enter the profession with on-the-job training or less than one year of education that results in a post-secondary certificate.</li> <li>• Certification is only required in four states, but employers often prefer that their employees are certified.</li> <li>• Certification is provided through the ASCP Board of Certification (BOC), American Medical Technologists, National Healthcareer Association, or the National Center for Competency Testing.</li> </ul>	<ul style="list-style-type: none"> <li>• Collect, transport, and process blood and other specimens to be analyzed in the laboratory or used for transfusions, blood donations, and research.</li> <li>• Perform health history screenings and explain specimen collection procedures to patients.</li> <li>• Prepare blood products for blood banks.</li> </ul>
Medical Laboratory Assistant	<ul style="list-style-type: none"> <li>• Typically a one-year post-secondary certificate program, which combines didactic learning with clinical practicum hours.</li> <li>• Some employers provide on-the-job training, which fulfills the necessary requirements without obtaining a certificate from an academic program or the ASCP BOC.</li> </ul>	<ul style="list-style-type: none"> <li>• Support other laboratory personnel and physicians in phlebotomy, specimen processing, quality control, and laboratory safety and regulation.</li> <li>• Prepare biological specimens, record laboratory test results, and perform lab maintenance tasks such as cleaning equipment and stocking supplies.</li> </ul>
Histotechnician (also known as Histology Technician)	<ul style="list-style-type: none"> <li>• Although certification is not required, it is encouraged in competitive markets. To qualify for the histotechnician certification exam, a histotechnician can attend an accredited program or train on-the-job after completing a two-year associate degree.</li> <li>• Some associate degree programs include a histology clinical rotation that allows students to complete their associate degree and histotechnician certificate program as one program.</li> <li>• Licensure is required in some states.</li> </ul>	<ul style="list-style-type: none"> <li>• Perform routine specimen preparation. A primary task involves preparing and slicing thin pieces of human tissue and mounting them on glass slides for examination under the microscope by the pathologist.</li> </ul>
Histotechnologist	<ul style="list-style-type: none"> <li>• Bachelor's degree from an accredited program or on-the-job training.</li> <li>• ASCP BOC provides certification.</li> <li>• Some 4-year programs are available which combine a Bachelor of Science (BS) degree in clinical chemistry or biology with a histotechnology specialization, post-baccalaureate certificates in histology, and Master of Science degree programs in clinical chemistry or biology with a histotechnology specialization. A one-year Master of Science in Histotechnology (MHP) is available to individuals with a BS in biological or allied health science.</li> </ul>	<ul style="list-style-type: none"> <li>• Like histotechnicians, histotechnologists prepare and process tissue samples, but they have more training than histotechnicians. They perform routine and more complex techniques (i.e., immunohistochemistry, in-situ hybridization, immunofluorescence) and stain human tissue in a way that differentiates distinct tissue and cellular structures, allowing a pathologist to ultimately provide a clinical diagnosis and guide treatment options for the patient.</li> </ul>
Medical Laboratory Technician (also called Clinical Laboratory Technician)	<ul style="list-style-type: none"> <li>• Associate degree typically required.</li> <li>• Most associate degree programs can be completed in two academic years but fast-track certificate programs are available to those who already have training or professional background in a related healthcare field such as nursing or phlebotomy.</li> <li>• Medical laboratory technicians may be certified through ASCP or American Medical Technologists.</li> <li>• Some states require licensure.</li> </ul>	<ul style="list-style-type: none"> <li>• Collect, process, and analyze biological specimens.</li> <li>• Perform lab procedures, maintain instruments, and relate lab findings to common diseases and conditions.</li> </ul>
Medical Laboratory Scientist (also called Medical or Clinical Laboratory Technologists)	<ul style="list-style-type: none"> <li>• BS in medical laboratory sciences or another biological science typically required.</li> <li>• With additional training and/or on-the-job experience medical laboratory scientists may become certified through the ASCP BOC as a medical laboratory scientist or a technologist in a specialized area (i.e., Blood Banking, Cytogenetics, or Molecular Biology).</li> <li>• For those with a BS in medical laboratory science, opportunities to earn a master's degree or doctorate in the clinical laboratory field are increasing.</li> </ul>	<ul style="list-style-type: none"> <li>• Medical laboratory scientists perform laboratory procedures including sophisticated analyses and evaluation of results, data integration, consultations, research, and development of new test methods.</li> <li>• Medical laboratory scientists have extensive knowledge and skills in the laboratory field, including in blood banking, clinical chemistry, hematology, immunology, microbiology, and molecular biology.</li> </ul>

Note: Adapted from Garcia E, Kundu I, Kelly M, Guenther G, Skillman SM, Frogner B. The Clinical Laboratory Workforce: Understanding the Challenges to Meeting Current and Future Needs. American Society for Clinical Pathology (Washington, DC) and Center for Health Workforce Studies, University of Washington (Seattle, WA), Apr 2021.

Data Sources: U.S. Bureau of Labor Statistics. Occupational Outlook Handbook. Phlebotomists. <https://www.bls.gov/ooh/healthcare/phlebotomists.htm>; Mayo Clinic College of Medicine and Science. Explore Health Careers. Explore Health Care Careers - Academics - Mayo Clinic College of Medicine & Science; National Society for Histotechnology. What is Histotechnology? <https://www.nsh.org/about/about-histotechnology>; The American Society for Clinical Laboratory Science. Becoming a Clinical Laboratory Professional. <https://www.ascls.org/careers-ascls/how-do-i-become-a-laboratory-professional>; American Society for Clinical Pathology. ASCP Board of Certification. <https://www.ascp.org/content/board-of-certification/get-credentialed>; TS Nadder. The Development of the Doctorate in Clinical Laboratory Science in the U.S. Journal of the International Federation of Clinical Chemistry and Laboratory Medicine. 2013;24(1):35-40.

Figure 2. Typical Years of Post-Secondary Education or Training Required for Select Clinical Laboratory Occupations



Source: Garcia E, Kundu I, Kelly M, Guenther G, Skillman SM, Frogner B. The Clinical Laboratory Workforce: Understanding the Challenges to Meeting Current and Future Needs. American Society for Clinical Pathology (Washington, DC) and Center for Health Workforce Studies, University of Washington (Seattle, WA), Apr 2021.

## SUPPLY AND DISTRIBUTION

Before the pandemic, clinical lab technicians and technologists and phlebotomists were projected to see an increase in employer demand over the next decade.<sup>12,13,16</sup> Laboratory managers were reporting high vacancy rates for clinical lab personnel across multiple lab departments including in histology, specimen processing, and cytology.<sup>11</sup> In addition, retirement rates for the clinical laboratory workforce exceeded the number of graduates.<sup>9,11,17</sup> The ASCP 2018 Vacancy Survey reported that between 9.6% and 27.1% of experienced clinical laboratory workers (depending on the laboratory department) were expected to retire between 2018 and 2023 while fewer students are graduating from accredited laboratory training programs.<sup>11</sup> The COVID-19 pandemic has had short-term effects on the clinical laboratory workforce and it remains unclear how the pandemic may alter forecasts of supply and demand in the future.

The demand for routine laboratory tests (i.e., tests not related to COVID-19) has generally decreased during the pandemic, but has fluctuated throughout.<sup>18-21</sup> Early in the pandemic overall lab testing volumes saw steep declines as patients and providers deferred preventive and primary care, specialty services, and emergency department visits.<sup>22-25</sup> For example, in March and April 2020, Pap smear testing decreased by 87% compared to pre-COVID-19 levels, prostate cancer screening declined by 60%, and other routine lab tests resulting from doctors' office and emergency room visits fell by 90%.<sup>19</sup> The decreased, but fluctuating, demand for laboratory testing has resulted in furloughs and hiring freezes in the clinical lab workforce. For example, in April 2020, after reporting a 40% drop in overall laboratory testing, Quest Diagnostics furloughed about 9% of its workforce (4,000 employees), dismissed temporary contract workers, and suspended 401(k) matching for

employees.<sup>24,26</sup> By June 2020, most of these furloughed workers had been reinstated, but the 401(k) match suspension remained in place.<sup>27</sup> Additionally, in June and July 2020 the ASCP reported that 30% of clinical laboratories had temporarily or permanently laid off staff and 26% had cancelled or closed all open employment requisitions.<sup>28</sup>

Industry experts projected a return to pre-pandemic lab volumes by Summer 2020 with the integration of COVID-19 testing into the workflow.<sup>29</sup> Instead, COVID-19 testing dropped by 40% between the last quarter of 2020 and the first quarter of 2021.<sup>18,29</sup> It remains unclear whether lab volumes will return to pre-pandemic levels even with ongoing demand for COVID-19 testing, which experts predict will continue through 2021 even with the rollout of COVID-19 vaccines.<sup>29</sup> Also, it remains unclear whether use of at-home COVID-19 testing or other innovations such as automation in lab processing may contribute to a decline in the demand for clinical laboratory workers into the future.<sup>29</sup>

## TYPES OF COVID-19 TESTS

Two types of COVID-19 tests – **diagnostic tests** and **antibody tests** – are routinely performed by the clinical laboratory workforce. In most cases, COVID-19 tests must be ordered and interpreted by a clinician.<sup>30</sup> In December 2020, the first over-the-counter and at-home test became available, but most COVID-19 testing is performed in clinical lab settings.<sup>30,31</sup>

- **Diagnostic tests** determine if a person has an active coronavirus infection.<sup>6,32</sup> Knowing about an active coronavirus infection decreases the chance that a person will infect others because their contacts can be traced, they can begin quarantining and, if needed, they can get earlier medical treatment, which may reduce disease severity and the risk of long-term illness.<sup>6</sup> There are two types of COVID-19 diagnostic tests: **molecular** tests and **antigen** tests. Each type of test detects a different part of SARS-CoV-2 (the virus that causes COVID-19).<sup>30</sup>
  - **Molecular tests** detect the genetic material or nucleic acid present inside a virus particle.<sup>30</sup> The FDA has authorized molecular tests for use in traditional laboratory and point-of-care (POC) settings. POC testing sites can only perform tests that have received a Clinical Laboratory Improvement Amendments (CLIA) waiver or have been authorized as a POC test by the U.S. Food and Drug Administration.<sup>33</sup> POC testing is done under the direction of an existing laboratory or testing site director.<sup>34</sup>

Most molecular tests are polymerase chain reaction (PCR) tests, which typically rely on a machine located in a traditional laboratory or a POC setting. Depending on the specific test, nasal or nasopharyngeal swabs, or saliva samples, are used for molecular testing.<sup>35</sup> PCR tests tend to be very accurate because they can sense low levels of viral genetic material in a patient's sample.<sup>35</sup>
  - **Antigen tests** detect one or more specific proteins from a virus particle.<sup>36</sup> Most currently-authorized antigen tests are used in POC settings and provide results in less than an hour.<sup>36</sup> Antigen tests tend to be less accurate than molecular tests.<sup>20</sup> Depending on the test, samples are collected using nasal or nasopharyngeal swabs.<sup>30</sup>
- **Antibody testing** shows whether a person has previously been infected with COVID-19 and now has antibodies against the virus.<sup>6</sup> Antibodies develop one to three weeks after an infection and are proteins made in response to infections.<sup>33</sup> Because of the time lag between infection and antibody development, experts caution against using antibody tests to diagnose someone with an active infection.<sup>33</sup> Scientists are still developing their understanding about the relationship between the presence of antibodies and the level (if any) of immunity. Research suggests that more than 95% of people who have recovered from COVID-19 are protected against the virus for up to eight months after infection.<sup>37</sup>

A benefit of accurate antibody testing is that people who have recovered from COVID-19 may be able to donate plasma, known as convalescent plasma, which contains antibodies to COVID-19.<sup>6</sup> Convalescent plasma can be given to patients who are severely ill to help boost the body's ability to fight the virus.<sup>6,32,38</sup> The Centers for Disease Control and Prevention have estimated the U.S. COVID-19 infection rate (including asymptomatic and unreported cases) by early 2021 at 35,047 per 100,000 population – indicating that more than a third of the population has been infected.<sup>39</sup>

While the pandemic and related testing demand clearly has an impact on the clinical laboratory workforce, it is unclear if increased demand for COVID-19 related laboratory tests will continue. Demand for other clinical laboratory services will likely increase in the long term due to multiple factors. First, expanded Medicaid coverage and general U.S. population growth have resulted in greater need for acute, chronic, and preventive primary care services, including laboratory testing.<sup>9,40</sup> Second, the aging of the American population has increased demand for diagnosing and managing chronic diseases common in older populations such as diabetes and heart disease.<sup>9,41</sup> The U.S. population age 65 and over increased by 33% between 2006 and 2016 (from 37.2 to 49.2 million) and is projected to nearly double to 98 million by 2060.<sup>41</sup> Third, personalized medicine is expected to increasingly use individualized genetic analyses to guide patient management, diagnosis, and treatment.<sup>9,42</sup> Finally, prenatal testing for various genetic conditions has increased.<sup>43</sup> The National Center for Biotechnology Information's Genetic Testing Registry lists more than 54,000 genetic tests related to over 11,000 conditions, representing a 300% increase in the number of available genetic tests between 2013 and 2018.<sup>9,43</sup>

## EFFECT OF THE COVID-19 PANDEMIC ON THE CLINICAL LAB WORKFORCE

### State and National Approaches for Emergency Increases to the Clinical Laboratory Workforce

As the COVID-19 crisis evolves, state and federal responses have expanded access to the clinical laboratory workforce and addressed potential shortages in a variety of ways. Selected examples are provided below.

#### Emergency use of non-laboratory space to expand COVID-19 testing

- **National:** Laboratories can perform tests in parking lots or any other designated overflow location in its facility as long as applicable CLIA regulations are followed.<sup>44</sup>

#### Extension of laboratory certificate expiration dates

- **National:** The Centers for Medicare & Medicaid Services (CMS) provide licenses for clinical laboratories; during the pandemic, CMS may evaluate expiration dates and extend laboratory certificates when certificates have expired or are near expiration.<sup>44</sup>

#### Expanded use of temporary COVID-19 testing sites

- **National:** To ensure continued workflow, CMS allows pathologists to use temporary COVID-19 testing sites to remotely review and report on laboratory data/slides/images as long as specific criteria are met.<sup>44</sup>

#### Out-of-state reciprocal licenses

- **New York:** Clinical laboratory technicians who are not licensed in the state, but who meet federal requirements for high complexity testing are allowed to perform COVID-19 tests.<sup>45</sup> (Note that not all states require licensing.<sup>9,10</sup>)

#### Non-laboratory personnel permitted to administer COVID-19 tests

- **New Hampshire:** Licensed pharmacists may administer COVID-19 tests.<sup>45</sup>
- **Ohio:** Pharmacy interns and pharmacists may administer COVID-19 tests.<sup>45</sup>

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