Implementation of large-scale laboratory-based detection of COVID-19 in the Veterans Health Administration, March 2020 − February 2021

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ABSTRACT

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) presented numerous operational challenges to healthcare delivery networks responsible for implementing large scale detection of Coronavirus Disease 2019 (COVID-19), the infection caused by SARS-CoV-2. We describe testing performance, review data quality metrics, and summarize experiences during the scale up of laboratory-based detection of COVID-19 in the Veterans Health Administration, the largest healthcare system in the United States. During March 2020 to February 2021, we observed rapid increase in testing volume, decreases in test turnaround time, improvements in testing of hospitalized persons, changes in test positivity, and varying utilization of different tests. Though performance metrics improved over time, surges challenged testing capacity and data quality remained suboptimal. Future planning efforts should focus on fortifying supply chains for consumables and equipment repair, optimizing distribution of testing workload across laboratories, and improving informatics to accurately monitor operations and intent for testing during a public health emergency.

1. Introduction

In December 2019, the emergence of a novel coronavirus causing severe acute respiratory syndrome (SARS-CoV-2) was reported in People's Republic of China and subsequently across the globe (Huang et al., 2020, World Health Organization et al., 2020, Wu et al., 2020, Zhou et al., 2020). The spread of SARS-CoV-2 prompted commercial vendors and health agencies to rapidly develop and deploy tests to support diagnosis and surveillance of Coronavirus Disease 2019 (COVID-19), the infection caused by SARS-CoV-2 (The species Severe acute respiratory syndrome-related coronavirus: classifying 2019-nCoV and naming it SARS-CoV-2, 2020). The initial diagnostic tests that received emergency use authorization (EUA) from the Food and Drug Administration (FDA) included the Centers for Disease Control and Prevention (CDC) in February 2020 followed by several large platform polymerase chain reaction (PCR) test and equipment manufacturers receiving EUAs in mid-March 2020. EUA approval for single use test kits for rapid testing platforms followed several months later. The need to rapidly meet testing demand posed challenges to healthcare delivery networks, which were tasked with developing, implementing, and optimizing operational procedures necessary to facilitate large scale detection of COVID-19.

The Veterans Health Administration (VHA) is the largest healthcare delivery network in the United States, serving a population of 9 million Veterans across US states, territories, and by special relationship within the Philippines. VHA provides a wide range of services including inpatient, outpatient, long-term care, and residential support. Administratively, VHA is divided into 21 regional units termed Veterans Integrated Service Networks (VISNs) to facilitate healthcare delivery within defined geographical service areas. In total, VHA provides care at 1,255 healthcare facilities, including 170 medical centers and 1,074 outpatient sites (US Department of Veterans Affairs 2021).

VHA undertook several key enterprise scale actions to support laboratory activities in response to COVID-19. First, information on equipment potentially available for SARS-CoV-2 testing was identified from the VHA property management tracking system; facilities confirmed the availability of the equipment, staff, and consumables required to conduct SARS-CoV-2 testing. VHA supports an internal Public Health Reference Laboratory (PHRL) to provide enterprise-wide support for infection outbreaks, emerging pathogens, and specialized genomics testing. PHRL deployed the CDC PCR assay for SARS-CoV-2 early in March 2020, and quickly reached capacity. In

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the ensuing months, other laboratories with PCR capabilities expanded capacity, and rapid PCR testing was made available at every major facility (Food & Drug Administration 2020). VHA established an operational goal to ensure test turnaround times of less than 48 hours at every major facility through a combination of local rapid testing, regional VHA referral laboratories for high-throughput PCR testing, and point-of-care antigen testing. This information supported centralized reagent contracts and prioritization of equipment and supplies during regionalized surges. VHA also developed guidance for naming tests across facilities and linking tests to Logical Observation Identifiers Names and Codes (LOINC) to promote uniformity in electronic recording and reporting. In December 2020, VHA issued guidance for adding keywords in test names to describe intent for testing. Guidance regarding testing for clinical diagnosis, staff screening, and public health surveillance purposes using PCR, antigen, and antibody testing for patients and staff under a variety of clinical presentations and exposure scenarios were issued in December 2020. The administrative diversity and wide range of services across VHA facilities presented significant barriers in standardizing SARS-CoV-2 testing across VHA.

Health agencies and healthcare institutions in several countries have described the experience of increasing diagnostic capacity for testing in response to the COVID-19 pandemic (Grotto et al., 2020, Huh et al., 2021, Sparks et al., 2021, Yang et al., 2020). However, the experience of implementing large scale laboratory testing for SARS-CoV-2 in the United States has yet to be described. Herein, we review SARS-CoV-2 testing in VHA. We describe availability for testing platforms at the start of the pandemic, characteristics during implementation of routine testing, and quality of key data elements for monitoring operations related to SARS-CoV-2 testing.

2. Materials and methods

Data of SARS-CoV-2 tests performed during March 1, 2020 to February 28, 2021 were obtained from the VHA Corporate Data Warehouse, a repository for VHA electronic health records; data describing the laboratory that performed an ordered test for SARS-CoV-2 were obtained from VHA Praedico Surveillance System (US Department of Veterans Affairs 2020, US Department of Veterans Affairs 2020). SARS-CoV-2 tests were identified by searching for lab test names compatible with variations of "SARS COV 2″, "COVID", "CORONA" or "NCOV"; records of coronaviruses other than SARS-CoV-2 were excluded. Records of tests that were cancelled or for which specimen processing was not performed were excluded. Classification of tests as antigen, antibody, or PCR was based on corresponding terms mentioned in laboratory workload codes associated with each test. Patient types were aggregated into three categories: Veterans, non-Veteran employees, and others. The instrument on which a test was performed was assigned by detection of names of instruments in test names or test comment fields. Subtypes of immunoassays were identified by searching for "IGG" or "IGM" in test names. Specimen collection location was determined by linking collection codes with those of the corresponding location types. Among PCR and antigen tests, identifiers indicating intent were detected by searching for character strings compatible with "diagnostic," "monitoring," or "screening" in test names. The VHA Property Management System was used to identify instruments available in VHA clinical laboratories; listed items were confirmed available for use by local managers. Proportions and medians were calculated. For percent positivity, the result of the first test for a unique person per monthly interval was counted.

Access to VHA data for public health activities is covered under the Privacy Act of 1974; System of Records entitled "National Patient Databases-VA" (121VA10P2) as set forth in the Federal Register 79 FR 8245. The data utilized in this study were obtained for the purpose of public health operations in VHA. No additional analyses were performed outside of public health operational activities; thus, it did not require VHA or facility Institutional Review Board review in accordance with 2019 Department of Veterans Affairs Office of Research & Development Program Guide 1200.21, VHA Operations Activities that May Constitute Research.

3. Results

3.1. Distribution of instruments and testing capacity

At the start of the pandemic, a wide variety of rapid and high-throughput instruments were available in VHA for PCR detection of SARS-CoV-2 across VISNs following corresponding FDA EUA approvals (Supplementary Fig A.1, Supplementary Figure A.2). Across VHA, platforms for rapid or point of care testing were widely available and were most represented by Cepheid GeneXpert ($n = 150$), BioFire FilmArray ($n = 103$), and Abbott ID Now (n = 20) instruments. Fewer high-throughput instruments were available; the most common high-throughput instruments were Abbott M2000 ($n = 16$), Becton-Dickinson BD Max ($n = 12$), and ThermoFisher TaqMan (n = 9).

3.2. Monthly volume of tests

The volume of tests performed increased during March 2020 to February 2021 (Fig. 1A). Monthly PCR tests increased from 15,023 performed in March to 351,646 in December, and then decreased to 216,715 by the end of February 2021. SARS-CoV-2 antigen tests increased in monthly volume from 442 in November 2020 to 90,059 by the end of the study period. Monthly SARS-CoV-2 antibody tests were 174 in April, increased to 10,802 in July and decreased to 7,159 in February. Among 91,792 antibody tests with the type of immunoglobin mentioned, 60,257 (65.6%) were IgG and 2,174 (2.4%) were IgM.

3.3. Tests by location of laboratory

More than 85% of completed PCR, antigen, and antibody tests were performed in VHA laboratories in contrast to external laboratories (e.g., commercial, local health department). By February 2021, the percentage of completed PCR tests performed in VHA laboratories increased to 97.3%, the percentage of completed antigen tests performed in VHA laboratories increased to 99.9%, and the percentage of antibody tested performed in VHA laboratories increased to 99.4% (Fig. 1B). Overall, among completed tests performed in VHA laboratories, the majority of PCR (94.8%), antigen (98.0%), and antibody (99.9%) tests were performed in a laboratory that was in the same VISN as that of the facility where the specimen was collected. Additionally, the percentage of overall SARS-CoV-2 PCR tests that were performed at PHRL reduced from 20.4% in March to less than 4% from May onwards (Fig. 2A).

3.4. Tests by type of patient

The number of tests performed varied by type of patient (Fig. 1C). Overall, Veterans accounted for the majority of antibody and PCR tests, while non-Veteran employees had the highest number of antigen tests. Persons who were not Veterans nor non-Veteran employees accounted for 4.4% of PCR tests, 4.4% of antigen tests, and 3.1% of antibody tests. In total, 91,792 antibody tests in 70,139 unique persons, 179,698 antigen tests in 41,970 unique persons, and 2,515,574 PCR tests in 1,139,425 unique persons were performed. Of the 1,139,425 unique persons who underwent PCR testing, 973,183 (85.4%) were Veterans and 110,508 (9.7%) were non-Veterans employees. Of the 41,970 unique persons who underwent antigen testing, 24,684 (58.8%) were Veterans and 15,628 (37.2%) were non-Veteran employees. Of the 70,139 unique persons who underwent antibody testing, 52,427 (74.7%) were Veterans and 15,633 (22.2%) were non-Veteran employees.
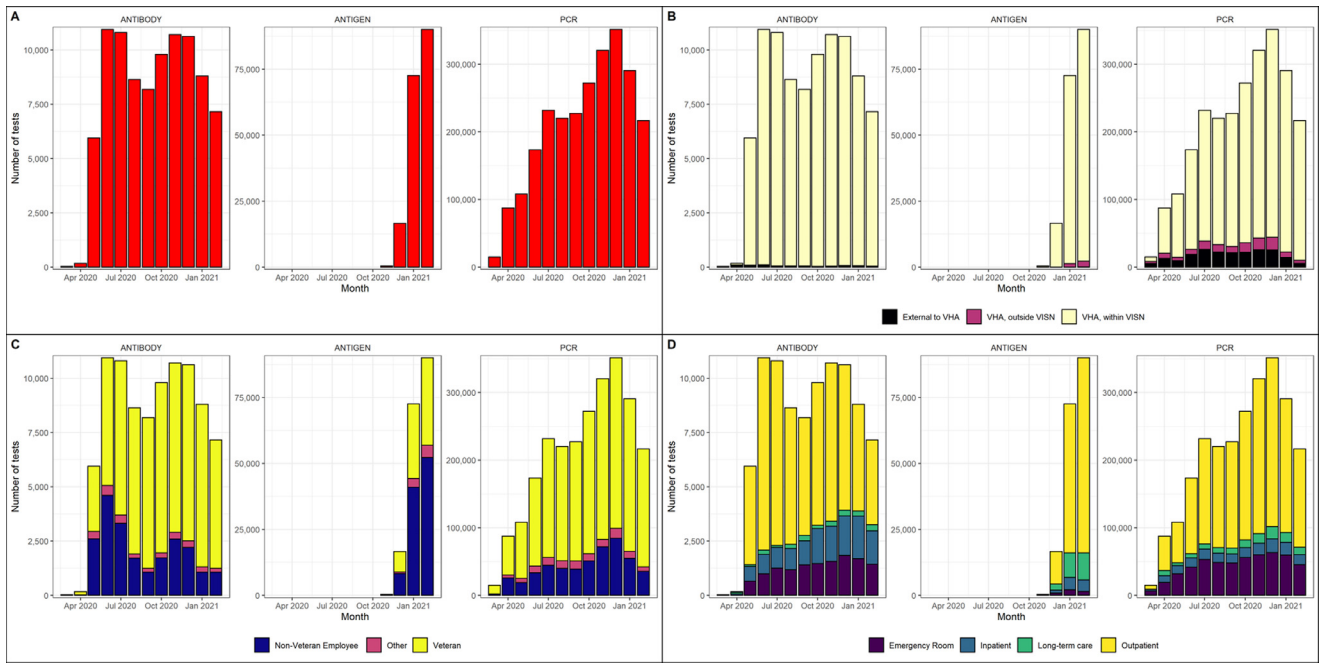
Fig. 1. Metrics of SARS-CoV-2 tests performed in Veterans Health Administration, March 2020 to February 2021. (A) Total monthly tests performed. (B) Monthly tests performed by location of performing laboratory. "Outside VISN" and "within VISN" describe whether the test performed in a VHA laboratory locate in a different or the same VISN as that in which the specimen was collected. (C) Monthly tests performed by type of patient. (D) Monthly tests performed by setting where specimen was collected. VISN = Veterans Integrated Health System. VHA = Veterans Health Administration.

3.5. Tests by setting of specimen collection

Testing volume differed substantially by the type of setting from where specimens for SARS-CoV-2 tests were collected (Fig. 1D). Among all location types, PCR tests were the most common. Outpatient locations accounted for the majority of PCR (67.7%), antigen (79.5%), and antibody (68.7%) tests. Antigen tests occurred in greater volume than antibody tests in long-term care and outpatient settings; in contrast, antibody tests occurred in greater volume than antigen tests in inpatient and emergency room settings.

3.6. Testing among hospitalized individuals

PCR or antigen testing of unique persons hospitalized in VHA facilities increased from 8.0% in March to >80% by June, and remained above that percentage thereafter (Fig. 2B). Overall, 77.0% of
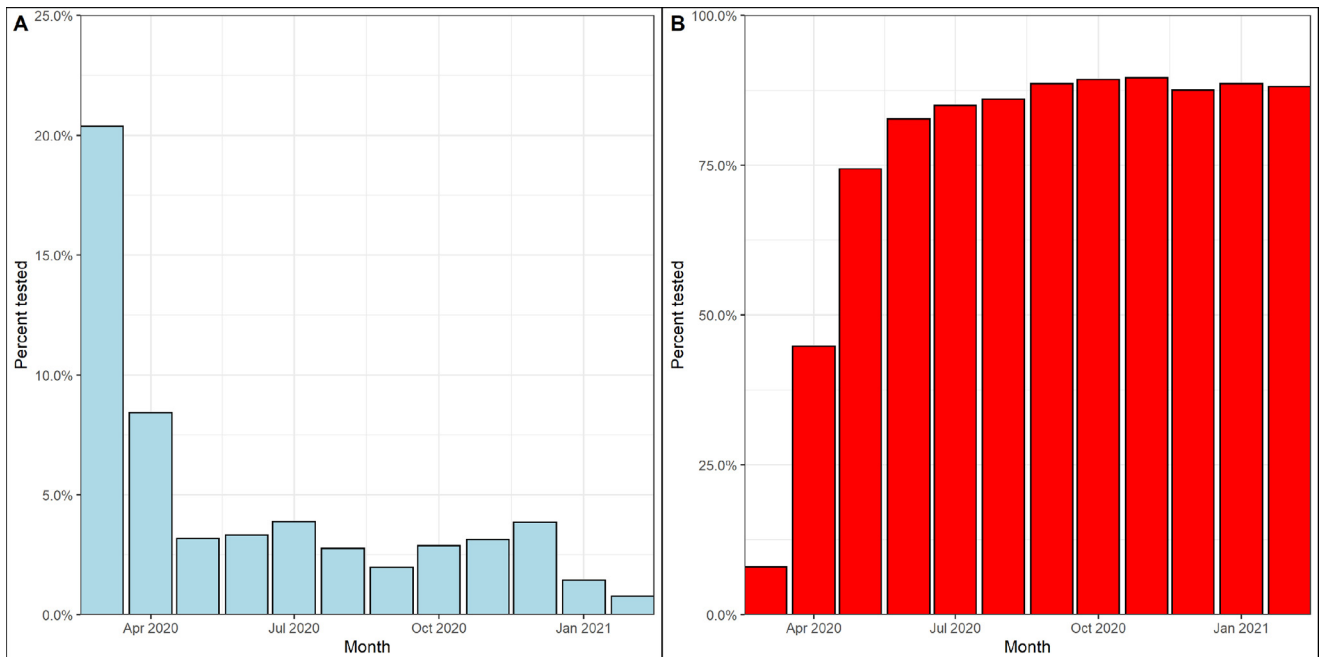

Fig. 2. Selected metrics of SARS-CoV-2 testing in Veterans Health Administration, March 2020 to February 2021. (A) Percentage of overall tests that were performed at the Public Health Reference Laboratory (PHRL). (B) Percentage of hospitalized persons tested for SARS-Cov-2 by PCR or antigen tests.
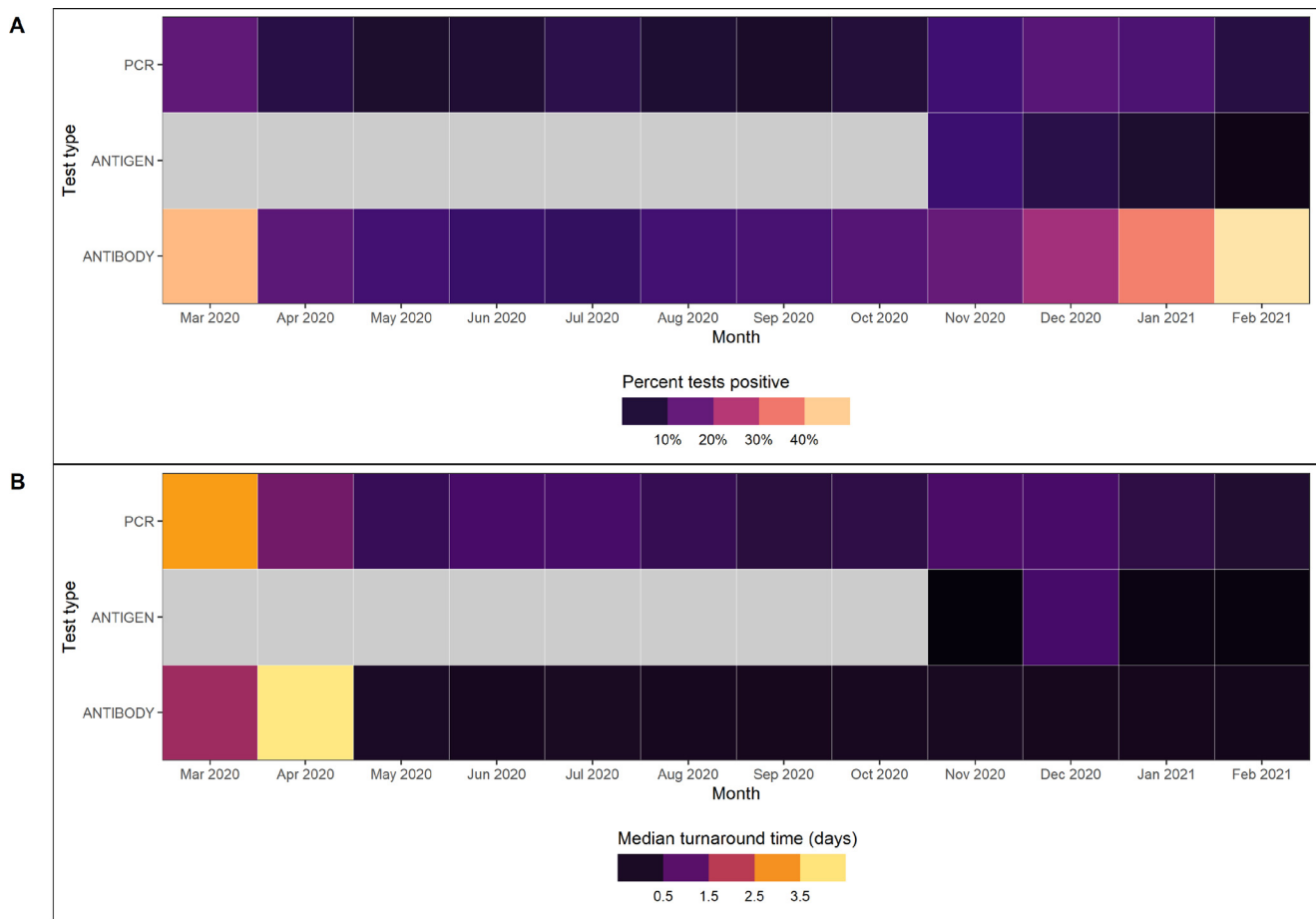
Fig. 3. Longitudinal characteristics of SARS-CoV-2 tests performed in Veterans Health Administration, March 2020 to February 2021. (A) Test positivity among unique persons tested by month. (B) Monthly median turnaround time.

hospitalized individuals were tested for SARS-CoV-2 by PCR or antigen test within 7 days of admission.

3.7. Test positivity

The positivity of tests varied during March 2020 to February 2021 (Fig. 3A). Among unique persons tested, PCR test positivity was 14.4% in March 2020, decreased to 3.4% in September 2020, rebounded to 13.3% in December 2020, and then decreased to 5.9% in February 2021. Antigen test positivity in unique persons decreased from 9.9% in November 2020 to 1.3% by the end of February 2021. Antibody positivity among unique persons tested was 13.8% in April, decreased to 8.6% in July, and then increased to 47.3% by February 2021. Overall, 7.6%, 3.1%, and 17.7% of unique persons had a positive PCR, antigen, and antibody test, respectively.

3.8. Turnaround time

Turnaround time decreased from March to February (Fig. 3B). The median turnaround time of all PCR tests was 3.1 days in March and decreased to and remained less than one day from May onwards. Among PCR tests performed on high-throughput instruments, the median turnaround time decreased from 1.5 days in March to 1.0 days in December, and then remained below 1 day. Among PCR tests performed on point of care instruments, the median turnaround time decreased from 3.0 hours in March to less than 2 hours from April onwards. The median turnaround time of antigen tests was consistently less than one day. The median turnaround time of antibody tests decreased from 3.8 days in April to less than 1 day by May.

Overall, the median turnaround times of all three types of tests were less than one day; 83.6% of antigen tests, 82.7% of PCR tests, and 91% of antibody tests were completed within 48 hours of specimen collection.

3.9. Data quality

Scale up of testing for SARS-CoV-2 was accompanied by increasing variability in laboratories test names used to record PCR, antigen, and antibody tests in VHA facilities in the EHR (Table 1). The number of unique test names for PCR tests per month increased from 218 in March 2020 to 267 in February 2021; similarly, the number of unique test names for antigen tests increased from 5 to 46, and the number of unique test names for antibody tests increased from 3 to 104. Overall, during March 2020 to February 2021, there were 652, 54, and 141 unique test names for PCR, antigen, and antibody tests, respectively.

From March 2020 to February 2021, the monthly proportion of PCR tests with a recorded Logical Observation Identifiers Names and Code (LOINC) increased from 4.1% to 66.4%. The proportion of antigen tests with a recorded LOINC increased to 43.0%, and the proportion of antibody tests with LOINC reduced from 100% to 62.5%. Overall, 28.4% of PCR tests, 39.2% of antigen tests, and 54.2% of antibody tests had a recorded LOINC.

In the first year of COVID-19 response activities in VHA, the monthly proportion of PCR tests with information describing the instrument on which tests were performed increased from 11.4% to 49.9%, the proportion of antigen tests with instrument-related data increased from 48.2% to 94.3%, and the proportion of antibody tests

Table 1
Key data quality metrics among SARS-Cov-2 tests performed in Veterans Health Administration, March 2020 to February 2021.

Test	Mar 2020	Apr 2020	May 2020	Jun 2020	Jul 2020	Aug 2020	Sep 2020	Oct 2020	Nov 2020	Dec 2020	Jan 2021	Feb 2021	Overall
Unique test names													
ANTIBODY	3	10	38	50	48	65	66	60	69	79	81	104	141
ANTIGEN	-	-	-	-	-	-	-	-	5	29	44	46	54
PCR	218	277	253	257	273	264	269	304	340	353	298	267	652
Percentage with LOINC recorded													
ANTIBODY	100.0%	100.0%	76.4%	62.2%	44.4%	40.8%	43.3%	49.1%	50.5%	58.4%	61.4%	62.5%	54.2%
ANTIGEN	-	-	-	-	-	-	-	-	48.2%	27.0%	37.4%	43.0%	39.2%
PCR	4.1%	1.5%	1.4%	2.0%	2.1%	5.1%	5.3%	15.5%	33.4%	57.6%	63.5%	66.4%	28.4%
Percentage with information describing instrument used													
ANTIBODY	0.0%	20.1%	31.0%	67.5%	49.9%	38.0%	41.1%	47.8%	52.3%	52.9%	53.5%	53.3%	49.8%
ANTIGEN	-	-	-	-	-	-	-	-	88.5%	85.2%	92.3%	94.3%	92.6%
PCR	11.4%	32.3%	46.2%	42.6%	45.9%	49.7%	52.3%	52.1%	47.4%	44.8%	45.7%	49.9%	47.0%
Percentage with information describing intent for testing													
ANTIGEN	-	-	-	-	-	-	-	-	0.0%	10.4%	14.4%	14.3%	14.0%
PCR	3.1%	9.3%	10.4%	13.3%	13.0%	14.4%	14.2%	14.0%	13.3%	17.3%	19.8%	20.3%	15.1%

with instrument-related data increased from 0.0% to 53.3%. Overall, 47.0% of PCR tests, 92.6% of antigen tests, and 49.8% of antibody tests had information available in comments or test name fields to identify the instrument on which the test was performed.

Addition of keywords in test names to describe intent for testing remained low during March 2020 to February 2021. Among antigen tests, usage of keywords describing intent increased from 0.0% in November 2020 to 14.0% by the end of February 2021. Keywords describing intent for testing among PCR tests rose from 3.1% in March 2020 to 20.3% by the end of February 2021. Overall, 14.0% of antigen tests and 15.1% of PCR tests had keywords describing intent. Among tests 12.4% of all tests with keywords indicating intent, 24.2% mentioned diagnosis, 22.3% indicated monitoring, and 53.4% were for screening.

4. Discussion

Within weeks of the emergence of SARS-CoV-2 and subsequent FDA EUA of SARS-CoV-2 diagnostic tests, VHA scaled up testing availability and performance across an integrated healthcare delivery network of 1,255 facilities. Metrics of laboratory performance and surveillance of COVID-19 improved during March 2020 to February 2021. A VHA operational memorandum requesting facilities to minimize the volume of tests ordered in VHA facilities that were completed in laboratories external to VHA was achieved as the proportion of tests completed in VHA laboratories reached more than 80% by late 2020. Despite these achievements, inconsistent recording of LOINC data, poor documentation of instruments on which tests were performed, and non-standardization of test names were persistently observed as areas in need of improvement.

Initial high percent positivity of PCR tests followed by a notable decrease likely occurred in the setting of changes in testing criteria by public health authorities and timing of regional surges. An early peak in volume of antibody tests followed by a steady decline likely reflects rapid uptake as these tests were made available followed by a reversion of testing frequency that largely mirrors that of PCR tests. Similarly, the sharp fall in PCR tests after December and the simultaneous rapid rise in antigen tests—particularly among non-Veteran employees—likely reflects the increasing use of the latter as the preferred method for screening, particularly in long-term care facilities following additional directives issued by VHA in December 2020. The high number of tests relative to unique persons reflects the multiple clinical encounters by patients, longitudinal screening of patients in long-term care facilities as well as employees, and clinical monitoring. Decreases in turnaround time occurred as laboratory staff resources, workload management, and supply chains improved. The increase in PCR volume and reduction in overall percentage of PCR tests performed at PHRL suggest that efforts to decentralize testing capacity were successful. COVID-19 screening in long-term care facilities, expanded testing for VHA employees, support for testing in state Veterans nursing homes and among non-VHA affiliated persons under the VA Fourth Mission (Massarweh et al., 2020), and enhanced screening of hospitalized persons contributed to the overall increase in testing volume. The rapid increase of diagnostic performance was critical in timely identification of COVID-19 and in facilitating response to COVID-19 outbreaks.

Monitoring laboratory operations is facilitated by accurate data describing usage of SARS-CoV-2 laboratory tests and corresponding instruments. Standardized test names and LOINC permit identification of laboratory related procedures and thereby can assist in accurately tracking utilization (McDonald et al., 2003, Panackal et al., 2002, Pinner et al., 2000). The number of unique test names for SARS-CoV-2 increased during 2020; additionally, though improvement in availability of LOINC data was observed over time, only 58% of SARS-CoV-2 antibody tests and less than 40% of PCR and antigen tests performed in VHA had recorded LOINC data. It is possible that

Table 2
Factors contributing to reduced laboratory testing capacity during enterprise scale response to public health emergencies.

Phase	Factor
Initial phase	Procurement of instruments and supplies
	Establishing contracts for instrument upkeep, repair, and replacement
	Establishing contracts for procurement and delivery of consumables
	Competing for procurement of limited resources with external laboratories
	Installation of new instruments in laboratories
	Hiring, onboarding, and training laboratory staff
	Managing space constraints due to newly procured equipment
Mature phase	Repair or replacement of broken instruments
	Disruptions in supply chains for consumables
	Disruptions in availability of transportation vendors
	Managing staff turnover
	Adapting to changes in testing recommendations by health agencies
	Responding to acute, disproportionate demand for testing due to regional outbreaks
	Managing space constraints due to surges in testing

instruments used in VHA for SARS-CoV-2 do associate tests with LOINC data; however, these data are not transferred to VHA electronic databases used for this analysis. Information regarding the instrument used to perform laboratory tests can provide early signals of disruption in supply chain of instrument-specific consumables; additionally, these data when combined with test results and clinical data could allow retrospective detection of statistical differences in performance characteristics of new assays. Few completed SARS-CoV-2 tests had information available in test comment fields or test names to identify the instrument on which the test was performed. Information describing intent for testing can provide useful operational information; however, usage of keywords describing intent remained suboptimal. Though lack of standardization may have initially stemmed from the need to urgently scale up test availability (de Sousa et al., 2014), notable data quality gaps were still present twelve months after the start of the pandemic. Data quality gaps might also hinder the accuracy of operational models used to forecast need for testing as well the detection of interrupted laboratory procedures that would requiring timely shifting of resources across facilities (Veterans Health Administration 2019). Enhancing data quality and standardizing testing identifiers will be vital to monitor operations and to ensure accurate surveillance as genomic testing is implemented to detect and track SARS-CoV-2 variants (Wilkinson et al., 2016).

Many factors can contribute to low or interrupted utilization of laboratory testing capacity during a national response to a novel infectious disease (Sayed et al., 2018, Bastiaens et al., 2014, Peter et al., 2017, Nolte et al., 2020); these factors may be considered during the initial and mature phases of the response (Table 2). Instrument procurement and reliable supply chains for reagents and consumables are difficult in the early stages of response when many clinical and public health laboratories are competing for limited resources. Supply chains may be disrupted due to delays in finalizing national contracts and executive decisions to divert limited resources to sites in geographical regions with rapidly increasing spread and corresponding need for testing. Existing equipment, not built to perform uninterrupted for 24/7, experiences more downtime, requires more frequent maintenance, and may require earlier replacement. Newly installed instruments and procured assays require calibration and validation before advancing to regular use. The demand for testing may outstrip the number of staff on hand to prepare specimens for testing, report laboratory results, and dispose of laboratory waste; new staff require training as well as administrative onboarding.

Instrument breakdown and interruptions in consumables or reagents may hinder utilization until replacements can be found and procured; unmet workload requires rerouting to alternative or contingency sites with sufficient capacity to maintain test performance metrics. The large volume of specimens collected for processing and newly installed instruments may generate space constraints that impede operations. Materials and mechanisms for safe packaging and transit of specimens to offsite laboratories may be delayed due to supply chain issues, staff shortages, or unavailability of transportation vendors. VHA facilities encountered and resolved many of these challenges.

There are limitations in this review. Tests names were used to identify unique tests performed as other identifiers were not universally available in the VHA Corporate Data Warehouse. Additionally, manual algorithms were used to identify the testing instrument due to lack of standardized data fields. It is possible that some records were missed or misclassified. Inventories of instruments for SARS-CoV-2 testing may have been incomplete. Some individuals may have been tested on point-of-care instruments, but the corresponding result may not have been uploaded; these tests would have been missed. Some persons may have been tested at a non-VHA hospital before being transferred to a VHA hospital but results might not have been entered into VHA databases; therefore, the proportion of hospitalized persons tested for COVID-19 might be higher. Persons with patient type of "Veteran" includes Veterans who might also be employees at VHA facilities; therefore, persons who are employees, account for a larger amount of tests than described by "non-Veteran employees." Testing protocols and factors associated with determinations to test or retest were not available for review as these are specific to individual clinical providers and facilities. Our administrative data did not allow us to determine issues associated with staffing, supplies, equipment function, and other variables that affect testing performance at individual clinical laboratories. Lastly, this review does not assess the appropriateness of testing, repeat testing, and utilization of test type.

The spread of COVID-19 across the United States presented numerous challenges to healthcare delivery networks tasked with detection, treatment, and containment of COVID-19. The experience at VHA serves as a useful example of the successes and challenges of scaling up laboratory testing in response to the pandemic. Healthcare administrators and laboratory managers should continue to monitor testing operations, fortify supply chains, and optimize data quality in the ongoing effort to curb the spread of SARS-CoV-2.

Author contributions

Aditya Sharma: Conceptualization, Methodology, Data Curation, Visualization, Formal analysis, Writing–Original Draft, Writing–Review and Editing. Gina Oda: Writing – Review and Editing. Michael Icardi: Writing–Review and Editing. Larry Mole: Data Curation, Writing – Review and Editing. Mark Holodniy: Conceptualization, Data Curation, Writing–Review and Editing, Supervision, Project administration

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Declaration of competing interests

The authors declare no competing interests.

Disclosures

The opinions expressed are those of the authors and do not necessarily reflect those of the United States Department of Veterans Affairs or United States Government.

Supplementary materials

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