

Successful implementation of SARS-CoV-2 testing in midst of pandemic with emphasis on all phases of testing

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INTRODUCTION

From its humble beginnings as a zoonotic coronavirus infection originating in Wuhan, China, the SARS-CoV-2 virus has spread worldwide to become an international pandemic.^{1–3} The World Health Organization (WHO), given the highly contagious and potentially lethal nature of this widespread virus, has classified this pandemic as a global health emergency, with significant impact and infection within the USA.²

The extraordinary circumstances of the highly contagious SARS-CoV-2 pandemic have led the Food and Drug Administration (FDA) to approve diagnostic assays for SARS-CoV-2 infection with emergency use authorisations (EUA).^{4,5} The use of EUA assays for a widespread pandemic in the absence of any non-EUA approved equivalent assays has led to an unprecedented situation for the clinical laboratory for which practical considerations of dealing with the aftermath have been described at a hospital in Singapore and in an abstract poster presentation of this manuscript's data at the 2020 national meeting of the American Society for Clinical Pathology.^{5,6} However, a description of the practical considerations has not been similarly well described for the severely affected USA or even for that matter within its large and integrated Veterans Affairs Medical System Center (VAMC).

CHALLENGES

Given the emergency requiring implementation of an in-house SARS-CoV-2 test to ensure adequate turnaround times (to allow clinical decisions to be influenced in a timely manner), several challenges arose. Initial challenges summarised in the valley of successful implementation (figure 1) included (1) selection of the testing platform(s), (2) ensuring that sufficient viral transport media (VTM) and reagent would be available for the selected testing platforms, (3) validating and composing standard operating procedures for assays despite the limited data presented by the EUA situation, (4) ensuring enough trained staff and (5) ensuring an appropriate environment with the appropriate biosafety level (BSL). As testing was being performed, additional challenges that arose included (1) handling the surge of test specimens from the clinical services including repeat serial specimens for high risk surveillance, (2) ensuring both rapid turnaround times and adequate staffing/reagents despite this surge and pandemic related illnesses/shortages, (3) troubleshooting errors and ensuring continuous

quality assurance and (4) ensuring communicating and reporting results to the clinicians to ensure quality care. These challenges were addressed as testing was brought in-house at the VAMC as below.

TEST VALIDATION PRIOR TO INTRODUCING TESTING CAPABILITIES

Given the extraordinary circumstance of a pandemic requiring laboratory testing for quality care while all available tests are approved only as EUAs, the question of how to perform an adequate test validation (compatible with the standard of care quality standards set by the College of American Pathologists would be expected to arise; this is particularly the case given that reagent and personal protective equipment (PPE) shortages would severely limit the number of validation tests that could be performed.⁷ For the regional northeastern United States VAMC, two reverse transcriptase PCR assays for testing were brought for clinical use including one test with a rapid turnaround time, the Xpert Xpress SARS-CoV-2 assay by Cepheid (Sunnyvale, California, USA), along with the Abbott RealTime SARS-CoV-2 assay by Abbott (Abbott Park, Ill) to handle the bulk of the testing within 24 hours. The rationale was to choose one rapid testing platform for critical needs, despite reagent limitations, and another assay (the Abbott) to support the workload. The Xpert Xpress SARS-CoV-2 assay by Cepheid was run on individual cartridges that could result within 45 min on the infinity platform, but there were significant limitations on the supply of cartridges that required judicious usage to preclude being out of supply for a critical case.^{4,8} The Abbott RealTime SARS-CoV-2 assay on the m2000 platform, which was performed in batches of up to 94 specimens per run with two controls per batch, could handle the rest of the workload; by staggering of the start time of each batch, more than one batch could be run over the course of 24 hours, and in practice within the regional VAMC, up to 2–3 batches were run per 24 hours period.^{4,9} Some sort of test validation is necessary to verify that the tests to be brought in-house performs as expected, and given the worldwide shortages and delays, also necessary to ensure a reasonably rapid turnaround time that could not be easily accomplished by sending tests to a backlogged distant reference laboratory.

For the Abbott RealTime SARS-CoV-2 assay with more available test kits, validation/verification was performed in three parts as part of quality assurance/



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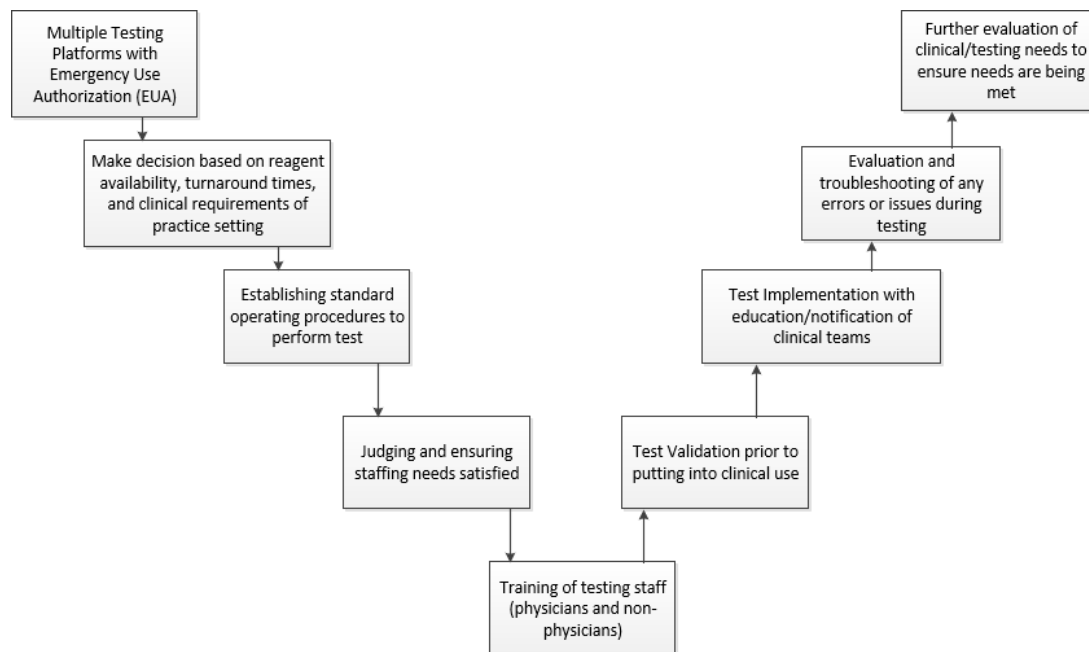


Figure 1 Summary flow chart of the valley of successful implementation of in-house SARS-CoV-2 testing in the midst of the pandemic.

quality improvement: (1) sample/patient correlation, (2) precision and (3) validation/verification of accuracy at the limit of detection (LOD) of 100 virus copies/mL as described by the manufacturer. In addition, LOD studies of samples to the level of 50 virus copies/mL (below the manufacturer's stated LOD of 100 virus copies/mL) were performed. The results from these studies was compiled (see [table 1](#)), reviewed by the laboratory, and after performance was deemed satisfactory, the test would be put for clinical use. For the sample/patient correlation (see [table 1](#)), a total of 68 known positive and 59 known negative samples were run; these included 56 positive contrived samples or controls, 12 known positive patient samples, 31 negative contrived samples or controls and 28 known negative patient samples. All results from the assay were as expected with 100% positive and negative per cent agreement except for one sample that was quantity not sufficient for testing (see [table 2](#)). The precision study with four known positive and four known negative samples run once per day for 5 days yielded perfect 100% precision for both the positive and negative samples. Replicates to determine accuracy at the lower LOD (100 virus copies/mL per instructions for use of the assay) demonstrated accuracy even with dilutions down to 50 virus copies/mL (see [table 3](#)). For this third step, three replicates each had been performed at 1000, 500, 250, 70, 60 and 50 virus copies/mL. As 100 virus copies/mL was the provided manufacturer LOD, seven replicates were performed at 100 virus copies/mL. Given these results (see [table 1](#)), the validation/verification study indicated that the Abbott RealTime SARS-CoV-2 assay performed with expectations including with real patient samples and could be put into clinical use at the VAMC. After this validation/verification, the assay has been very successfully used for in-house testing for SARS-CoV-2. In fact, the validation demonstrated an LOD as low as 50 virus copies/mL, suggesting the assay may be even more sensitive to low levels of viremia than is stated in the EUA.

For the Cepheid Xpert Xpress SARS-CoV-2 assay, the regional VAMC took part in a nationwide Veteran Affairs validation study (the VA National Combined Verification Study for Cepheid SARS-CoV-2 Assay-Study Plan) in order to preserve

scarce Cepheid testing cartridges. As part of this nationwide study, on the first day, two external positive controls and two external negative controls were run on the Cepheid Xpert Xpress SARS-CoV-2 assay by different operators with records of the results on the standardised data collection form. On the second day, one external positive and one external negative control was run. All results were as expected, and the based on the validation study, the assay was placed into clinical use.

LABORATORY PREPAREDNESS DESPITE PANDEMIC-RELATED SUPPLY SHORTAGES

After the introduction of testing, the seriousness of the nationwide reagent shortages including for commercial VTM and swabs became increasingly apparent.^{10 11} Shortages for reagents such as VTM, swabs, PPE and test supplies were handled with active procurement whenever possible. However, procuring adequate transport media was not always possible. Therefore, preparation and validation of in-house VTM with phenol red and of phosphate buffered saline as the transport media was performed as summarised in [table 1](#). The VTM shortage was also an information challenge as the peer-reviewed literature to guide preparation is sparse.^{10 11} The inclusion of phenol red was decided on because phenol red can be an indicator of sterility by yellowing in the presence of acidity from bacterial growth.^{10 11} The in-house preparation of VTM and vials of phosphate buffered saline was performed in these temporary times of transport media shortage.

The pandemic-related supply shortages also impacted the supply of Cepheid Xpert Xpress SARS-CoV-2 test cartridges required to perform rapid testing. As testing reagents were relatively more abundant for the Abbott RealTime SARS-CoV-2 assay compared with the Cepheid Xpert Xpress SARS-CoV-2 assay, tests for SARS-CoV-2 were triaged by the clinical team. Tests of highest clinical urgency to positively impact patient care were triaged to receive the rapid Cepheid Xpert Xpress SARS-CoV-2 assay; other less urgent SARS-CoV-2 tests would be performed on the batched Abbott RealTime SARS-CoV-2 assay.

Table 1 Tabulation of the validation studies run at the regional VAMC for reference

Test and media validations summary	
Abbott RealTime SARS-CoV-2 Assay	
Known Positive Samples Run	68
Known Negative Samples Run	59*
Precision Runs	4+and 4–samples daily over 5 days
Limit of Detection (LOD) Study	Three replicates each at 1000, 500, 250, 70, 60, and 50 virus copies/ml Seven replicates each at manufacturer LOD of 100 virus copies/ml
Cepheid Xpert Xpress SARS-CoV-2 Assay	
Known Samples Locally Run on Day 1	2+and 2–samples
Known samples Locally Run on day 2	1+and 1–samples
Intrafacility Viral Transport Media Emergency Usage	
Sterility	Two 3 mL aliquots to be cultured per 500 mL of Hanks Balanced Salt Solution Base
Initial Efficacy	Day 1: 3+and –samples refrigerated
	Day 2: 3+samples at room temperature, 3+samples in refrigerated, and 3 –samples refrigerated
	Day 3: 3+samples and 3 –samples refrigerated, 3+samples frozen at –20 C then thawed
Ongoing Efficacy	2+and 2 –samples per 500 mL of Hanks Balanced Salt Solution Base
Phosphate Buffered Saline Media Emergency usage	
Abbott RealTime SARS-CoV-2 Assay	ten known samples after 6 hour incubation (half +/-)
	ten known samples after 12 hours incubation (half +/-)
	ten known samples after 24 hours incubation (half +/-)
	ten known samples after 48 hours incubation (half +/-)
Cepheid Xpert Xpress SARS-CoV-2 Assay	ten known samples after 6 hour incubation (half +/-)

All samples run for the validation reacted or had results as expected.

*One negative sample was quantity not sufficient, and so 58 known negative sample results were available for the validation.

–, negative; +, positive; VAMC, Veteran Affairs Medical Center.

LABORATORY PREPAREDNESS PRIOR TO ANALYSIS

In addition to test validation to enable laboratory diagnosis of SARS-CoV-2 in house in a timely manner, a pandemic situation of a highly contagious emerging pathogen would require the implementation of appropriate precautions.¹² As noted by the WHO guidelines, all specimens collected to diagnose SARS-CoV-2 are potentially infectious, and therefore, as delineated by CDC

Table 2 Precision study

	Day 1	Day 2	Day 3	Day 4	Day 5
Known positives run	4	4	4	4	4
Known negatives run	4	4	4	4	4
Percentage results as expected	100%	100%	100%	100%	100%

This table was presented in an abstract presentation at the American Society for Clinical Pathology National 2020 Annual Conference on 9 September 2020 to 12 September 2020 (see reference ⁵).

Four known positives and four known negative samples were run once per day for 5 days with all results as expected (100% agreement).

Table 3 Validation via replicates run near the limit of detection (LOD) for the Abbott m2000, with 100% positive agreement even below the manufacturer published LOD of 100 virus copies/mL

Virus copies/mL	No of replicates run	Percentage positive results
1000	3	100
500	3	100
250	3	100
100	7	100
70	3	100
60	3	100
50	3	100

This suggests that the assay remains sensitive to detect even very low levels of virus in specimens. This table was presented in an abstract presentation at the American Society for Clinical Pathology National 2020 Annual Conference on 9 September 2020 to 12 September 2020 (see reference ⁵).

guidelines, molecular testing for the diagnosis of SARS-CoV-2 would need to take place in at least a BSL-2 laboratory using standard precautions.^{12–14} Specimens specifically for the diagnosis of SARS-CoV-2 should be hand-delivered double-bagged in appropriate zip-locked biohazard labelled bags instead of delivered via pneumatic tube to reduce the risk of breakage or spilling of the sample.⁶ Preparations within the accessioning and molecular areas of the laboratory are also necessary to prevent laboratory staff from becoming overwhelmed by a wave of SARS-CoV-2 specimens for urgent processing. In addition, as not all test reagents are in abundant supply, particularly the VA experience with scarce Cepheid cartridges requiring rationing with only very limited numbers of tests available on a weekly basis, communication in a timely manner between the clinical teams and the laboratory is of utmost importance.⁶ Particularly, for this regional VA, this included communication about the reagent issue with Cepheid with the clinical teams, leading to an active collaboration between the laboratory and clinical teams to prioritise which specimens must be run by the Cepheid assay with rapid turnaround time and which others could wait for batched daily Abbott testing. Prioritisation of tests based on the patient and location in medical centre required this clinical collaboration to identify the patients with urgent testing needs. Additionally, as unwell staff members would need to be quarantined, measures to ensure appropriate and adequate staffing are necessary for the adequate uninterrupted performance of the laboratory.⁶

Lastly, prior to implementation of an assay, there is a valley of decision making, standard operating procedure writing and validation to be performed based on the unique institutional characteristics and testing platform parameters (see figure 1). The use of both the Abbott m2000 and Cepheid Infinity platforms ensured that the available test platform characteristics were compatible with the regional VAMC's pandemic needs, namely that the Abbott m2000 had relatively abundant capacity per run (94 specimens) and supply while the Cepheid Infinity assay could result urgent cases within an hour. Therefore, with adequate staffing (including all worked shifts per day), extensive cross training of laboratory medical technologists, information technology support and logistics, both platforms were validated, brought in-house and used for clinical testing for SARS-CoV-2 successfully. This capacity to meet needs was particularly important as on implementation there was significant clinical demand for testing from multiple services (such as inpatient/outpatients, employee health and community living centres/nursing homes). Lastly, the importance of education of

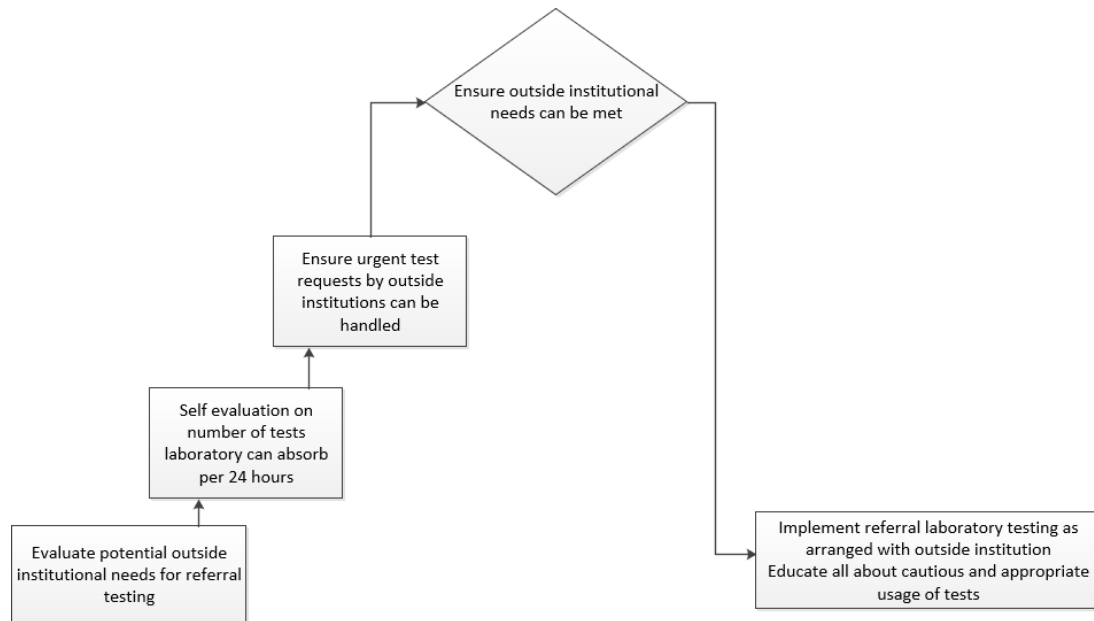


Figure 2 Summary flow chart of the mountain of successful implementation of referral testing arrangements to regional Veteran Affairs (VA) from other institutions.

the clinical team of all the efforts by the laboratory to lead to cautious and appropriate usage of tests considering the shortages cannot be emphasised enough.

LABORATORY PREPAREDNESS AS A REFERRAL LABORATORY

Further successful meeting of clinical needs led to consideration of meeting outside institutional needs in the Mountain of Successful Implementation of Referral Testing (see [figure 2](#)), which involved ensuring the laboratory could absorb the additional testing without compromising within institution laboratory care while also meeting all needs by the outside institutions, both for their bulk or routine testing and for their urgent test requests.

The initial preparation for becoming a referral laboratory for other outside institutions included setting up a line of communication prior to referral arrangement. A 15 min phone call would need to be set up by the relevant stakeholders (ie, the chief of the laboratory of the testing and requesting facility and the medical technologists/supervisor involved in either testing the specimens at the testing facility or sending the specimens at the requesting facility). Clear communication of the acceptable swabs, media (VTM or phosphate buffered saline), and media volume would be given to the requesting facility to ensure receipt of specimens acceptable for testing. Several of the steps of the Mountain of Successful Implementation of Referral Testing ([figure 2](#)) involve information from the outside institution (ie, what are outside institutions needs and how can outside institutions urgent needs be addressed) as well as communication of testing laboratory's capabilities (how many outside institution tests can be absorbed while both maintaining an appropriate workload balance for the laboratory and continuing an suitable turnaround time). Therefore, to satisfy these steps, the establishment of communication at the beginning is important. At the regional VAMC, samples in bulk for screening/testing would be requested to be communicated at least 5 days in advance prior to specimen collection in order to ensure adequate preparation to handle the volume of testing. Completion of testing and reporting of results at the regional VAMC would generally be expected by 24 hours

after specimen receipt in pathology and laboratory medicine for all, including but not limited to, diagnostic samples from the Medical Intensive Care Unit (MICU), Surgical Intensive Care Unit (SICU), Emergency Room (ER), and others.

ANALYTICAL CONSIDERATIONS

Although not all patient samples with suspected COVID-19 are identified on arrival in the laboratory, biosafety was ensured by handling all potentially infectious samples using the standard precautions of the VA's BSL-2 laboratory.^{6 13} With the progression of the pandemic, patient samples for respiratory viruses were increasingly including SARS-CoV-2 testing making the completely unidentified swab specimen ever more uncommon by mid-pandemic. Both clinical recognition of the substantial symptom overlaps of the progressively more common SARS-CoV-2 infection with other respiratory virus infections and increasing clinical knowledge of the availability of testing contributed to the increased inclusion of SARS-CoV-2. As the institution prepared its initial phases of reopening in July, testing for SARS-CoV-2 was expanded to include routine screening of all admissions, surgical or preprocedure patients, and selected employees, nearly eliminating the issue of the completely unknown COVID-19 swab specimen. In addition, routine preoperative or presurgical results were available within 48–72 hour after laboratory receipt.

Before the SARS-CoV-2 pandemic, it had been recognised that a typical PCR diagnostic reaction can generate as many of 10^9 copies of the target sequence that could potentially contribute to contamination of laboratory surfaces if/when transiently aerosolised.¹⁴ Contamination of the laboratory environment with either PCR amplicons or whole infectious SARS-CoV-2 virus is a significant concern that not only requires the undertaking of standard precautions to protect laboratory personnel, but also care to ensure that this potential for contamination does not affect the accuracy of the laboratory results.¹⁴ The potential of SARS-CoV-2 patients, even if only mildly symptomatic, to contribute to extensive contamination of their hospital rooms has been documented, and further suggests a danger of

environmental contamination (ie, from the specimen bags or external surface of the specimen vial) when the specimens are brought into the laboratory.^{15 16} Measures undertaken to prevent contamination at the regional VAMC included but not limited to mechanical barriers (separating preparation areas from both amplification and amplification analysis areas) and chemical barriers (ensuring appropriate disinfection of laboratory surfaces with bleach), as is standard practice for PCR tests.¹⁴ Routine environmental testing of the molecular laboratory areas for quality assurance were also routinely undertaken to ensure that swabs of the laboratory environment do not produce PCR positive specimens. Finally, all batched runs on the Abbott included internal quality control specimens (a positive and negative control that must react accordingly for a valid run), and the Cepheid assay's results are also regularly monitored for quality assurance.

TROUBLESHOOTING ERRORS AND ISSUES

Inevitably, during the performance of testing, specific cases of issues, originating both totally or in part from the clinical collection process and the instrument analysis process, did occur. Preanalytically, during the clinical workflow of the collection site, specimens would occasionally come to the laboratory in a compromised state. These cases will require recollection of the specimen; these may often require clinical review and correlation with input from the laboratory staff and pathologist/director to both bring these cases to the clinician's attention and for determination of next steps if the specimen cannot be recollected.

In regard to result reporting, error codes can be produced by the instrument that would require a laboratory director's review to troubleshoot the reason for the error codes, while simultaneously ensuring steps to maximise the chance of a successful result on the repeat run. Analytical error situations that have been encountered can range from sample specific issues such as inadequate sample detected by machine, the failure of the internal control, or widespread systemic issues leading the platform to be temporarily offline. For example, in a number of sample specific error codes due to insufficient amplification of the internal control on the Abbott m2000, it was found that the sample itself was more mucoid in nature than the average specimen, and this mucoid nature was most likely inhibiting the internal control. The presence of two separate platforms that can both test for SARS-CoV-2 is an advantage in these cases as it allows the repeat run to be done on the other platform in order to maximise the chances of a successful test result. With input from the lab director, laboratory staff, and the manufacturer of the assay, these sample specific error codes can be troubleshooted and ultimately with the use of any assay, the troubleshooting of errors that arise is a part of the laboratory work for continuous quality assurance. Having both a backup testing platform and access to manufacturer assistance is a valuable asset for the laboratory to have for SARS-CoV-2 testing as it allows the laboratory to continue testing even if one or the other platform has a systemic issue requiring temporary downtime and the latter is helpful in ensuring this downtime is kept to a reasonable minimum while still ensuring quality patient and laboratory care.

POST-TEST COMMUNICATION TO THE CLINICAL TEAMS

After testing is completed, the communication of test results to the provider without excessive delay is important to ensure quality of care; positive results may carry a special urgency.⁶ Results provided in a timely basis within 24 hours, which in the VAMC's experience could only be provided from in-house tests offered 7 days a week, is important to inform clinicians to take

appropriate clinical steps. Delays, whether due to delay in analysis due to time needed to send out a specimen to a reference laboratory and await completion in the backlogged reference lab or due to a postponement of prompt clinician notification of test results, can negatively impact clinical care by prolonging the time period of uncertainty (ie, clinical ambiguity on whether the test will be positive or negative). To ensure clinician notification in all cases, test results at the regional VAMC are promptly entered into the Computerised Patient Record System with an automated Vista View Alert to the clinician punctually alerting them to the test result. For critical time-sensitive cases performed on the faster Cepheid assay for SARS-CoV-2 or other critical results done on the Abbott m2000 assay, real-time verbal communication to the clinical team is also available as necessary to ensure quality care. All of this is consistent with previously reported experiences.⁶

Lastly, infection control measures in the community for the SARS-CoV-2 pandemic would be hampered unless there is proper reporting of the positive cases to the proper Public Health authorities who can perform contact tracing, provide further advice and take necessary steps to stem the community impact of the pandemic from the public health standpoint.¹⁷

CONCLUSION

Altogether, the experience of the regional VAMC is instructive in this challenging emerging pandemic of SARS-CoV-2. Unique in this pandemic is the proliferation of EUAs and only EUAs by the FDA of diagnostic laboratory tests that, due to the urgent clinical needs, must be implemented to ensure adequate patient care with appropriate laboratory testing availability and turnaround time. Unprecedented was the shortages in reagents, supplies, PPE and the potential for staff quarantines requiring thorough actions to provide for the continuity and availability of laboratory care. In this regional VAMC, an appropriate test validation (under the EUA and mindful of the shortages and challenges) was performed with measures taken at all levels of testing (before, during and after) to accomplish successful and uninterrupted laboratory testing that serves the veteran population. This is a useful mid-pandemic experience to inform SARS-CoV-2 laboratory practice, both for in-house testing and as a referral laboratory.

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