Detection of SARS-CoV-2 at the point of care

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Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the etiologic agent of COVID-19. Testing for SARS-CoV-2 infection is a critical element of the public health response to COVID-19. Point-of-care (POC) tests can drive patient management decisions for infectious diseases, including COVID-19. POC tests are available for the diagnosis of SARS-CoV-2 infections and include those that detect SARS-CoV-2 antigens as well as amplified RNA sequences. We provide a review of SARS-CoV-2 POC tests including their performance, settings for which they might be used, their impact and future directions. Further optimization and validation, new technologies as well as studies to determine clinical and epidemiological impact of SARS-CoV-2 POC tests are needed.

Current global COVID-19 situation, & role of laboratory testing

Severe acute respiratory syndrome coronavirus (SARS-CoV-2), the etiologic agent of COVID-19, was first detected in Wuhan, Hubei Province, China in December of 2019 [1]. The rapid increase and spread in reported cases triggered the World Health Organization to declare COVID-19 to be a global pandemic on 11 March 2020. As of 20 April 2021, over 140 million confirmed COVID-19 cases and over 3 million deaths have been reported globally (https://www.who.int/emergencies/diseases/novel-coronavirus-2019).

Testing for SARS-CoV-2 infection is a critical component of the public health response to COVID-19, in part because asymptomatic infections are common and contribute to COVID-19 transmission [2,3]. Testing identifies infected individuals to be quarantined or isolated for infection control purposes [4], (1) impacts patient management decisions [5] (2), and guides therapeutic strategies (https://www.covid19treatmentguidelines.nih.gov/). Antivirals and monoclonal antibody therapies are available for COVID-19, and their initiation is dependent upon positive results of SARS-CoV-2 testing.

Laboratory tests for SARS-CoV-2

Laboratory tests for SARS-CoV-2 infection include nucleic acid amplification, antigen detection and antibody or serologic tests [6–8]. Nucleic acid amplification tests (NAATs) and antigen tests provide diagnosis of acute infection when viral titers are highest. In addition, NAATs can reliably detect asymptomatic and pre-symptomatic infections [9,10], including in pooled specimens [10–14] due to their high sensitivity [15]. Because of their high sensitivity and specificity, NAATs are considered the gold standard for diagnostic detection of SARS-CoV-2 (https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html). Because it may take 10 or more days after symptom onset for development of detectable levels of antibodies to SARS-CoV-2 to occur [16,17], serologic tests should not be used alone to diagnose acute COVID-19 [18,19].

Point-of-care laboratory tests for SARS-CoV-2 & their regulation in USA

The current widely accepted definition of point of care (POC) testing includes testing that occurs at or near the point of patient care, such that the results drive patient care decisions made during that encounter [20,21]. POC tests are performed in a variety of settings including physician offices, emergency department, urgent care facilities, school health clinics and pharmacies. Some POC tests are approved, cleared or authorized by regulatory bodies to

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Table 1. Rapid antigen tests with US FDA EUA for use at settings operating under a CLIA certificate of waiver.						
Assay name	Manufacturer	Assay format	SARS-CoV-2 limit of detection[†]	Published studies describing performance	Published outcome studies	Ref.
BD Veritor SARS-CoV-2; BD Veritor SARS-CoV-2 & Flu A + B	Becton, Dickinson and Company	Digital chromatographic immunoassay; instrument read	2.8×10^2 TCID50/ml		None	[24,25]
BinaxNOW COVID-19	Abbott Diagnostics Scarborough, Inc.	Lateral flow; visual read	140.6 TCID50/ml		None	[26–32]
CareStart COVID-19	Access Bio, Inc.	Lateral flow; visual read	8×10^2 TCID50/ml	None	None	
Clip COVID	Luminostics, Inc.	Lateral flow immunoluminescent; instrument read	0.88×10^2 TCID50/ml	None	None	
Ellume COVID-19	Ellume Limited	Lateral flow; fluorescence; instrument read	$10^{3.80}$ TCID50/ml	None	None	
LumiraDx SARS-CoV-2	LumiraDx UK Ltd.	Microfluidic immunofluorescence; instrument read	32 TCID50/ml		None	[33,34]
QuickVue COVID-19 and QuickVue SARS	Quidel Corporation	Lateral flow; visual read	1.91×10^4 TCID50/ml	None	None	
Sofia SARS Antigen FIA	Quidel Corporation	Lateral flow; fluorescence; instrument read	1.13×10^2 TCID50/ml		None	[35–38]
Sofia 2 Flu + SARS	Quidel Corporation	Lateral flow; fluorescence; instrument read	91.7 TCID50/ml		None	[24]
Status COVID-19/Flu	Princeton BioMeditech Corp.	Lateral flow; visual read	2.7×10^3 TCID50/ml	None	None	

[†]Information from manufacturers' instructions for use available at [39].

be performed by non-laboratory professionals [22,23]. Recently, the COVID-19 pandemic has shined a spotlight on Clinical and Laboratory Improvement Amendments (CLIA)-waived diagnostic testing. Some SARS-CoV-2 tests have received Emergency Use Authorization (EUA) from the US FDA for use in CLIA-waived testing sites. Waived testing is defined by CLIA as simple tests that carry a low risk for an incorrect result. Waived tests can be performed without the need for the conduct of more stringent quality standards imposed by CLIA for non-waived testing. Both waived and non-waived tests can be performed at the POC. But the complexity of tests performed at a testing site is determined by its type of CLIA certificate; a testing site with a certificate of waiver can perform only waived tests. Under CLIA, testing sites with a certificate of waiver are generally exempt from most US regulatory oversight requirements for non-waived laboratories, including personnel qualifications, training, test method verification and proficiency testing or external quality assessment. However, some accreditation agencies in the US and local or state governments may have more strict quality requirements for POC sites that perform testing for SARS-CoV-2. For a list of SARS-CoV-2 antigen tests with EUA for settings operating under a CLIA Certificate of Waiver, see Table 1. Additional FDA authorizations for at-home use are described separately.

Commercially available SARS-CoV-2 NAATs and antigen tests are available in both high throughput batch-based format often employing large instrumentation, and single-use portable sample-to-answer format that can be performed on demand for fast results. Rapid, single-use tests are often used at the POC. The World Health Organization (WHO) developed the ASSURED criteria as a standard for rapid tests for detection of sexually transmitted infections in resource-limited settings [40]. These criteria can be applied to POC tests for all infectious diseases, including COVID-19. The ASSURED criteria describe the most desirable attributes of POC tests, and are **A**ffordable, **S**ensitive, **S**pecific, **U**ser-friendly, **R**apid and robust, **E**quipment-free and **D**eliverable to end-users [41]. Some of these criteria, such as equipment-free, are more relevant for resource-limited, remote settings with unreliable electrical power. But affordability, test accuracy and rapid time to result are attributes of POC that are important universally.

POC rapid antigen tests

Rapid antigen tests with US FDA EUA as of 4 April 2021, for use in patient care settings operating under a CLIA certificate of waiver are listed in Table 1. In general, the analytical sensitivity, or lower limit of detection of rapid antigen tests is several logs less than that of the most sensitive NAATs. This consistently translates in lower

diagnostic sensitivity, or positive agreement with NAATs [42]. In direct comparisons against RT-PCR, rapid antigen tests were most likely to produce false-negative results from specimens with late RT-PCR cycle threshold values (>30) corresponding with lower viral loads.

An evaluation of the BD Veritor SARS-CoV-2 test (Becton, Dickinson and Company, MD, USA) in a symptomatic population with median age of 43 years showed positive percent agreement (PPA) with RT-PCR ranged from 87.5% for specimens collected within 1 day after symptom onset, to 76.3% for specimens collected 7 days after symptom onset [24]. Most specimens with false-negative Veritor results had RT-PCR cycle threshold (Ct) values of 25 or greater. The same study also directly compared the Veritor assay with the Sofia 2 Flu + SARS assay (Quidel Corporation, CA, USA), and showed high (>97%) PPA and negative percent agreement (NPA). Another evaluation of the Veritor SARS-CoV-2 test, also performed in a symptomatic population with a similar median age, showed Veritor sensitivity of 66.4% compared with an EUA RT-PCR test (Simplexa COVID-19; Diasorin Molecular LLC, CA, USA) [25]. Again, specimens with discordant negative Veritor results had higher Ct values by RT-PCR.

Several studies have evaluated the performance of the BinaxNOW test (Abbott Diagnostics Scarborough, Inc., ME, USA) [26–32]. Prince-Guerra reported high specificity of BinaxNOW in a population with median age of 41 years, but sensitivities of 35.8 and 64.2% from asymptomatic and symptomatic patients, respectively [26]. When viral culture was positive, BinaxNOW sensitivity increased to 78.6 and 92.6% among asymptomatic and symptomatic subjects, respectively. James *et al.* reported slighter higher sensitivity of BinaxNOW than reported by Prince-Guerra, (51.6 and 83.3% in asymptomatic and symptomatic persons, respectively) [30] but their study was conducted in an entirely adult population. Another study reported BinaxNOW sensitivity of specificities of 93.3 and 99.9%, respectively, in subjects with high viral loads (RT-PCR Ct values <30) [27]. Pollock *et al.* evaluated the performance of BinaxNOW in a community drive-through testing site. BinaxNOW specificity was high in both adults and children. Sensitivities were 96.5 and 84.6%, compared with RT-PCR, in adults and children, respectively, within 7 days of symptom onset. In asymptomatic adults and children, sensitivities were 70.2 and 65.4%, respectively [31]. As reported elsewhere, sensitivity was highest (95.8%) when RT-PCR Ct values were ≤30. Okoye *et al.* evaluated BinaxNOW in an asymptomatic university setting (mean age 24 years) and found 53.3% sensitivity compared with RT-PCR.

As described above, the Sofia 2 assay was shown to have high agreement with BD Veritor assay for SARS-CoV-2 antigen detection. Another study reported Sofia PPA with Aptima SARS-CoV-2 TMA test (Hologic, Inc., CA, USA) of 82% in patients presenting within 5 days of symptom onset, and 54.5% when specimens were collected greater than 5 days after symptom onset [32]. Unlike other studies which showed lower sensitivity/positive agreement for antigen tests performed in children, the positive agreement of Sofia did not vary substantially between children and adults. Evaluation of Sofia at a university setting (primarily students) showed sensitivities of 80 and 41.2%, compared with RT-PCR, in symptomatic and asymptomatic persons, respectively [35]. Kohmer *et al.* compared the LumiraDx SARS-CoV-2 test (LumiraDx UK Ltd, Alloa, UK) to quantitative RT-PCR [33]. Among residents of a shared living facility, screened without regard for clinical symptoms, LumiraDx sensitivity and specificity were 50 and 100%, respectively. Of RT-PCR positive specimens containing ≥6 log10 RNA copies/ml, LumiraDx sensitivity was 100%. Drain *et al.* compared LumiraDx to the cobas 6800 RT-PCR test (Roche Molecular Systems, NJ, USA) in a multi-site study [34]. Most subjects (81%) were symptomatic and the mean age was 34 years. Overall, the LumiraDx assay had a reported sensitivity of 97.6% and specificity of 96.6% up to 12 days post symptom onset for nasal swab samples.

A recent meta-analysis reported the sensitivities of rapid POC antigen tests [43]. Time post symptom onset and viral loads [as estimated by PCR cycle threshold (Ct) values] impacted the sensitivity of antigen tests. Average sensitivity of antigen tests was higher when specimens were collected during the first week compared with second week post symptom onset (78.3 vs 51.0%, respectively). Average sensitivity in specimens with PCR Ct values ≤25 was 94.5%, compared with 40.7% in specimens with Ct values >25. Unfortunately, we were unable to find any published peer-review studies evaluating the outcomes provided by rapid antigen tests performed at the POC.

POC NAATs

NAATs, particularly RT-PCR, are considered the gold-standard for laboratory diagnosis of SARS-CoV-2 infection because of their high sensitivity and specificity. However, some rapid NAATs are less sensitive than RT-PCR-based POC tests. Table 2 provides a list of SARS-CoV-2 NAATs with EUA for use in CLIA-waived testing sites, as of 3 April 2021. Additional authorizations for at-home use are described separately.

Table 2. Nucleic acid amplification tests with US FDA EUA for use at settings operating under a CLIA certificate of waiver.

Assay name	Manufacturer	Assay format	SARS-CoV-2 limit of detection[†]	Published studies describing performance	Published outcome studies	Ref.
Accula™ SARS-CoV-2	Mesa Biotech, Inc.	RT-PCR; lateral flow; visual read	150 copies/ml		None	[44]
BioFire® Respiratory Panel 2.1-EZ	Biofire Diagnostics, LLC	Reverse transcription; nested multiplex PCR; instrument read	500 copies/ml	No evaluations of 2.1-EZ. Studies of *de novo* 510(k)-cleared Respiratory Panel 2.1 for non-waived testing laboratories	None	[45,46]
cobas® SARS-CoV-2 & Influenza A/B; cobas Liat System	Roche Molecular Systems, Inc.	RT-PCR; instrument read	0.012 TCID50/ml		None	[47]
Cue™ COVID-19	Cue Health, Inc.	Reverse transcription; isothermal amplification; mobile smart device read	20 genome copies/sample wand		None	[48]
ID NOW COVID-19	Abbott Diagnostics Scarborough, Inc.	Reverse transcription; isothermal amplification; instrument read	125 genome equivalents/ml			[30,43,49–63]
Lucira™ COVID-19	Lucira Health, Inc.	Reverse transcription; isothermal amplification; disposable device read	2700 copies per swab	None	None	
Xpert® Xpress SARS-CoV-2	Cepheid	RT-PCR; instrument read	0.0200 PFU/ml			[43,53,56,59,60, 62,64–8283,84]
Xpert Xpress SARS-CoV-2/Flu/RSV	Cepheid	RT-PCR; instrument read	131 copies/ml		None	[85,86]
Visby Medical™ COVID-19	Visby Medical, Inc.	RT-PCR; visual read	435 copies/swab	None	None	

[†]Information from manufacturers' instructions for use, available at [87].

Hogan *et al.* compared the Accula™ SARS-CoV-2 test (Mesa Biotech, Inc., CA, USA) to a laboratory developed RT-PCR test [44]. The Accula test had poor PPA of 68%, missing specimens containing low viral loads. We were unable to find published studies of the performance of the BioFire® Respiratory Panel 2.1-EZ panel (BioFire Diagnostics, LLC, UT, USA). However, the non-waived version of the panel has been evaluated and demonstrated good agreement with laboratory-developed and EUA RT-PCR tests [45,46]. Analytically, the BioFire SARS-CoV-2 assay was less sensitive than the Xpert® Xpress SARS-CoV-2 (Cepheid, CA, USA) and cobas tests, but more sensitive than ID NOW [46]. A multi-site study comparing the cobas Liat SARS-CoV-2 & influenza A/B nucleic acid test to the cobas 68/8800 SARS-CoV-2 test showed PPA and NPA for SARS-CoV-2 of 100 and 97.4%, respectively [47]. Donato *et al.* compared the Cue™ COVID-19 test (Cue Health Inc., CA, USA) to the Aptima SARS-CoV-2 on a Hologic Panther instrument. In a community drive through collection setting including both symptomatic and asymptomatic outpatients the overall PPA and NPA were 91.7 and 98.4%, respectively [48].

The ID NOW COVID-19 test (Abbott Diagnostics Scarborough, Inc.) has been extensively evaluated [30,43,49–62]. Analytically, ID NOW is substantially less sensitive than RT-PCR-based methods [62]. This lower analytical sensitivity translates into lower PPA compared with RT-PCR, which ranged from 48 to 94% in the cited studies. As expected, specimens positive by RT-PCR that were negative by ID NOW had higher Ct values (lower viral loads). In one study, ID NOW PPA was 34.3% among specimens with RT-PCR Ct values >30 [60]. Processing nasal swabs directly by the ID NOW assay, versus pre-elution in 3 ml of viral transport medium (VTM), has been recommended to improve sensitivity. However, two studies showed that direct processing of swabs actually decreased ID NOW PPA compared with swabs in VTM [53,88]. Studies showed high NPA of ID NOW, near or at 100%.

The Xpert Xpress SARS-CoV-2 test (Cepheid) has also been extensively evaluated [43,53,56,59,60,62,64–82]. Most studies have reported high sensitivity or PPA- >98%- compared with other RT-PCR-based tests. Lowe *et al.* reported 100% PPA between Xpress SARS-CoV-2 test and cobas among specimens with cobas Ct values between 30 and 33.9, but Xpress test failed to detect three of nine specimens with cobas Ct values ≥34 [67]. Most studies also report high NPA with other RT-PCR-based tests. When positive Xpress SARS-CoV-2 results were discordant

with the comparator method, testing with a third highly sensitive method usually agreed with Xpress test [65,79]. Falasca *et al.* described specimens with late Xpress SARS-CoV-2 Ct values for the N2 target [73]. Authors attempted to concentrate specimens by centrifugation to increase the positive signal. This failed in some instances, but the relative centrifugal force used may have been insufficient to pellet free virus. Khoshchehreh *et al.* reported that Xpress SARS-CoV-2 results with late Ct values occurred in symptomatic patients with new COVID-19 diagnosis, and in asymptomatic patients with clinical findings consistent with sub-clinical disease [74]. In one study, the Xpert Xpress test was compared in parallel to two SARS-CoV-2 assays (BioGerm and Sansure) cleared by the Chinese National Medical Products Administration in China. The sensitivity of Xpress SARS-CoV-2 test was 100% compared with 96.15% for the BioGerm and 90% for the Sansure kits. The specificity was 100% for all three assays. The limit of detection is 100 copies/ml for Xpert Xpress and 500 copies/ml for the BioGerm kit and Sansure kit [66].

Recognizing that SARS-CoV-2 transmission may occur during seasonal influenza and concurrent with transmission of other respiratory viruses such as respiratory syncytial virus (RSV), several manufacturers have created multiplexed assays for simultaneous detection of SARS-CoV-2 and additional respiratory viruses. These include the BD Veritor SARS-CoV-2 & Flu A + B (Becton, Dickinson and Company), Sofia 2 Flu + SARS (Quidel Corporation), Status COVID-19/Flu (Princeton BioMeditech Corp.), BioFire® Respiratory Panel 2.1-EZ (Biofire Diagnostics, LLC), cobas® SARS-CoV-2 & Influenza A/B (Roche Molecular Systems, Inc.), and Xpert® Xpress SARS-CoV-2/Flu/RSV (Cepheid) (Tables 1 & 2). The performance of the Xpert Xpress SARS-CoV-2/Flu/RSV test has been described in two studies [85,86]. PPA and NPA were high when compared with other RT-PCR based tests.

Impact of SARS-CoV-2 NAATs performed at the POC

We identified three peer-reviewed studies that evaluated the impact of rapid NAAT performed at the POC, including one which involved the Xpert Xpress SARS-CoV-2 test. Hinson *et al.* performed the Xpress SARS-CoV-2 test on demand in the Emergency Department and compared impact with batch RT-PCR testing in a central laboratory [89]. Rapid testing at the POC was associated with a significant reduction in the time to removal from isolation for patients with negative test results, an increase in COVID-19 treatment capacity, and conservation of personal protective equipment. Another study compared the impact of a non-EUA NAAT performed at POC, to a batch-based RT-PCR performed in a central laboratory [89]. The time to result for the POC NAAT was significantly shorter than the standard lab RT-PCR, and POC testing resulted in faster time to final bed placement from the Emergency Room, increased isolation room availability, and faster patient discharge. Brendish *et al.* reported that time to arrival in a definitive clinical area was significantly shortened by rapid POC molecular testing [90].
Hengel *et al.* described a model for the implementation of decentralized COVID-19 POC testing in remote locations by use of the Cepheid GeneXpert® platform, which has been successfully scaled up in remote Aboriginal and Torres Strait Islander communities across Australia. The analysis indicated that implementation of the decentralized POC testing model should be considered for communities in need, especially those that are undertested and socially vulnerable [91].

At-home testing for SARS-CoV-2

SARS-CoV-2 tests with FDA authorization for use at home are primarily based on rapid isothermal amplification of nucleic acids or antigen detection. The advantages and limitations of these methods have been described [92]. At-home testing (specimen collection, test and result interpretation) is performed by an individual on their own without supervision of a trained health professional. For the purpose of this review, we considered at-home tests separately from POC tests, because they are not performed at the same location where care is provided. At-home test results do not guarantee initiation of treatment or other interventions. Nonetheless, at-home tests have the potential to broaden access to testing and increase testing rates [93,94]. To date the US FDA has granted EUA to five SARS-CoV-2 tests for at-home use. Four of these at-home tests have received EUA for over-the-counter (OCT) use without a prescription, and one has received EUA for prescription home testing. Rapid antigen tests with at-home OTC use authorization include the QuickVue® At-Home OTC COVID-19 test (Quidel), BinaxNOW™ COVID-19 Antigen test (Abbott), and Ellume COVID-19 Home Test (Ellume Limited, East Brisbane, Australia). A single NAAT has received EUA for OTC at-home use: Cue™ COVID-19 Test (Cue Health). Finally, one NAAT has EUA for prescription home testing: Lucira™ COVID-19 All-In-One Test (Lucira Health, Inc., CA, USA).

Challenges

While there are now many commercial options for SARS-CoV-2 POC testing, challenges remain. These challenges include maintaining a reliable supply chain, and a lack of healthcare infrastructure to manage a pandemic the scope of COVID-19, particularly in low and middle-income countries [95]. The accuracy of SARS-CoV-2 POC tests varies widely as described in this review and many published studies. Providing access to highly accurate primary testing is ideal, and assuring prompt confirmatory testing is critical when less accurate POC tests are used. It is important that providers understand the characteristics of the SARS-CoV-2 tests that they perform.

Rapid antigen SARS-CoV-2 tests are substantially less sensitive than most NAATs. POC rapid antigen tests have higher sensitivity when viral loads are high, allowing these tests to identify infected persons at highest risk of transmission. However, it is important to identify all infected persons, even those with low-to-moderate viral loads, as these infections represent opportunity for the virus to mutate. Additionally, identification and tracking all infections is necessary to have a full understanding of the COVID-19 pandemic epidemiology, and effectiveness of interventions. Cases with low to moderate viral loads could represent early infection, or pre-syndromic cases. Identifying and isolating these persons before they have high viral loads and are most contagious is important to control the spread of SARS-CoV-2.

Additionally, the global COVID-19 public health emergency will eventually end and EUAs expire, but the need for SARS-CoV-2 testing will remain. It is crucial that manufacturers of SARS-CoV-2 tests have a long-term strategy for product registration beyond EUA. Finally, studies evaluating the impact of NAATs versus rapid antigen tests performed at the POC are urgently needed. The higher sensitivity of SARS-CoV-2 NAATs may provide greater impact than rapid antigen tests, as has been shown for influenza virus testing performed at the POC [96]. While more impact studies including cost-benefit analysis are needed for SARS-CoV-2 POC tests, the decentralized POC testing model should be part of the core global response toward suppressing COVID-19.

Conclusion

There are a number of new point-of-care tests for SARS-CoV-2. The performance of these tests varies greatly. Rapid antigen SARS-CoV-2 tests and some rapid NAATs are substantially less sensitive than most RT-PCR based NAATs. While all POC SARS-CoV-2 tests are able to identify most highly infectious cases when viral loads are high, sensitive tests that allow detection of early pre-symptomatic infection prior to peak contagiousness are also important to prevent disease transmission. Detection of asymptomatic infections, often with low viral loads, is crucial for bringing the COVID-19 pandemic to an end as these infections represent opportunity for the virus to mutate. Studies evaluating the impact of NAATs versus rapid antigen tests performed at the POC are urgently needed. While more impact studies including cost-benefit analysis are needed for SARS-CoV-2 POC tests, the decentralized POC testing model should be part of the core global response towards combating COVID-19.

Future perspective

The scope of the COVID-19 pandemic and the impact on testing access has driven heightened interest in new and portable diagnostic technologies. A challenge is the often-conflicting test characteristics of speed (time to result) and sensitivity; as we attempt to make tests faster we often must compromise on sensitivity. Portability, an essential characteristic of POC tests, is also a challenge. Nanotechnology, including novel sensors to detect low concentrations of SARS-CoV-2 proteins, supported by artificial intelligence and integration within the internet for wireless operation and connectivity has the potential to revolutionize POC diagnostics [97–99]. Another technology which could contribute to near patient testing is digital PCR (dPCR). While its attributes are mainly related to target quantification, dPCR increases the signal-to-noise ratio, making it highly sensitive and amenable to a rapid time to result [100,101].

Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

Executive summary

- Laboratory tests for SARS-CoV-2 include those performed at or near the point-of-care (POC). In USA, most SARS-CoV-2 tests have received emergency use authorization (EUA) from US FDA. SARS-CoV-2 POC tests designed to detect acute infection include those that detect SARS-CoV-2 antigen or nucleic acid.
- At the time of writing, only three studies evaluated the impact of POC NAATs, and these studies demonstrated positive impact including more rapid isolation of hospitalized patients and appropriate use of PPE. There have been no published studies evaluating the impact of POC antigen tests.
- At-home SARS-CoV-2 tests are now available. These have the potential of increasing access to testing.
- POC SARS-CoV-2 tests are now widely used, and while their rapid time to result has positive impact, challenges remain. These challenges include testing access in many parts of the world, adequate public health infrastructure and accurate performance of many POC tests. New technologies have the potential of increasing the sensitivity of POC tests that detect SARS-CoV-2 antigens.

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