Delphi Panel on the Recommended Use of the Cue® COVID-19 At-Home Diagnostic Test

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Background

Immunocompromised (IC) patients represent 3% of Americans; an estimated nine million individuals[1]

While the risk of severe COVID-19 in the general population has subsided, IC patients:

- Continue to be impacted with severe disease and worse outcomes[2]
- May not have the ability to produce an appropriate immune response to combat the COVID-19 virus[3]
- Are at a substantially elevated risk for severe COVID-19 outcomes[4]
- Three times more likely to be admitted to the ICU and are at significantly higher risk of death as a result of COVID-19[5]

Vaccination is not as effective in IC individuals[6]. Patients who are most at risk for lower vaccine effectiveness include solid organ transplant recipients, blood cancer patients, stem cell transplant recipients, solid tumor patients, patients on immunosuppressive drugs, advanced or untreated HIV patients, and patients with primary immunodeficiencies[7]

Treatment of severe COVID-19 is also very costly, with hospitalization due to COVID-19 averaging between $74,000 and $317,000 per patient in the United States (US)[8]

Although antiviral treatments are available, effective treatment requires that the infection is accurately detected early in the disease course[9]

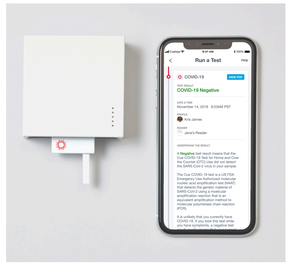
Current COVID-19 testing methods can leave a critical gap in patient care **(Table 1)**

Table 1. Limitations of current COVID-19 testing methods

Test	Limitation
Rapid antigen tests (RATs)	• Have only moderate sensitivity for COVID-19 (overall sensitivity of 50%)[10] • Due to lower sensitivity of antigen tests early in the disease course[10], RATs have limited utility during the optimal window for initiating antiviral treatment • False negative COVID-19 results and the need to retest (as recommended by the FDA) are of particular concern for IC patients as early detection of COVID-19 is essential to enabling effective antiviral treatment
Reverse transcriptase polymerase chain reaction (RT-PCR) tests	• While highly accurate, most are administered at the point-of-care or a testing facility, requiring IC patients to leave their homes, risking additional exposure to the environment to IC patients[11] • RT-PCR tests can take up to three days to receive results, and communication breakdowns among various parties involved in testing can result in diagnosis errors and treatment delays[11,12]

Abbreviations: IC = immunocompromised; RAT = rapid antigen tests; RT-PCR = reverse transcriptase polymerase chain reaction.

The Cue COVID-19 Test



To address these gaps and limitations in COVID-19 testing for IC patients, there is a need for an accurate at-home test

The Cue COVID-19 test is an at-home molecular test that provides patients the ability **to quickly get polymerase chain reaction (PCR)-quality accurate results at home within 20 minutes**

The Cue COVID-19 test has been demonstrated to have an **accuracy rate of 98.9%** and confirmed sensitivity between 95.7% and 100%13,14

The accuracy is significantly better vis a vis to RATs

Re-testing after a negative result (as is needed with RATs) is not required because of Cue's high sensitivity

The high sensitivity rate of an at-home test could help close the gap in testing options for IC patients, and help **ensure that SARS-CoV-2 can be detected early enough in the disease course to initiate effective antiviral treatment.**

Objective

A modified Delphi panel was conducted to understand the critical impact of COVID-19 on IC patients, the burden of current testing options, and the opportunities to improve patient outcomes with new accurate at-home COVID-19 tests

Methods

Clinicians specializing in oncology, hematology, and immunology with extensive experience treating IC patients in the US were surveyed

Clinicians were provided a detailed description of Cue's COVID-19 test, a summary of which is as follows (paraphrased):
The Cue COVID-19 test detects the RNA of SARS-CoV-2 using a nasal swab sample taken from the lower part of the nose. The Cue COVID-19 Cartridge is inserted into the reusable Cue Reader and the nasal swab is inserted into the cartridge. After 20 minutes, the results, either positive or negative, are displayed via the Cue Health App

Two sets of surveys were administered anonymously in the Fall of 2022, eliciting the opinions of expert panelists on:

- The value of the Cue COVID-19 test
- Which IC patient population should regularly test for COVID-19 at home
- Recommendations on when and how these patients are tested

Consensus rules were defined a priori; consensus was defined as agreement by ≥75% of the panelists

Results

Consensus Findings:

All clinicians surveyed agreed they would prescribe or recommend Cue's COVID-19 test to IC patients

Most clinicians (88%) agreed that Cue's COVID-19 test provides value to IC patients **(Figure 1)**

There was clinician consensus that all IC patients (including solid organ or stem cell transplant patients, hematological cancer or solid tumor patients, advanced HIV patients, and patients with primary immunodeficiencies or on immunosuppressive drugs) would benefit from an accurate at-home NAAT **(Figure 2)**

There was clinician consensus that IC patients would benefit if they were symptomatic, exposed to COVID-19, undergoing chemotherapy, or have HIV with CD4 count <200 cells/mm3

Most clinicians (>50%) also thought that patients 30 days before or 120 days after a solid organ or stem cell transplant, patients who had received cancer treatment within the last three months, and IC patients who are to receive a surgical procedure, would benefit from the Cue COVID-19 test, however consensus was not reached

Cue's COVID-19 test compared with RATs and RT-PCR

When asked to compare Cue's COVID-19 test with RATs and RT-PCR **(Figure 3)**:
All clinicians agreed that the Cue COVID-19 test provides better clinical value compared to RATs, and clinician consensus (75% agreement) was reached that it provides better value compared to RT-PCR

In open forum comments provided by panelists, most clinicians (75%) noted that the high sensitivity of Cue's COVID-19 test would results in fewer false negative results, giving Cue better value compared to RATs

Most clinicians noted that the timely results and the ability for patients to do the test at home gave Cue better clinical value compared to RT-PCR

Access to Cue COVID-19 tests:

Clinician responses varied when asked how many Cue COVID-19 tests IC patients should be allowed to access through insurance, with responses ranging from at least one to two per month to six per month, with panelist recommendation averaging 2.5 tests per month

All clinicians agreed that patients should be able to access Cue COVID-19 tests through insurance

Figure 1. Physician agreement on the value of the Cue COVID-19 test to IC patients

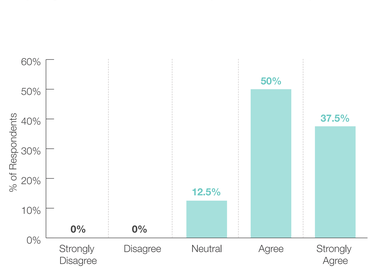


Figure 2. Patient populations that would benefit from an accurate at-home molecular test

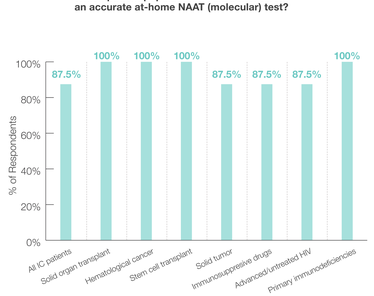
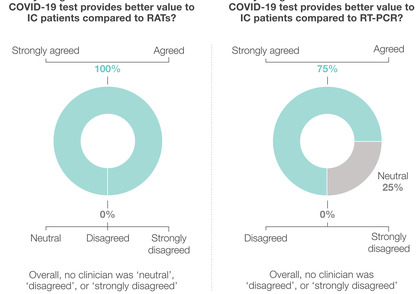


Figure 3. Value of the Cue COVID-19 test compared to RATs and RT-PCR



Conclusions

This Delphi panel highlights that there is consensus among clinicians with extensive experience treating IC patients that there are gaps in current COVID-19 testing methods and that accurate at-home testing could greatly benefit IC patients

Allowing IC patients access to more accurate at-home molecular diagnostic tests, such as Cue's COVID-19 test, would be beneficial to patients as it provides an at-home testing option with high sensitivity to detect COVID-19 early in the disease course

This understanding of the current gaps in patient care and opportunities to improve COVID-19 testing in IC patients with NAATs, such as Cue's COVID-19 test, will help to optimize patient outcomes and potentially reduce the impact of severe COVID-19 for IC patients as well as the economic burden on the healthcare system

Accurate COVID-19 testing will allow early treatment that can significantly reduce the risk of COVID-19-related hospitalization and death in the vulnerable IC patient population

Abbreviations
CD4 = cluster of differentiation 4; HIV = human immunodeficiency virus; IC = immunocompromised; NAAT = nucleic acid amplification tests; RAT = rapid antigen test; PCR = polymerase chain reaction; RNA = ribonucleic acid; RT-PCR = reverse transcriptase polymerase chain reaction; SARS-CoVo2 = severe acute respiratory syndrome coronavirus 2; US = United States.

Cue's COVID-19 test has not been FDA cleared or approved, but it has been authorized by FDA under an Emergency Use Authorization (EUA). This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

References
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