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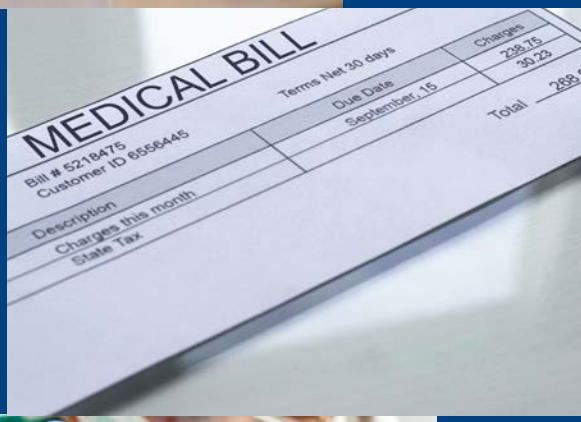
Testing for Respiratory Infections: Beyond the COVID-19 Public Health Emergency



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EXECUTIVE SUMMARY

Recent progress in diagnostic testing for respiratory infections has created a powerful and effective tool to prevent the spread of the COVID-19 virus and protect the most vulnerable, by enabling everyone to take common-sense measures to avoid infecting others and helping those who need treatment to access it in a timely manner. Requirements for broad insurance coverage, along with continued federal and state purchases and distribution of tests, have supported access to testing throughout much of the Public Health Emergency (PHE), but are tied to the emergency declaration.

The end of the PHE on May 11, 2023 will impact Americans' free access to tests and diminish the national and state ability to access early testing and prevent infectious disease spread. COVID-19 testing with no cost-sharing for any American will no longer be guaranteed. The cost of COVID-19 tests, even if low, will decrease demand for available testing, even for people at high risk, and will result in continued reduced manufacturing, positioning the United States once again to face any new surges without enough tests.

Innovative approaches to diagnostic testing for respiratory infections have provided new ways for Americans to protect themselves and their communities from potential COVID-19 surges and severe health complications from other serious respiratory infections. In early 2023, COVID-19 continued to account for nearly 4,000 Americans being hospitalized with COVID-19 every day, and more than 3,700 dying every week. Moreover, COVID-19 only accounted for just over half of the hospitalizations for common identifiable viral respiratory infections in fall and early winter 2022. Flu and respiratory syncytial virus (RSV), which can be detected using similar diagnostic tests, accounted for the rest. This report sets out policy steps to support practical information, availability, and affordability for innovative and convenient testing capabilities to empower Americans to protect themselves from a broad array of respiratory infections and other health risks, especially people with high risks of complications or from vulnerable communities, without substantial restrictions, extraordinary measures, or very large new government appropriations.

Innovations in Tests, But Most People Aren't Testing

Innovations in testing and increased availability of tests have been core elements of the national and global response to COVID-19. These innovations include more accurate molecular tests[1], which are typically performed at a pharmacy, doctor's office, or laboratory, with versions that have become somewhat less costly, easier, and faster to perform. They also include over-the-counter (OTC) rapid antigen tests[2] that can miss some early infections but are inexpensive to manufacture and can provide rapid results anywhere. Coupled with use of effective treatments, testing by individuals at high risk of severe disease when symptomatic or exposed can substantially reduce hospitalizations and deaths, while reducing burdens on hospital systems.

The innovations in testing, however, have not yet realized their full potential to limit the burden of COVID-19. At the start of the pandemic and during subsequent major surges, testing was not easily or rapidly available. Emergency policies intended to make tests widely available, including federal purchases and broad insurance coverage requirements, were too late to meet the demand from the Omicron surge. By spring 2022, when

[1] For the purposes of this issue brief, we refer to molecular tests as point-of-care (POC) or lab-based tests.
[2] For the purposes of this issue brief, we refer to rapid antigen tests as over-the-counter (OTC) tests.

free or reimbursable tests were broadly available, most Americans did not follow and may not have been aware of the evolving public health guidance to protect and monitor their health through COVID-19 testing. Most do not have and do not use tests when they have respiratory symptoms, even if they are at higher risk, or they rely on a single negative result from a home test, which can miss some infections if not repeated.

After the 2020-2021 surges, demand for tests declined and manufacturers reduced production capacity. After the PHE ends, demand and capacity is likely to fall further. PHE coverage and purchasing policies were temporary, and no clear policies and strategies have been proposed to replace them and leverage the major innovations in testing achieved over the past three years to help keep Americans safe. As a result, Americans will continue to face uncertainties about how affordable and accessible tests will be, and whether and how they should test. This uncertainty likely will lead to further reductions in testing supplies, higher costs, and less access. Compounding these challenges, other respiratory infections, including influenza and RSV, are adding to the burdens on health care systems and businesses.

The Future Role of Testing for COVID-19 and Other Respiratory Infections

Americans are tired of restrictions and disruptions from COVID-19, have returned to pre-pandemic activities, and want to avoid future disruptions. More routine use of innovative tests for COVID-19 and other potentially serious infectious diseases, especially by people at higher risk or close to someone who is, can enable this resilience. For this to happen, Americans need new habits for testing that are easy to follow and not disrupted by unreliable access and uncertain costs. They should test when respiratory symptoms appear, especially if they are at higher risk or close to someone who is. Best practice for COVID-19 testing after the PHE means having easy access to OTC tests or point-of-care (POC) and lab tests, for consumers having trouble testing on their own. To make this possible, OTC tests should be reliably available and less costly to purchase, no more than $3-$5 per test retail, down from approximately $6-$12 per test today, and freely available to low-income individuals and those at high risk. POC and lab tests should continue to be covered through insurance designs that encourage further innovation to reduce costs and time. Lower-cost and more reliable capacity for performing the innovative tests developed in the past three years will protect US citizens from a range of respiratory illnesses, and can provide timely and effective responses to future emerging infectious disease threats.

The Way Forward

With limited use of testing under current PHE policies, and with the end of the PHE just months away, it is time to ask: what are our testing goals beyond the PHE? What post-PHE policies for testing will lead to efficient and effective test use to contain the impact of infections, future variants, and potential surges? What feasible policies related to test manufacturing, regulation, coverage, and payment can best encourage these strategies and engage the public in a way that limits disease burdens and disruptions to their lives?

Table 1 summarizes the key policy recommendations in this issue brief to achieve a longer-term U.S. vision for testing to contain COVID-19 and other infectious disease threats. These recommendations include:

- ***Engaging the public*** in using tests effectively, through clear and straightforward guidance supported by education and outreach
- ***Ensuring access to and reducing costs for lab-based and POC testing*** by providing more efficient ways to cover such tests and by allowing and encouraging insurers to rely on high-performing networks of accessible labs
- ***Ensuring access to and reducing costs for OTC testing,*** through encouraging bulk purchasing arrangements and low- or no-cost access to tests for individuals at high risk of complications who would benefit from treatment
- ***Providing incentives for health plans and health care organizations to increase use of testing and treatment*** in high-risk individuals, reflecting evidence of substantially improved health outcomes

These further reforms must reflect the practical realities of public engagement in testing and the limited public funding available to support testing strategies. Broad insurance coverage of testing, particularly OTC testing, is unlikely to be sustainable or cost-effective after the PHE ends. At the same time, OTC tests provide a timelier and more accessible alternative to lab-based and POC tests, with the potential for lowering overall health care costs compared to strategies that rely on continued coverage of only the costlier and less accessible tests. After the PHE, POC and lab-based tests will likely continue to be covered, at least in part, by insurers. Medicare, Medicaid, and other public insurance programs traditionally have low or no out-of-pocket costs to individuals for laboratory services, but individuals with public or private insurance may be responsible for additional co-pays or other charges for the clinical services associated with professionally administered testing. Commercial coverage likely also will include significant patient cost-sharing. These impacts of the end of the PHE are on track to further reduce demand for testing, as well as exacerbate exist-

ing health disparities and inequities. Our recommended policy actions will preserve testing access for those at highest risk and provide lower-cost, more accessible tests for those who wish to use them.

The remainder of the brief provides an updated framework for why testing remains important—indeed, given progress in testing technology and capabilities, testing can be more impactful than ever in preventing severe illness and death from COVID-19 and other infectious disease threats—and then describes the recommendations for supporting such a strategy in more detail.

This brief was informed by a literature review, informational calls and discussions, and a private, high-level roundtable convening of federal policymakers, health system leaders, insurers, academics, and other experts held in October 2022.[3]

TABLE 1 Summary of Recommendations for Endemic COVID-19 Testing Strategies

Engaging the Public and Promoting Uptake	Ensuring Access and Reducing Costs for OTC Testing	Ensuring Access and Reducing Costs for Lab-Based and POC Testing
Clear, updated guidance should be made available to the general public, health care providers, and other trusted authorities, with the acknowledgement that recommendations will evolve with the COVID-19 threat and new evidence on testing. Updated guidance is also needed on when to use emerging multiplex testing[4]. Accurate information should be available from a range of trusted sources. Health providers, public health agencies, employers, community leaders, and businesses can help promote straightforward messages to ensure that individuals are aware of whether they are at elevated risk of hospitalization or death from COVID-19 or other infections, and the importance of testing and early treatment. The Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and provider associations like the American Medical Association (AMA) and others should work together to ensure that guidance on testing recommendations for clinicians and community and public health workers is clear and up-to-date, with the supporting research to justify those recommendations.	**Reducing Prices Through Reliable Supply** OTC tests should be the first-line testing response, and therefore, must be free or very affordable ($3-$5 per test), especially for those at higher risk or with limited means. Federal and state governments, as well as health plans and health systems supplying OTC tests to patients at elevated risk, should enter purchase agreements with select OTC test manufacturers to improve access for such individuals. The purchasing power and greater test purchase leads to lower prices per test, greater use among the high-risk, and more predictable demand for capacity investment and supply maintenance. **Insurance Coverage** OTC tests are substantially less costly and more readily available than laboratory tests. The Centers for Medicare and Medicaid Services (CMS) should establish a new demonstration program for OTC test access as the PHE ends to evaluate whether Medicare and Medicaid coverage of OTC tests using advance bulk purchases can achieve better outcomes and lower costs than only coverage of professionally administered testing. This coverage should prioritize allowing patients to access tests easily, through options like mail-order and pick-up at the pharmacy counter. Private insurers should implement strategies to assure timely and efficient testing, including mechanisms to procure and use low-cost OTC tests effectively, at least for their higher-risk members who will benefit from timely treatment. The federal government should implement OTC test purchase contracts for uninsured individuals. **Incentives for Health Plans and Health Systems** CMS should implement accountability measures and financial incentives related to testing and treatment for common, high-burden respiratory infections like COVID-19, to encourage Medicare and Medicaid health plans and health systems to assure timely access and evidence-based use of OTC tests for their higher-risk patients. States and employers should adopt similar accountability measures and incentives for their health plans and providers.	Lab-based and POC tests should be accessible and affordable, especially for those unable to test themselves, unlikely to test serially, at higher risk, or already experiencing significant symptoms. **Public Payers** Because a large proportion of Medicare and Medicaid beneficiaries are at elevated risk from COVID-19, CMS should clarify that laboratory tests (and OTC tests prescribed by a clinician) continue to have no co-pays in Medicare, Medicare Advantage, and Medicaid. This clarification should also include no co-pay for prescribing and sample collection. **Commercial Payers** The US Department of Health and Human Services (HHS) should take steps based on the COVID-19 experience to encourage efficient and adequate networks of test providers, leading to lower prices with sufficient access. Commercial insurers should have incentives to maintain access to no-cost COVID-19 testing, especially for high-risk individuals and families, with reasonable in-network restrictions. The United States Preventive Services Task Force (USPSTF) should evaluate whether COVID-19 or other respiratory infection testing has achieved an "A" or "B" rating, for high-risk individuals and for all other individuals, requiring coverage from most insurers without cost-sharing (in network) under the Affordable Care Act. States can enact legislation to require private coverage of in-network tests without cost-sharing under state-regulated non-ERISA health plans, at least for higher-risk individuals.

[3] Participants in the roundtable are listed in the appendix. Please note that the discussion and recommendations within this paper do not necessarily reflect the opinions or position of all participants.

[4] Multiplex tests are those that can differentiate between multiple conditions (for example, flu, COVID-19, and RSV) with a single test process.

Testing During the Pandemic

Lab-based polymerase chain reaction (PCR) and similar molecular tests have long been the "gold standard" for diagnosing respiratory infections like COVID-19. During the COVID-19 PHE, all insurers have been required to cover these tests, as well as other POC and OTC tests, with no cost-sharing borne by the patient. For lab-based and POC testing (generally PCR tests, but also rapid molecular tests such as LAMP), insurers are required to reimburse *any* lab's published cash price for COVID-19 tests, unless they have negotiated a lower price. Plans are also prohibited from imposing limits on the number of tests covered, although they are not required to cover testing used for screening of healthy individuals for school or employment.

OTC rapid antigen tests are not as sensitive as molecular tests, but if used serially can detect infections that might have been missed on a single test. Since early 2022, insurers have been required to reimburse for the full cost of eight OTC tests per enrollee per month, and that coverage requirement will continue until the end of the PHE. To address concerns about equitable access while limiting adverse incentives to increase prices for OTC tests under the coverage requirement, HHS introduced a "safe harbor" option for private insurers. Plans with an adequate network of options for beneficiaries to obtain OTC tests with no up-front cost could limit any "out-of-network" reimbursement to $12 per test.

No such "safe harbor" was established for lab-based and POC tests, and there have been many reports of laboratories charging very high prices for such out-of-network tests, with an expectation that insurers must pay those laboratories' published cash price in full, giving out-of-network providers little reason to negotiate with insurers.

Federal, state, and local governments also have funded free lab-based and POC testing through government-funded COVID-19 testing centers and the distribution of bulk-purchased OTC tests through community centers and the post office.

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Test supply was a challenge at the beginning of the pandemic and during each major surge. By February 2022, in the wake of the Omicron surge, manufacturers were able to ramp up production to over 900 million tests per month. But with less severe subsequent surges, more immunity, and limited policy guidance on longer-term test coverage, manufacturing capacity and the supply of tests started substantially outpacing demand. Manufacturers have been reducing production in response. In September 2022, the monthly supply of OTC and POC and lab-based tests together exceeded 400 million. Reports on POC and lab-based tests administered in the U.S. that month were in the range of 10-15 million, so even assuming home tests are being used at five times the rate of reported tests (50-75 million tests), supply appears to be much greater than current demand. Manufacturers largely kept capacity fairly flat through the fall and early winter of 2022. In the absence of further policy clarifications, however, test manufacturers are unlikely to retain such excess capacity to meet any sudden rises in demand due to disease surges.

A Long-Term Strategy: Testing with Purpose

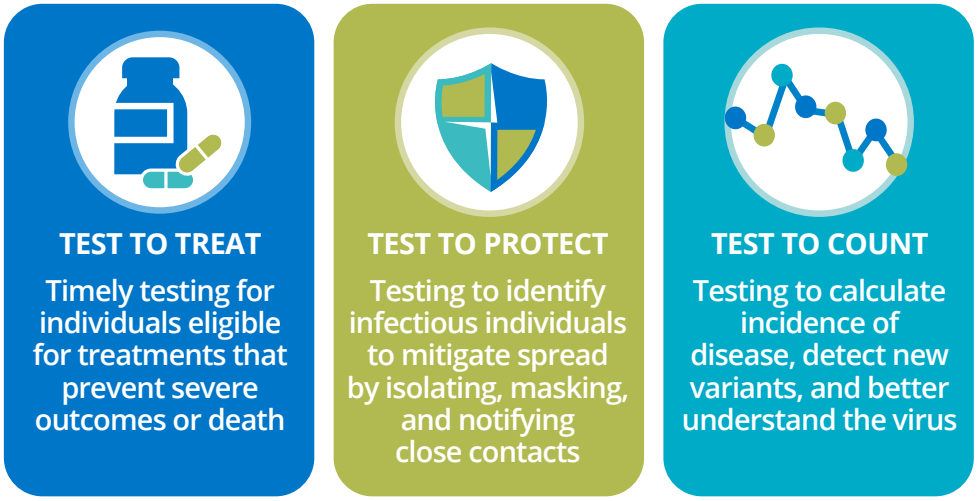
Testing serves three major aims to address ongoing infectious disease threats: 1) "test to treat"—diagnosing individuals at higher risk of severe illness in time to deliver treatments that can prevent severe outcomes and lower overall costs; 2) "test to protect"—identifying infectious persons to prevent further spread; and 3) "test to count"—giving health care providers, public officials, and the public information about the current incidence of disease, how it is evolving and spreading, and how they might respond. The first aim is in the interest of individual health. The second and third aims are more in the interest of public health, although they depend on individuals' choices and have implications for individual health.

While the COVID-19 threat has evolved rapidly, the guidance around when to test and how to interpret the results has been slower to change as new variants emerged. The U.S. Food and Drug Administration (FDA) and NIH's RADx have partnered to examine the performance of COVID-19 tests as new variants have taken over, but the current key findings and their practical implications for individual choices about testing have not been clearly communicated to health care workers or the public. The purpose of infectious disease testing should be to protect Americans' health and wellbeing, with a specific focus on those at highest risk of severe illness who could benefit from timely treatment. Beyond the PHE, we propose a strategy prioritizing "test to treat" and then "test to protect," to connect those at highest risk with treatment and to enable others around them to stop the spread. The approach can be broadened to address other major respiratory infectious disease threats.

The purpose of infectious disease testing should be to protect Americans' health and wellbeing, with a specific focus on those at highest risk of severe illness who could benefit from timely treatment.

This starts with clear, straightforward communication. CDC, NIH, and relevant clinical societies should work together to assure that there is clear, straightforward, and up-to-date guidance on testing recommendations and the supporting evidence for clinicians and community and public health workers. This guidance should include concise, practical information that can be used by health systems, employers, and state and local public health agencies for informing the public and answering questions about when to test and how to act on the results. This guidance depends on an individual's risk of severe disease. The following sections provide some principles and insights about what that updated guidance might include.

FIGURE 1 The Different Purposes for Testing, Based on How the Tests Results are Used



TEST TO TREAT

Going forward, the highest priority group for testing should be individuals at elevated risk of severe illness or death who have symptoms consistent with COVID-19 – and in the future, those at high risk for complications of other common respiratory illnesses with treatments available, like the flu. We call this the "test to treat" group. This group makes up a substantial part of the US population. It currently includes individuals ages 50 and older (with those at higher ages at increasingly elevated risk), immunocompromised individuals, and individuals with other underlying medical conditions (such as obesity, diabetes, or lung disease) associated with higher risk of severe COVID-19. About 117 million Americans are 50 years old or older, about 25 million have asthma, about 34 million have diabetes—and the list goes on. This already elevated risk is further increased if these individuals are not up to date on their COVID-19 vaccinations and boosters, and at least two-thirds of Americans are not.

For older individuals and those with underlying conditions placing them at higher risk, easy access to testing should be combined with the ability to rapidly access treatment. This access should be supported by the ready availability of OTC testing upon symptom onset or after exposure. Equally important is informing patients when tests should be used and how to interpret the result. For example, that a single negative OTC test may not be sufficient for COVID-19: if a symptomatic person tests negative on the first OTC test, they need to wait 48 hours and test again with another OTC test before fully ruling out infection (and stay masked around others in the meantime).

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While OTC testing should be a readily accessible and inexpensive first line of defense for those at higher risk of complications after symptoms and exposure, some may not be able to use those tests effectively due to visual, physical, and other challenges in performing the most common tests. Some people may also be unable or unwilling to wait the recommended 48 hours to test again if their initial OTC test is negative. In addition, some public health experts and clinicians recommend laboratory testing, especially for those at very high risk or who may expose many others. For all these patients, being able to quickly access professionally administered PCR tests or rapid molecular tests will be critical to ensuring timely treatment, and should remain freely accessible through pharmacy clinics and community health sites. (See the *Ensuring Access and Payment After the PHE* section of this brief below for potential models to achieve this.)

The enhanced diagnostic testing capacity that has been developed and expanded during the COVID-19 pandemic is expanding to other types of respiratory infections, including flu and RSV. The FDA has granted several POC and lab-based multiplex tests (which also include flu and potentially RSV) Emergency Use Authorization or FDA's traditional marketing authorization, and authorized the first OTC multiplex test in February 2023, with more OTC authorizations likely. As these tests become more available and less costly, multiplex tests may be appropriate in some patients. Such tests would be most beneficial in regions where multiple infections are prevalent, for individuals at risk of severe illness from various respiratory conditions, and in cases in which test results will meaningfully inform treatment decisions. Further evidence and guidance development should address these "test to treat" opportunities as well. As multiplex and other OTC respiratory tests demonstrate their effectiveness, policies to support rapid and timely testing for these other major respiratory infections would be synergistic in protecting high-risk individuals.

TEST TO PROTECT

As discussed above, a substantial proportion of Americans have some degree of increased risk for severe COVID-19, so it is likely that most people have some regular contact with someone at higher risk. Therefore, the next two priority groups for updated guidance and support include (1) diagnostic testing for individuals with new COVID-19 symptoms, regardless of risk of severe disease, and (2) asymptomatic screening for those that work with individuals at the very highest risk from COVID-19 (for example, nursing home staff or cancer center clinicians) due to the potential high consequences of transmitting the disease. For both of these groups, testing is less about changing an individual's own disease course through timely treatment but instead giving them the ability to take precautions to avoid infecting others at higher risk of severe disease.

Since symptomatic individuals at lower risk of severe disease are less likely to discuss symptoms and test results with a health care professional, this is a critical group to reach with clear and practical guidance from trusted sources on how to perform OTC testing, how to interpret an initial negative result, and what to do next if they test positive.

Since symptomatic individuals at lower risk of severe disease are less likely to discuss symptoms and test results with a health care professional, this is a critical group to reach with clear and practical guidance from trusted sources on how to perform OTC testing, how to interpret an initial negative result, and what to do next if they test positive. Though affordability is still an issue with OTC tests in the US, their convenience and cost has appropriately made them a first-line diagnostic for many people. Greater awareness and access to OTC tests also has the benefit of helping to avoid more costly and disruptive use of doctor's offices and pharmacies during upticks in cases and ensuring that patients can test promptly, assuming OTC tests are available.

While "test to protect" is intended to support better community health—that is, containing spread and protecting at-risk individuals–there is utility in primary care providers, employers, and insurers supporting focused test accessibility for individuals who are likely to spread infections to higher-risk people with whom they interact with for long periods indoors, such as household members and close co-workers. However, steps by providers, employers, and insurers to promote more routine access will leave out underserved portions of the population, creating a need for focused supplemental public purchases and distribution of tests for more equitable access (see section *"Ensuring Equity Through Public Supports for Testing").*

Asymptomatic workplace screening can be costly and generally is not covered by insurers. In focused settings, it can be an effective way to prevent spread to the most vulnerable—especially if targeted appropriately based on the likelihood of transmission and the consequences of infection in a given setting. For example, CMS could develop clear evidence-based requirements for returning to regular screening for health care workers at nursing homes in areas with high CDC Community Levels. OTC or pooled lab-based testing are generally the low-cost options for facilities.

TEST TO COUNT

While surveillance is not the focus of this brief, understanding current incidence of COVID-19 and other major respiratory infections is critical to planning by health care organizations and public officials, and to enabling the public to make informed decisions. POC and lab-based COVID-19 test result reporting has been required by the CARES Act throughout the length of the PHE. However, the vast majority of testing is now performed with OTC tests, which do not require reporting. The federal government recently opened up a test agnostic reporting website called Make My Test Count that allows individuals to report their OTC test result with age and ZIP code as the only required data elements. While use appears to be limited and unlikely to result in widespread or representative reporting, analysis of this experience is needed to understand how widely this option is being used and how the data can be interpreted alongside other sources.

Alternatives for public health surveillance exist. Reporting of respiratory symptoms (influenza-like-illness) and confirmed flu and COVID-19 cases from outpatient visits and inpatient hospitalizations is a valuable, if less sensitive, indicator of community spread and health system impact. Similarly, skilled nursing facilities and other health care organizations can provide insights about case trends in their communities.

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Wastewater testing also remains an important surveillance mechanism—while there continue to be difficulties in understanding the data, it is a passive testing method that has been shown to be a leading indicator of surging case rates.

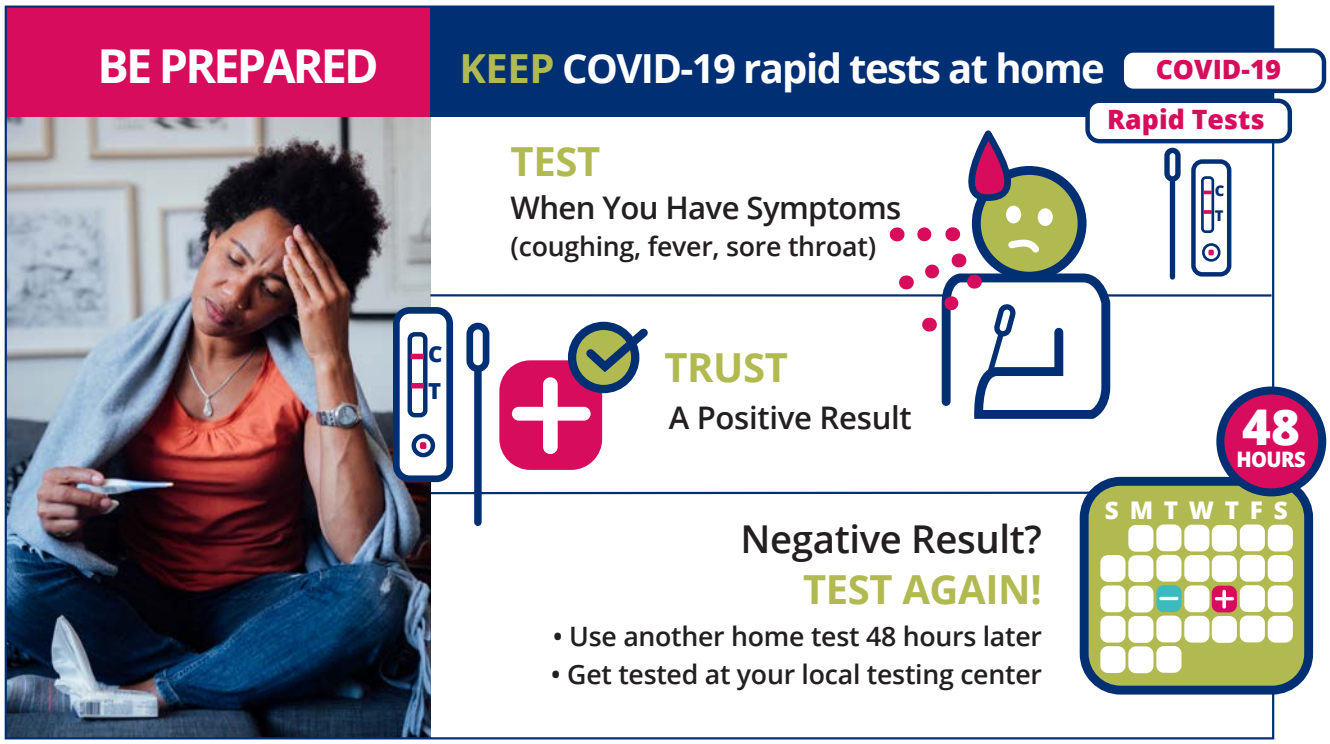
Key Recommendations

Engaging the Public and Promoting Uptake

To help people make informed decisions about testing, clear and practical guidance from trusted sources needs to be combined with steps to make testing easier and less inexpensive when appropriate. Public information and awareness has not kept up with progress in OTC testing—not just for COVID-19 but for other infectious disease threats. As mentioned above, CDC, NIH, CMS, and relevant clinical societies should collaborate to provide clear and up-to-date guidance on testing for the public, and that clinicians and other trusted sources of health information can share with the public, with supporting evidence to justify recommendations. Guidance should highlight the value of serial testing with the use of OTC tests. Straightforward, evidence-based guidance is also needed on when to use multiplex testing, as lab-based, POC, and OTC multiplex tests become more available.

Straightforward messages about testing should complement ongoing messages about the availability of boosters and treatments for those at high risk. These initiatives should focus on sharing easy-to-use information and tools with trusted community partners, who can then use their networks to widen the reach. Public-private partnerships could support health care providers, businesses, community organizations, and health plans in providing accurate and relevant information to help make testing more routine and more actionable. An example of such guidance is provided in **Figure 2,** which is relevant to people who could benefit from both "test to treat" and "test to protect." Community influencers should be engaged along with other trusted authorities in those spaces. In addition, the public health guidance for health professionals and employers—among the most trusted sources of health information for most Americans—should include steps for engaging their patients and workers. CMS also should support outreach to Medicare and Medicaid beneficiaries, particularly because many beneficiaries are at elevated risk. Medicare could build on its substantial communication networks, which are already being used to increase awareness about boosters, COVID-19 treatments, and (during the PHE) free COVID-19 tests. CMS can also help provide educational supports for Medicare Advantage plans and health care providers. These efforts should be prepared to adapt quickly and scale messaging when there are signs of a serious surge.

FIGURE 2 Example of Simple Testing Guidance for Individuals Who Have COVID-19 Symptoms



Ensuring Access and Reducing Costs for OTC Testing

Reducing Prices

The relatively high price of COVID-19 OTC tests in the U.S., compared to other countries or to similar tests such as pregnancy tests, still poses a substantial challenge to broad accessibility of testing, especially after the end of the PHE. Some European countries have achieved retail prices in the range of $2-$5. Test affordability is critical to encourage people to keep a few tests on hand and not to hesitate to use them when appropriate, similar to other medicine cabinet essentials like thermometers and OTC medicines.

Competition, demand reliability, scale, and manufacturing innovations are all levers that can lower prices. FDA has now authorized more than 25 rapid self-tests for COVID-19. Competition among manufacturers has reduced prices in some very large retail marketplaces such as Amazon, where multiple FDA-authorized brands of home tests have been available for $5-$7 per test.[5] However, the typical price of a test in major U.S. pharmacy chains is still $12 a test, which is too high for frequent home testing for most Americans.

To get OTC test prices under $5 per test, manufacturers need more certainty about the ongoing demand for reliable, low-cost tests, and purchasers need to provide more support to maintain reliable demand reflecting the underlying health benefits of larger-scale test use. Periodic, large-scale advance purchases linked to reliable, non-emergency policies on test coverage would create more predictable demand for manufacturers, reducing risk of sustaining manufacturing capacity. Long-term predictability about broader use would also give large-scale buyers more negotiating power to lower prices per test for higher volumes of tests. As discussed in more detail below, these bulk purchases can be supported through focused ongoing coverage requirements as well as value-based incentives and accountability for health plans and providers to reduce COVID-19 hospitalizations in high-risk populations. The federal government and state governments (potentially through multistate purchasing collaborations) should also plan for focused bulk purchasing and distribution programs targeted to uninsured populations, and to provide stockpiles and commitments to rapid increases in test supplies for future surges.

Bulk purchases of tests to be distributed more reliably over time have already yielded lower costs. For example, the federal government's November 2022 contracts for 200 million tests offered $800 million in total, about $4 per test. States, too, have negotiated prices in the range of $5 per test for their own bulk purchases, and initiatives like Project Access COVID Tests (Project ACT) have helped states band together for group purchases—a model that could be extended in the future in the potential absence of further federal purchases. As we describe below, ongoing coverage and payment supports for appropriate access, especially for high-risk populations in Medicare and Medicaid, coupled with incentives for reliable, low-cost testing networks would further encourage longer-term, low-cost purchasing arrangements. Provisions in the Congressional Omnibus package that propose more sustainable purchasing practices for the Strategic National Stockpile (SNS) to support warm-base manufacturing capacity[6] for medical products needed in an emergency could also be helpful. Bulk purchasing with more predictable demand would also create stronger incentives for companies to demonstrate the stability of their products to FDA to allow extended expiration dates. Longer expiration dates will facilitate both stockpiling for surges and programs to encourage high-risk patients to keeps tests available at home for use when needed.

More predictable demand and enhanced price competition around reliable supply over time for larger populations of patients would encourage manufacturer investments to reduce prices further. It would also help incentivize the market to create more reliable, cheaper tests not just for COVID-19 but other infectious diseases. NIH's RADx-Tech has already demonstrated that it is possible to accelerate the development of OTC molecular testing products. This relatively low-cost research could continue to catalyze innovation that could lead to more accurate and inexpensive home testing.

[5] On Jan 31, 2023, there were four different brands of COVID-19 home tests (packaged as two or five tests per box) that cost less than $7/test on the first page of Amazon.com results for "covid home test".

[6] Warm-base manufacturing capacity refers to manufacturing facilities that are able to rapidly scale up production when needed.

Insurance Coverage

Some continued insurance coverage of OTC tests post-PHE would support a culture of prompt testing to start effective treatment in high-risk individuals, leading to lower burdens of COVID-19 and other infectious diseases without public health restrictions. Health plans will continue to cover laboratory tests after the PHE, and lab services are generally provided without co-pays in Medicare and no or nominal co-pays for Medicaid.

Medicare and health plans generally have not covered OTC diagnostic tests unless prescribed by a clinician. But OTC tests for potentially serious respiratory infections represent a new and valuable tool for preventing serious illness and hospitalizations by quickly identifying COVID-19 infections, as an alternative to simply continuing traditional coverage in more costly settings and for infection complications that are now easier to avoid. For example, UnitedHealth Group piloted a program called "Well at Home" early in the pandemic that supplied higher risk members with a kit that contained a COVID-19 test, a thermometer, and prescription flu medicine – members contacted a "Well at Home" doctor if they started to have symptoms and the doctor walked them through how to test for COVID-19 and if they should take the flu medication.

Even in the absence of coverage requirements, health plans have a financial and population health interest in avoiding health complications and costs for their covered populations, particularly high-risk individuals and households. When possible, this coverage should be organized such that tests are free or low-cost at point of purchase, either at a pharmacy counter or through a mail-order program, to encourage patients to keep tests at home ready to use. Coverage of serial OTC tests is likely significantly less expensive than only covering traditional provider-administered lab-based or POC tests, especially with the steps we have described to achieve low per-unit test costs.

Congress should consider updating Medicare, Medicaid, and private insurance coverage requirements or options to reflect the emerging medical reality that future infectious disease containment can occur less expensively and more effectively by supporting individuals in using OTC tests themselves.

This more timely and convenient testing option can potentially achieve lower rates of serious infectious disease complications and associated costs, but such innovations in coverage and changes in care are difficult for individual plans to undertake on their own. CMS action to encourage continued OTC test coverage through Medicare and Medicaid is likely the most promising approach to support OTC testing, especially because Medicare and Medicaid cover many Americans at elevated risk for severe COVID-19. Policies set by CMS have the potential to mitigate some of the inequitable impacts of the end of the PHE, and simultaneously set the standard for continued coverage of OTC testing. CMS also should provide guidance on how Medicare Advantage plans, Medicare accountable care organizations, and Medicaid managed care plans can continue to cover OTC tests as a permitted benefit, using a network of manufacturers and distributors to encourage efficient pricing and delivery, since such coverage can lead to lower medical costs and complications.

Currently, a system-wide Medicare demonstration project provides free OTC test access through pilot access networks for Medicare Part B beneficiaries (including Medicare Advantage) throughout the duration of the PHE. The project could potentially be reestablished after the PHE since section 402 authority for demonstration projects is not intrinsically linked to the PHE. Rather, the demonstration authority aims to enable Medicare to promote innovative approaches to improving outcomes and lowering overall costs for Medicare beneficiaries, almost all of whom are still at relatively high risk for COVID-19 and other infectious disease complications. CMS has said that they are willing to work with lawmakers to maintain access to these OTC tests, but may need new authorities. This new demostration project could be designed to assess whether Medicare coverage of COVID-19 OTC tests in an efficient manner (i.e., by contracting for long-term predictable supply from competitive manufacturers) can reduce beneficiary hospitalizations and associated Medicare costs.

Timely treatment has been shown to reduce the risk of hospitalization by about 50 percent, but not many high-risk individuals are accessing treatment. On average during the fall of 2022, 1,300 individuals over 65 were hospitalized weekly. Reducing hospitalizations by 25 percent through an efficient testing access and beneficiary communication program would save Medicare

over $30 million each month, along with improved patient outcomes and reduced strain on the health system. If not successful, the demonstration could be modified or ended.

Pairing OTC test availability with programs meant to speed risk assessment and treatment access would help ensure these outcomes and savings. CMS could implement accountability measures and financial incentives related to preventable hospitalizations from treatable respiratory infections (e.g., a quality measure for primary care providers, accountable care organizations, health systems, and health plans on how quickly at-risk individuals receive treatment from symptom onset, or a measure of the share of patients in a health plan with a hospitalization or emergency room visit for a treatable respiratory infection without prior testing and treatment as an outpatient).

While a large share of high-risk individuals have coverage through Medicare and Medicaid, CMS should collaborate with commercial insurers to identify and expand best practices for continuing OTC test coverage. This should include clarifying pathways for commercial coverage as a medical or pharmacy benefit, highlighting examples of promising mechanisms for OTC test integration into coverage in private insurance plans (including in Medicare Advantage and Medicaid managed care plans), and development and implementation of measures of adequacy of testing for high-risk patients to provide transparency about how health plans are supporting access to testing among high-risk patients.

Finally, with the potential for further progress in OTC tests for many other infectious diseases, Congress should consider updating Medicare, Medicaid, and private insurance coverage requirements or options to reflect the emerging medical reality that future infectious disease containment can occur less expensively and more effectively by supporting individuals in using OTC tests themselves.

These steps for more predictable and efficient coverage after the PHE would not only improve access to tests, but reduce prices by enabling advance purchase contracts by insurers and accountable health systems. The additional, more predictable demand and the use of preferred manufacturers and distributors would enable insurers to use their purchasing power to negotiate lower per-test prices, and pass those saving on to their enrollees. For example, insurers and health systems could promote "test discount cards" that allow their patients to purchase tests at a significant discount at specified sites where manufacturers, pharmacies, and other retailers have agreed to participate in an initiative to encourage effective test use. These discounts also could be offered through plans' mail-order pharmacy programs.

Ensuring Equity Through Public Supports for Testing

An insurer-based approach to subsidize OTC testing will leave out many already underserved and low-income populations, including people who are uninsured and those without ready access to traditional points of care like pharmacies or health care providers' offices. But these are the same populations that are disproportionally likely to have severe outcomes or to live or work with individuals at higher risk. As such, continued public funding for accessible OTC testing is important for individuals who would not otherwise have easy access to COVID-19 tests. Offering uninsured Americans (approximately 30 million people) six free tests per year, purchased in bulk by the federal government and distributed through the mail for $6 per test delivered, would cost just over $200M annually if 20 percent of those eligible took advantage of the program.

The White House COVIDTests.gov program has offered 16 free tests to every U.S. household via mail (across three rounds of ordering in 2022, with four tests per household offered in January, another eight in the spring, and four more in December). Online ordering was available in English and Spanish, with a broader range of language and accessibility options offered by phone. As the country moves forward, this type of distribution campaign should be more focused on the

underserved to ensure that those individuals can test appropriately. However, the government's efforts to ensure equitable distribution of these tests to a more targeted population should continue through a variety of community sites in underserved areas and sites that serve low-income individuals and families, with mail-order options available as well. These sites include libraries, food banks, designated pharmacies, federal qualified health centers, and the like, based on learnings in such efforts like the ICATT program and RADx-UP. Schools also have been a useful distribution point, by testing children who develop symptoms at school and sending tests home for the family members with the sick child. These efforts should be prioritized in areas that have experienced disproportionate burdens of illness and mortality from COVID-19, in accordance with disadvantage indices, historical trends in cases or mortality, or other metrics of public health inequities.

Sustainable funding for significant routine government purchases to ensure access for underserved populations would have the added benefit of helping to maintain active test manufacturing capacity even when consumer demand drops, allowing faster scale-up in case of a future surge. Coupled with the steps we have described to promote public awareness and engagement, and to encourage appropriate use, building such costs into routine budgets will have limited incremental costs and greater impacts compared to testing in the PHE.

Ensuring Access and Reducing Costs for Lab-Based and POC Testing

As mentioned above, OTC tests will be the first-line diagnostic for many, but POC and lab-based tests need to remain accessible pathways. However, as with OTC tests, costs of lab-based and POC tests will remain higher and access lower than they could be if better long-term policies are implemented.

For the duration of the PHE, insurers have been required to cover both the cost of these tests and the costs for a health care professional to prescribe the test and collect the sample without cost-sharing for their patients and without limits on out-of-network prices. Generous coverage has been important for promoting broad use of professionally managed testing, as many patients at elevated risk may not be able or willing to test themselves. Broad access for those at high risk will remain important in the future, not only for patient at high risk for COVID-19 complications, but also for those at high risk for other respiratory illnesses, as more multiplex tests become available.

However, the broad coverage requirements in the PHE have led to excess costs associated with lab and POC testing in commercial insurance. The CARES Act has required commercial insurers to reimburse such tests at the provider's publicly listed cash price, giving out-of-network providers little reason to offer lower prices in negotiations with insurers. The resulting unduly high costs for out-of-network POC and lab-based testing are ultimately borne not just by insurers, but also by patients and employers through higher premiums.

These excess costs could have been avoided by setting up mechanisms to protect against excessive pricing by laboratories and providers as part of coverage requirements. This could include allowing health plans to set up preferred networks of test providers, with requirements for testing network adequacy to assure timely and convenient access, and steps to ensure that patients would not be exposed to surprise bills for out-of-network test services. After the PHE, private insurers will be able to implement these types of testing networks. CMS and HHS should work with insurers to develop guidance based on the PHE experience, potentially coupled with performance measures, on network adequacy and best practices for assuring appropriate use of laboratory tests at a lower cost than during the PHE. This guidance could support the implementation of a network-based approach to assure appropriate testing access with lower costs in the event of expanded coverage requirements in future PHEs.

One previous concern with the network approach was that unknowing patients could receive an unexpected bill for the balance of services, as out-of-network testing facilities would not be required to simply accept the capped reimbursement amount. However, the No Surprises Act (a law that went into effect in 2022, intended to protect patients from unexpected out-of-network medical bills) would now require these testing facilities to disclose to patients that they may be responsible for some portion of the testing costs. Patients would then likely avoid those testing facilities, creating an incentive for testing facilities to reduce prices or negotiate with the insurer.

The CARES Act-based requirements of no patient cost sharing for lab-based and POC testing will also end when the PHE does. The Affordable Care Act (ACA) lists lab services, which include both POC and lab-based testing, among the 10 essential services so insurers are required to cover them. Within Medicare, cost-sharing is not permitted for lab services. State Medicaid programs will be required to continue to cover COVID-19 testing without cost-sharing through September 2024, as part of the American Rescue Plan Act of 2021. After that date, Medicaid plans generally require coverage of necessary laboratory tests with no or nominal cost-sharing. But commercial insurers may impose cost-sharing on patients. Further, the lab service charge is separate from charges from pharmacy clinics, urgent care sites, or doctors' offices for prescribing the test and collecting the sample, and there can be cost-sharing for patients for those clinical services. It is likely that significant new patient cost-sharing for POC or lab-based COVID-19 test services would significantly reduce individuals' willingness to test, especially in the absence of easy access to OTC testing, resulting in both greater community transmission and more complications and hospitalizations among undertreated patients at high risk.

To address this, CMS could implement financial performance incentives to encourage testing by providers in traditional Medicare, and in Medicare Advantage and Medicaid managed care plans to encourage low-cost and reliable lab-based and POC testing access, in conjunction with encouraging the development of efficient and accessible lab and POC testing networks. In particular, the same performance measures and incentives we have proposed to encourage OTC test use – indicators of whether high-risk patients are getting timely testing and treatment – could apply here. Together, these steps would aim to support coverage that uses OTC as well as POC and lab tests appropriately to improve access to testing and treatment for high-risk patients.

In addition, Congress has set up a mechanism for coverage of certain preventive tests and services without co-pays across all health insurance plans based on a recommendation of the United States Preventive Services Task Force (USPSTF) that the test has an "A" or "B" (i.e., strong) rating in terms of supporting evidence of a health benefit. Based on the evidence reviews, most USPSTF recommendations have clear limits on who is eligible for testing and involve screening on a specific periodic basis, although certain sexually transmitted disease (STD) screening tests are recommended any time a new or persistent risk factor is present. The USPTF recommendation around a provision of the FDA-approved smoking cessation pharmacotherapy also includes both prescription and OTC products. Given this precedent, if appropriate evidence exists, this recommendation could be extended to OTC testing as well as POC and lab-based testing for potentially serious infections. The strength of the evidence of health benefits will likely be greater for high-risk patients, but an evidence review for all types of patients may be a valuable (if not quick) step to improve public understanding of the current state of the evidence on testing.

Finally, individual states can take legislative action to require coverage of medical products and services without cost-sharing for state regulated, non-Employee Retirement Income Security Act (ERISA) plans, at least for high-risk individuals. Guidance to states about the costs, benefits, and implementation challenges of such a requirement could help determine the feasibility and effectiveness of such insurance mandates.

CONCLUSION

Innovation in COVID-19 testing has advanced the development of powerful and effective tools to prevent the spread of potentially serious respiratory infections and protect the most vulnerable, by helping Americans make better informed decisions in their daily lives and take steps to get treated if they are infected and at high risk of complications. Requirements for broad insurance coverage, along with continued federal and state purchases and distribution of tests, have supported access to testing throughout much of the PHE and the development of testing technologies that can also reduce the spread and health and economic impact of other major respiratory infectious diseases. But these policies are generally tied to the emergency declaration, which will be ending in May 2023. They were not designed to address the opportunities for new, low-cost, reliable testing and timely treatment for respiratory infections to reduce disruptions and improve outcomes for Americans' lives in the longer term.

Building long-term regulatory and legislative frameworks to address these new opportunities for lab-based and OTC testing after the PHE is critical for achieving these long-term goals, especially for individuals who remain at relatively high risk of significant and costly medical complications from COVID-19 and other respiratory infections.

These policy reforms would align with the continuing shift in medical technology and public health toward more home-based, person-centered preventive care. Achieving these health benefits depends on reliable information and access to inexpensive rapid diagnostic tests to better protect Americans against a broad range of infectious illnesses and potential future public health threats. Given the public's increasing familiarity and comfort with OTC diagnostics and the significant successes of OTC tests for COVID-19, OTC tests for more respiratory and infectious diseases are likely to be introduced in the coming years. Finding effective ways to modernize coverage, payment, and access along with these improvements in OTC diagnostic testing will save lives now and in the future.

Policymakers have not yet described their goals for ongoing testing in this new environment, despite opportunities to develop a more sustainable long-term strategy accounting for post-PHE policy changes and a broader range of respiratory viruses. The policy actions recommended in this issue brief to promote availability, reduce costs, maintain insurance coverage, establish payment mechanisms, and create clear public communication can ensure testing is utilized to its full potential in protecting Americans.

APPENDIX: ROUNDTABLE ATTENDEES

The authors are thankful to the participants for sharing their expertise, however, the views expressed in this paper do not necessarily reflect the views of the individuals below or their organizations.

Mara Aspinall – Professor of Practice, Diagnostics, Arizona State University College of Health Solutions

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John Bridgeland – Co-Founder and CEO, COVID Collaborative

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Alexander Ding – Associate Vice President for Physician Strategy and Medical Affairs, Humana

Angela Dunn – Executive Director, Salt Lake County Health Department

Gary Edson – President, COVID Collaborative

Marcia Eisenberg – Chief Scientific Officer and Senior Vice President, Labcorp

Lee Fleisher – Chief Medical Officer and Director of the Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services

Mollie Gelburd – Senior Director, Delivery System and Payment Transformation, America's Health Insurance Plans

Trina Gilligan – Director of Clinical Product Planning, Premier Inc.

Katie Greene – Project Director for Public Health, National Academy for State Health Policy

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Tom Inglesby – Director, Johns Hopkins Center for Health Security at the Bloomberg School of Public Health

Benjamin Jacobson – White House COVID-19 Response Team

Ashish Jha – COVID-19 Response Coordinator, White House COVID-19 Response Team

Ravi Kavasery – Vice President for Cost of Health Care, Blue Shield of California

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William Meyer – Technical and Medical Science Liaison Director, Quest Diagnostics

Ajani Nimmagadda – Medical Officer, Cigna

Leah Perkinson – Director of Research Translation and Evaluation, Brown University School of Public Health

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