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Community Pharmacies and COVID-19 Testing

SARS-CoV-2 (COVID-19) has been running rampant in the United States since it was first detected in late January. The number of cases has exponentially grown since then. As of May 2020, there are over one million cases in the U.S. with deaths climbing to nearly eighty thousand.[1] As with any new disease, healthcare professionals and researchers are scrambling to find a reliable testing method and potential treatment. One of the biggest concerns among healthcare professionals is that the lack of testing has obscured the extent of the outbreak. Moreover, the shortages of testing supplies, personal protective equipment (PPE) and other resources used for extended patient stays in hospitals has made it difficult for healthcare providers to navigate this pandemic efficiently and effectively. This paper will explore what tests are available for community pharmacies and how such pharmacies can implement the tests in practice.

Community pharmacies are often the front-line responders to questions concerning COVID-19. In many communities, pharmacists are the most accessible healthcare providers and the first touchpoint of patient engagement with the healthcare system.[2] During this current pandemic, it is expected that community pharmacies often will be the first point of contact for patients seeking reliable information, advice, and services.

The Center for Disease Control has been the main powerhouse responding to COVID-19 in the United States. As an essential healthcare provider, being informed on the most current information about COVID-19 is critically important-- not only to respond to the disease but also to reduce stress in times of uncertainty for our patients. The American Pharmacists Association (APhA) and CDC both have useful information for patients and pharmacists to utilize during the pandemic. For instance, APhA has a list of resources and practical information for pharmacists to know including practicing on the front lines, managing pharmacies, preparing health systems and utilizing personal protective equipment, testing, immunizations, and treatments [3]

Despite not having enough resources for testing, it is still important for pharmacies to implement policies and procedures to ensure that when testing is more widely available, pharmacists will respond quickly. However, testing comes with its own concerns, and as pharmacists it is important to recognize: what options are available for testing, what steps pharmacies need to take in order to provide testing in their various facilities, which tests are applicable to a community pharmacy, how sensitivity and specificity play a role in testing and what potential options may be available in the future?

AVAILABLE TESTING OPTIONS

Currently, there are two types of testing available for COVID-19: viral tests (molecular assays) and antibody tests (serology assays). Broadly speaking, Viral tests test for current infections whereas antibody tests test for previous infection with the virus. Viral tests check samples from a patient's respiratory system. The tests are designed to target the upper respiratory tract or the lower respiratory

tract. The CDC recommends that nasopharynx samples be used to detect Covid-19. However, nasal swabs (collected from anterior nares) or oropharyngeal swabs may be acceptable alternatives.[4] These tests are specific for upper respiratory tract specimens. Lower respiratory tract specimens are also an option for testing and have been found by some researchers to yield higher viral loads and thus more likely to yield positive tests compared to upper respiratory tract specimens. For instance, in a study with 205 patients with COVID-19, 1070 specimens were collected from various sites and results showed that bronchioalveolar lavage fluid specimens and sputum (both lower respiratory tract specimens), had the highest yields of positive rates, 93% (14 of 15) and 72% (72 of 104), respectively. Nasal Swabs and pharyngeal swabs accounted for 63% (5 of 8) and 32%(126 of 398) respectively.[8] However, this study had limitations, including the number of some types of samples being small. A more consistent approach to site-collecting specimens is warranted.

Data comparing the accuracy of testing from various sites is limited. Although it is difficult and impractical for community pharmacies to test lower respiratory tract specimens, they may be used in hospital settings to diagnose COVID-19. For example, the Infectious Disease Society of America (IDSA) suggests reserving lower respiratory tract specimen collection for hospital-settings where an initial upper respiratory tract specimen tested negative despite suspicion of COVID-19.[5] For patients who develop a productive cough in either the community or hospital setting, sputum should be collected and tested. However, sputum should not be induced in a patient suspected of COVID-19 because it is an aerosol-generating procedure that runs the risk of spreading the disease.[5]

COVID-19 diagnosis is currently based on using a reverse transcriptase polymerase chain reaction (RT-PCR) assay to detect viral RNA in respiratory samples. Of the 112 available molecular assays for detecting SARS-CoV-2, 90% utilize PCR or RT-PCR technologies.[6] RT-PCR relies on its ability to amplify a small amount of genetic material in a sample with the use of thermal cycling. It generally uses samples collected from the upper respiratory tract using swabs. The other 10% of molecular assays used for diagnosis include nucleic acid assays such as isothermal amplification, hybridization microarray, amplicon-based metagenomics sequencing, and CRISPR-related technologies that are either under development or have resulted in approved tests.

Serological testing is another testing method that has been used to detect and track COVID-19. The John Hopkins Center for Health Security explains serology-based tests as "blood-based tests that can be used to identify whether people have been exposed to a particular pathogen."[3] Serology tests examine the components of blood, which includes antibodies against specific antigens that are recognized by the immune system as foreign. They have been used to determine if a patient has had an infection based on the patient's immune response. It is important to recognize that this test measures the amount of antibodies produced in response to SARS-CoV-2 infection and does not test for the presence of the virus itself. Consequently, the FDA highlights that serologic tests should not be used as the sole test to diagnose or exclude SARS-CoV-2 infections.[5] According to the CDC, it typically takes 1-3 weeks for a patient to develop antibodies to COVID-19 and would not be useful in someone with a suspected active infection. Instead, Serological tests should be used in conjunction with molecular tests and clinical features to diagnose COVID-19.

In summary, the two types of tests available can help determine if a patient has an active COVID-19 infection or if they have had it in the past. The tests that detect active infection include the molecular assay tests like RT-PCR, which may take up to two days to analyze and which requires swabs be sent to a lab. Fortunately, rapid molecular assays such as rapid RT-PCR are also being developed which can be analyzed in 15-20 minutes and can be done in a point-of-care fashion that circumvents the need to send

tests to a lab for independent analysis. Serology assays are typically used to detect previous infection. These tests can also be conducted at point-of-care and can take as little as 10 minutes or as long as 5 days to analyze the results.[3] Serology tests should not be used as the sole test for diagnostic decisions because the current landscape is varied and clinically unverified and these tests are more likely to be used for public health surveillance and vaccine development in the future.

HOW TO IMPLEMENT TESTING IN COMMUNITY PHARMACIES

While testing is available for patients, there are some barriers that community pharmacies must overcome to provide patient-care services. On April 8, 2020, the U.S. Department of Health and Human Services authorized pharmacists to order and administer COVID-19 tests. But there were multiple issues that needed to be sorted out to utilize pharmacists' access to accurate and reliable test kits. One of the biggest issues that pharmacies have faced is that while they can provide testing services for patients, the services were not reimbursable through Medicare because pharmacies are not considered providers through CMS. This limited pharmacists' abilities to provide services to patients.

Fortunately, this hurdle was recently addressed in a May 8, 2020 document released by The Centers for Medicare & Medicaid Services. This document details how pharmacies and other suppliers can apply for waivers that will allow them to temporarily enroll as independent clinical diagnostic laboratories, which are regulated by the agency.[9] The implications of this include a workaround: allowing community pharmacies to offer tests in more convenient locations and allowing the public access to quicker results. Up until this point, most pharmacies would only have been able to offer testing services as a cash service to patients because they were not being reimbursed through Medicare. This recent development is a huge step towards combatting the disease in terms of increasing COVID-19 testing capabilities and reimbursing pharmacies for this specific service.

Another obstacle that pharmacies have had to overcome is that while testing is available, there was unclear guidance by state laws as to whether pharmacies would be able to administer the COVID-19 tests during the public health emergency. The Department of Health and Human Services issued an advisory opinion on May 19, 2020, laying down the reasoning why the PREP Act preempts state law and allows pharmacists to order and administer tests. As explained in the April 14, 2020 Advisory Opinion, the Secretary of Health designated pharmacists as "qualified persons" under his declaration. By designating licensed pharmacists as "qualified persons," the Secretary authorized licensed pharmacists to order and administer FDA-authorized COVID-19 tests in states where the licensed pharmacists are not authorized to do so.

For pharmacists to be able to perform COVID-19 diagnostic testing (including serological and antibody testing) under Medicare, they must be enrolled in Medicare as an independent clinical laboratory, in accordance with scope of practice and state laws.[11] Depending on the CLIA certificate a pharmacy wishes to pursue, pharmacies can perform moderate and/or high complexity tests or tests categorized as waived by the FDA. The CLIA-waved tests would be most applicable to community pharmacies as they are "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result."[12] Moreover, pharmacies with a CLIA-waiver can perform certain diagnostics for COVID-19 that have emergency use authorization (EUA) status from the FDA. Additional benefits of a CLIA waver include pharmacies being able to perform other CLIA waved/point of care tests such as A1c, blood glucose, influenza, and Strep A. Pharmacies who obtain a CLIA waver for the purposes of "providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" are considered a laboratory. To obtain a CLIA Certificate of

Waiver, a CMS-166 CLIA application form must be submitted to the state where your laboratory is located.[10]

To initiate this temporary service, the Medicare-enrolled pharmacies and other Medicare-enrolled suppliers should contact their local Medicare Administrative Contractor (MAC) serving their geographical area. The information that needs to be provided is limited to the pharmacies': legal business name, National Provider Identifier (NPI), Tax Identification Number (TIN), state license, CLIA certificate number, address information and contact information.[10] Pharmacies that are not currently enrolled in Medicare and want to enroll as an Independent Clinical Diagnostic Laboratory, must submit a CMS-855B enrollment application to their local MAC. It is also important to note that in order to maintain billing privileges, the pharmacy or other supplier must also submit a CMS-885B enrollment application, but this can be done 30 days after the public health emergency ends.[11] For a helpful NCPA instructional video on "How to File for a CLIA Certificate of Waiver" click this link: http://www.ncpa.co/media/webinar/Fill-Out-CLIA-FORM.mp4

Table 1: A sample of available diagnostic molecular tests for COVID-19, May 2020.

Test Kit Manufacturers Molecular Tests	**Diagnostic Test**	**Sensitivity & specificity [95% CI] (Positive percent agreement & Negative percent agreement*)**	**Time to Get Results**	**Type of Specimen Collected via swab**	**Point of care testing**	**Cost**	**Additional information/ Information from the manufacturer**
Rutgers Clinical Genomics Laboratory (848) 445-7081	Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2-Assay (H)	Package insert: PPA: 100% [88.7-100%] NPA: 100%[88.7-100%]	48 hours	Nasal, oropharyngeal, nasopharyngeal, Saliva	N	N/A	First diagnostic test with a home-collection option of saliva specimens. Ideal for patients not wanting to leave their home to get tested. Results are sent to Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics in New Jersey
Quidel corporation (800) 874-1517	Sofia 2 SARS Antigen FIA (H,M,W)	Package insert: PPA: 80%[68-88%] NPA: 100%[96-100%] PPV: 100%[92-100%] NPV: 88% [79-93%] Prevalence: 41%[34-49%] Agreement: 92%	15 minutes	Direct or Viral Transport Medium (VTM): Nasal, Nasopharyngeal	Y	N/A Healthcare professionals can purchase through distribution representatives (i.e Mckesson, Cardinal Health, Henry Schein)	Materials required but not provided: SOFIA analyzer instrument
Abott Diagnostics Scarborough, Inc. (855) 731-2288	ID NOW COVID-19 (H,M,W)	Package insert: PPA: 100%[83.9-100%] NPA: 100%[88.7-100%] Independent study[13]: PPA: 87.7%[76-95%] NPA:100%[93-100%]	5-13 minutes	Oropharyngeal, nasal, nasopharyngeal	Y	N/A	Materials required but not provided: ID NOW instrument & Nasopharyngeal swabs
Mesa Biotech Inc (858) 800-4929.	Accula SARS-CoV-2 Test (H,M,W)	Package insert: PPA: N/A NPA:N/A	30 minutes	Nasal	Y	N/A	Materials required but not provided: Accula Dock, Silaris dock, Accula SARS-CoV-2 control kit
Cepheid (408) 541-4191	Xpert Xpress SARS-CoV-2 test (H,M,W)	Package insert: PPA:100% [83.9-100%] NPA:100%[88.7-100%] Independent study[13]: PPA: 98.3%[91-100%]	45 minutes	Nasopharyngeal, Nasal/mid-turbinate	Y	$110 for the test kit	Materials required but not provided: GeneXpert Xpress System instrument (tablet and hub configuration), SeraCare

		NPA: 100%[93-100%]					Accuplex™ Reference Material Kit
GenMark Diagnostics, Inc (760) 448-4300	ePlex SARS-CoV-2 test (H,M)	Package insert: PPA: 94.4%[74.2-99%] NPA: 100%[92.4-100%] Independent study[13]:PPA:91.4%[81-97%] NPA:100%[93-100%]	~ 2 hours	Nasopharyngeal	N	N/A Instrument cost $60-250,000	Materials required but not provided: GenMark ePlex instrument and software
Everlywell, Inc.	Everlywell COVID-19 Test Home Collection Kit(H)	Package Insert: PPA: N/A NPA: N/A	3-5 days	Nasal	N	$135 for the test kit.	Materials required but not provided: N/A

H- laboratories that meet requirements to perform high complexity tests. M- laboratories that meet requirements to perform moderate complexity tests. W- patient care settings operating under a CLIA certificate of waiver.

*PPA- the proportion of individuals with the target condition by the imperfect reference standard who test positive. NPA- the proportion of individuals free of the target condition by imperfect reference standard who test negative. In the absence of a clinical reference standard, the performance of a test against an imperfect comparator is reported using the PPA and NPA.

Table 1 focuses on molecular assays as these are the tests used to diagnose patients with an active infection. As highlighted in the table, information about these diagnostic molecular tests are limited. Unfortunately, with SARS-CoV-2 being a novel virus, and with the molecular diagnostic tests being EUA status, there is no standardized way to claim sensitivity and specificity. Instead, companies must report positive percent agreements and negative percent agreements against an imperfect reference standard, although these are typically reported as sensitivity and specificity. For clarification, the ID NOW, Xpert Xpress, and ePlex tests PPA and NPA were determined from a study using a Hologic Fusion assay as its reference standard.[13] But this was not a manufacture specific study. Those companies wherein PPA and NPA were not readily noticeable in their package inserts were contacted for clarification on their sensitivities and specificities. Currently, those companies only disclose their information to community pharmacies that they plan to do business with, or they could not be reached. Also, cost is a variable factor among the different tests provided. Cost may be better established by directly calling the manufacturers' sales representatives to inquire about the costs for one's specific practice. Cost may depend on several factors such as the number of tests ordered, the cost of the instrument, and the logistical cost of implementing testing in a pharmacy setting.

Despite a lack of data, community pharmacies have still offered various tests to their patients. Moreover, each EUA also includes the settings in which the test is authorized, noted in column two as "H," "M," or "W." Currently the tests listed as "H" are limited to use in laboratories certified under CLIA that meet requirements to perform high-complexity tests. The tests listed as "M" are limited to use in laboratories certified under CLIA that meet requirements to perform moderate-complexity tests. The tests listed as "W" are deemed to be CLIA-waived for use in patient care settings operating under a CLIA certificate of waiver.[16] "W" tests are the most applicable to a community pharmacy that has a CLIA-waved certificate and should be considered if a community pharmacist wishes to offer on-site testing. Moreover, if the "Authorized Laboratories and Other Authorized Testing Locations" section on the FDA EUA webpage indicates "patient care setting," the test may be provided by pharmacies that have CLIA Certificates of Waiver.[3] For specifics, the package insert of each test is available on the FDA EUA webpage under the title "Test Kit Manufacturers and Commercial Laboratories." [14]

TESTS APPLICABLE TO A COMMUNITY PHARMACY

There are currently four diagnostic tests that may be applicable in a community pharmacy setting. These tests include the manufacturers Quidel Corporation, Abbott Diagnostics, Mesa Biotech Inc, and Cepheid. These four tests are authorized for use in both high-and moderate- intensity laboratories as well

as point-of-care testing facilities operating under a CLIA Certificate of Waiver.[14] Quidel Corporation provides the SOFIA 2 SARS Antigen FIA test which is the newest of the tests available. It is the first EUA authorized antigen test used to diagnose the virus by testing samples collected from the nasal cavity using swabs.[17] The antigen test is a new type of test that circumvents the need for PCR testing and is designed for rapid detection of the virus that causes COVID-19. However, a drawback of this test is that it may not detect all active infections. Antigen tests are specific for the virus but are not as sensitive as molecular PCR tests. This means that positive results from antigen tests are accurate but there is a higher chance of false negatives which may lead a community pharmacist to re-order a test, using a PCR test to confirm that the result is negative.

Abbott Diagnostics provides the ID NOW COVID-19 test. ID NOW COVID-19 assay performed on the ID NOW Instrument is a rapid molecular in vitro diagnostic test.[14] It utilizes an isothermal nucleic acid amplification technology intended for the qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal, nasopharyngeal or throat swabs. The test is currently being used by large, corporate community pharmacies like Walgreens and CVS that have drive-through services to test patients in as little as 5 minutes.[18] However, the ID NOW COVID-19 test has come under scrutiny. In one, non-peer reviewed study, the Abbott ID NOW COVID-19 test was found to miss one-third of the samples accurately detected positive by its competitor, Cepheid Xpert Xpress, regardless of the method of collection or sample type.[19] Moreover, when using samples collected with dry nasal swabs, the test missed more than 48% of positive cases. The FDA commented on May 14, 2020, with a news release that they have received 15 adverse event reports that show concern of the test returning false negative results. They are working with Abbott to evaluate accuracy issues and will publicly communicate any updates. Although these reports are preliminary and should not be regarded as conclusive, it could have huge implications on how Abbott's diagnostic testing is performed in the future.

Mesa Biotech Inc. provides the Accula SARS-Cov-2 test. The Accula SARS-Cov-2 Test performed on the Accula™ Dock or the Silaris™ Dock is a molecular in vitro diagnostic test utilizing polymerase chain reaction (PCR) and lateral flow technologies for the qualitative, visual detection of the coronavirus SARS-CoV-2 viral RNA.[14] The Accula SARS-CoV-2 Test uses nasal swab specimens, collected from patients suspected of COVID-19 by their healthcare provider. The Accula SARS-CoV-2 Test using nasal swab specimens is authorized to be distributed and used in patient care settings outside of the clinical laboratory environment.

Cepheid provides the Xpert Xpress SARS-CoV-2 test. The Xpert Xpress SARS-CoV-2 test is a rapid, real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory specimens.[14] The Xpert Xpress SARS-CoV-2 test is performed on GeneXpert Xpress System. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Conversations with a Cepheid sales representative highlighted some information that was not publicly available.

SENSITIVITY AND SPECIFICITY

Sensitivity and specificity are two of the most important factors regarding testing. Broadly speaking, test sensitivity is the ability of a test to correctly classify an individual as "diseased." Specificity is the ability of a test to correctly classify an individual as "disease-free." Both are needed to determine the accuracy of a test. There is no clear guidance from the FDA regarding sensitivity and specificity for diagnostic molecular tests besides what is reported in the package inserts. However, community pharmacies should

be wary of the package insert and note the methods used in testing to determine if the testing was done with a true sample of COVID-19 or if the results were based off a computer-calculated model.

The FDA has supplied a recent report on the sensitivities and specificities of 12 serological tests.[20] In terms of sensitivity and specificity for serological tests, sensitivity refers to the ability to identify those with antibodies to COVID-19 (true positive rate) and specificity refers to the ability to identify those without antibodies to COVID-19 (true negative rate). The test's sensitivities have been evaluated by determining whether or not it is able to detect antibodies in blood samples from patients who have been confirmed to have COVID-19 using nucleic-acid amplification test (NAAT). The test's specificities have been evaluated by samples collected and frozen before the outbreak to demonstrate that the test does not produce positive results in other respiratory infections, such as other coronaviruses.

Positive and negative predictive values (PPV & NPV) are also taken into consideration. These measures are calculated based on sensitivity, specificity, and a pre-set assumption of individuals in the population who have antibodies to SARS-CoV-2, which the FDA has set at 5%.[20] The PPV and NPV help with the interpretation of results to determine how likely it is that a person who receives a positive result from a test truly has antibodies to the disease(PPV) and how likely it is that a person who receives a negative result from a test truly does not have antibodies to the disease(NPV). But because we do not currently know the actual prevalence of SARS-CoV-2 individuals in the population this data should be approached with caution.

FUTURE TESTING OPTIONS

One exciting prospect that is not readily available for purchase or FDA authorized yet is Sense Biodetection's instrument-free COVID-19 diagnostic test. It uses a nasal swab sample to give a rapid result without the need for an instrument.[21] The company has announced an accelerated program to launch the self-contained test, which overcomes the challenges of existing machine-based testing processes or the need for highly secure category 3 laboratories to analyze results. However, the test does not use PCR technologies, which is the current gold standard. Instead, it would use a nucleic acid test for SARS-CoV-2 which would be disposable after use. It would be offered for use at the point of care and would offer reliable results in under ten minutes. Sense CEO Harry Lamble stated that "Due to its flexibility, speed and accuracy, the test can be deployed for rapid patient triage within hospitals as well as primary care practices, pharmacies and community centers and even distributed for use by individuals in isolation who suspect they may have Covid-19." The company is hoping that the tests will be available in a few months.

The diagnostic tests listed above are only a starting point for community pharmacies consideration. As more research and data is conducted in the coming weeks and months, a dramatic shift in the way we test COVID-19 is plausible. Some important aspects to keep in mind for all testing options include that while a positive test may be indicative of COVID-19, clinical correlation and patient history is necessary to determine patient infection status. Likewise, positive results do not rule out bacterial or co-infections with other viruses that may be prevalent upon patient diagnosis. Negative results do not necessarily rule out COVID-19. Instead, caution is advised with patients who test negative and much like positive results, clinical observations, patient history, and epidemiological factors should be considered. No diagnostic test will be 100% accurate due to differences between study design in a lab and applicable scenarios in the real world. Which is why it is important to study patterns and identify potential causes of inaccuracy to improve clinical knowledge about the coronavirus.

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