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COVID-19: FDA Pulls the Plug on EUA Review of Laboratory Developed Tests for COVID-19

On Oct. 9, the U.S. Food and Drug Administration (FDA) dropped a bombshell by announcing that it would no longer review applications for Emergency Use Authorization (EUA) submitted by test makers for laboratory developed tests (LDTs) to diagnose COVID-19. The announcement, which caught the laboratory industry by surprise, came weeks after the Department of Health and Human Services (HHS) announced that the FDA would no longer be able to regulate LDTs by informal decrees but would instead have to go through the customary notice and comment rulemaking process required for new regulations.

The Context: FDA Regulation of LDTs

The original legislation that created the FDA and current regulatory system of medical drug and device regulation did not specifically

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Testing Strategy: Saliva and Oral Swabs Emerge as Scalable Alternative to Nasopharyngeal SARS-CoV-2 Testing

The standard method for detecting upper respiratory viruses is to perform tests on tissue sample from the back of the sinus cavity collected by inserting a long nasopharyngeal swab deep into the patient's nostril. However, when the COVID-19 pandemic first broke out across the country, the obstacles to implementing testing using such sample collection methods on a mass scale quickly became clear. The good news is that as the pandemic drags into its ninth month, COVID-19 testing on saliva samples is starting to emerge as a workable alternative.

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provide for oversight of diagnostic laboratory tests. So, the agency has relied on its powers to regulate devices to regulate laboratory tests. That is the reason why LDTs must obtain premarket approval through the 510(k) pathway for medical devices.

In addition to challenging the FDA's authority over LDTs, the laboratory industry has long objected to the agency's practice of skirting the regulatory process and relying on guidance, website statements and other informal issuances to make regulatory policy. Without clear and codified regulation, it seemed as if the agency was making up the rules as it went along.

HHS Reins in FDA Informal Regulation of LDTs

On Aug. 19, HHS raised eyebrows by taking the same position and essentially stripping the agency of its authority to regulate LDTs via informal methods. From now on, the FDA rules over LDTs would have to go through the normal notice and comment rulemaking process required to establish new federal regulations, HHS mandated.

One result of the HHS decision, which is part of the Administration's broader policy to cut government regulation over business, was to enable laboratories to offer LDTs for SARS-CoV-2 without going through the EUA process. "Those with an active EUA to use an LDT to detect the virus causing COVID-19 or its antibodies are unaffected by this announcement," HHS added.

FDA Abdicates EUA Review

So far, so good. But on Oct. 7, during its weekly virtual town hall briefings, the FDA turned the tables by announcing that it would longer review COVID EUA submissions for LDTs. Whether deliberately spiteful or not—so, you want us to go through formal rulemaking, then we'll show you—the agency said that dropping EUAs for LDTs was consistent with the recent HHS announcement and necessary to prioritize its scarce review resources.

"We are currently in a different phase of the pandemic with respect to tests," explained **Timothy Stenzel**, director of the Office of In Vitro Diagnostics and Radiological Health at FDA's Center for Devices and Radiological Health, noting that the FDA has authorized more than 250 tests to be run in labs. Stenzel also clarified that the agency would prioritize review of EUA requests for point-of-care tests, home collection tests, at-home tests, tests that reduce reliance on certain types of test supplies and high-throughput, widely distributed tests.

The new approach applies not only to new EUA submissions but also to those already submitted for review, although Stenzel offered assurances

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that the agency had made last-ditch efforts to wrap up review of submissions "close to the finish line" in the interest of fairness. But LDTs that were "further out from potentially being authorized" will progress no further through the pipeline. And no new submissions will be accepted.

The Aftershocks

The announcement caught the industry off-guard. The American Clinical Laboratories Association (ACLA), which had generally supported the August HHS announcement, criticized the FDA's decision. In a statement, ACLA president **Julie Khani** called on the FDA to continue to let labs voluntarily submit EUAs for COVID-19 LDTs, noting that many of the tests that have received EUA are precisely the kinds of "innovative, high-throughput [tests] that have reduced reliance on supplies and been integral to expanding testing capacity" that the new FDA policy is purportedly designed to promote.

The FDA decision to stop reviewing LDTs may thwart development of innovative tests. Specifically, it gives test makers three good reasons not to launch new COVID-19 LDTs:

1. Reimbursement Uncertainty

One problem is the new uncertainty the new policy creates over reimbursement. That is because the Family First Coronavirus Act (FFCRA) requires commercial payors to cover medically necessary SARS-CoV-2 testing without cost sharing, but only if they have EUA from the FDA. Consequently, laboratories developing new SARS-CoV-2 LDTs face the prospect of not being reimbursed for their tests.

2. Liability Risks

In addition to reimbursement risk, taking EUA off the table heightens test makers' liability exposure by stripping away the immunity protections afforded by the Public Readiness and Emergency Preparedness (PREP) Act. Like reimbursement under FFCRA, immunity from claims for use of tests during the public health emergency under PREP applies only to tests with EUA. And because of the urgency of the situation and need to get tests out faster than normal, test makers need these liability protections in case things go wrong. COVID-19 litigation has already become big business for trial lawyers and laboratories that develop inaccurate or faulty LDTs will be sitting ducks.

3. Harm to Competitiveness

While it does not represent full FDA approval, EUA status raises the credibility of a laboratory test product in the eyes of payors, clinicians and even patients. So, taking EUA off the table may make it harder for new LDTs to compete in the market, particularly against tests that have garnered EUA.

FDA Pulls the Plug on EUA Review of Laboratory Developed Tests for COVID-19, *from page 3*

Takeaway

While deregulation of LDTs has long been an industry goal, the FDA's new policy of completely bowing out of EUA review of new SARS-CoV-2 tests is a wrong-headed and perhaps even spiteful decision that works against the very goals it is designed to promote.

FDA WATCH

Agency Temporarily Allows Modifications of Influenza and RSV Tests Without Premarket Notification

On October 13, the U.S. Food and Drug Administration issued new guidance on molecular diagnostic tests for influenza and respiratory syncytial virus (RSV). The upshot of the guidance is to temporarily allow makers of flu and RSV tests that the agency has already cleared to make certain modifications to those products without submitting 510(k) premarket notification in the interests of making the tests more widely available while also not using up reagents needed for SARS-CoV-2 testing.

There is significant overlap in warning signs and symptoms between SARS-CoV-2 and other respiratory viral infections, including influenza and RSV, the guidance explains. "Increased availability of molecular influenza tests during the COVID-19 pandemic is important due to the similarity in symptoms between COVID-19 and the seasonal influenza." The guidance also notes that because of this overlap in symptoms, molecular influenza tests are often offered as part of a panel of tests including RSV.

Diagnostic tests for SARS-CoV-2 and other respiratory viral infections generally use many of the same components. For example, the same specimen collection devices and transport media required to perform many FDA-cleared molecular influenza tests are also needed for most molecular diagnostic SARS-CoV-2 assays. And, of course, those devices and media are currently in short supply.

Accordingly, the guidance states that for the duration of the COVID-19 public health emergency, the agency "does not intend to object" to the addition of certain transport media types and sample types for previously FDA-cleared molecular flu and RSV tests. Such modifications will not require submission of a 510(k) premarket notification so long as they do not "create undue risk in the light of the public health emergency." The policy does not apply to tests and devices for other viruses, antigen-based

tests, multiplex respiratory panels, or multiplex molecular tests that include SARS-CoV-2 targets, the guidance specifies.

Modifications Not Requiring Premarket Notification

Specifically, tests previously indicated for use with samples collected in viral transport media may now be modified to use samples collected in sterile phosphate buffered saline, "including molecular grade PBS and other similar formulations such as Dulbecco's PBS," as well as into sterile normal saline. Also on the agency's "does-not-intend-to-object" list are modifications to add healthcare provider-collected anterior nares or mid-turbinate specimens, provided that the test is already cleared for use with nasopharyngeal swab samples.

Modifications Still Requiring Premarket Notification

The guidance also cites specific modifications that the agency believes *would* create undue risk and thus not subject to the temporary relaxation of premarket notification requirements, including:

- Adding a sample type not identified in the examples cited as not creating undue risk to an FDA-cleared molecular influenza and RSV test;
- Adding an indication for use with self-collected specimens to an FDA-cleared molecular influenza and RSV test;
- Adding a transport media not identified in the not-creating-undue risk examples to an FDA-cleared molecular influenza and RSV test; or
- Adding an over-the-counter (OTC) use or new patient population (e.g., pediatrics) to the indication for an FDA-cleared molecular influenza and RSV test.

The guidance also instructs developers to provide labeling information to help users understand whatever modifications have been made and to verify and validate performance of the modified test.

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Here are the key new FDA EUAs and clearances announced during the month of October:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Scopio Labs	510(k) clearance for X100 hematology imaging and analysis system and Full Field Peripheral Blood Smear application
Abbott Laboratories	EUA for SARS-CoV-2 IgM antibody test
Thermo Fisher Scientific	EUA for OmniPath COVID-19 Total Antibody ELISA Test

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FDA Watch: Agency to Provide Emergency Clearance for Multi-Analyte Respiratory Panels, *from page 5*

Manufacturer(s)	Product
DNA Genotek	EUA for OMNIgene·ORAL OM-505 and OME-505 saliva collection devices
Clinical Enterprise	EUA for EmpowerDX At-Home COVID-19 PCR Test Kit
LumiraDx	EUA for SARS-CoV-2 RNA STAR Complete assay
MiR Scientific	Breakthrough Device Designation for MiR Sentinel PCC4 Assay for prostate cancer
Spectrum Solutions	EUA for SDNA-1000 Saliva Collection Device
Access Bio	EUA for CareStart COVID-19 Antigen test
Genalyte	EUA for Maverick SARS-CoV-2 Multi-Antigen Serology Panel v2
Beckman Coulter	EUA for Access SARS-CoV-2 Immunoglobulin M (IgM) assay
Beckman Coulter	EUA for Access Interleukin-6 (IL-6) immunoassay
Seasun Biomaterials	EUA for AQ-TOP COVID-19 Rapid Detection Kit Plus
Zeus Scientific	EUA for ELISA SARS-CoV-2 IgG Test System
UCLA	EUA for SwabSeq COVID-19 Diagnostic Platform
BioFire Diagnostics	EUA for BioFire Respiratory Panel 2.1-EZ
Quidel	EUA for Sofia 2 Flu + SARS Antigen FIA
Becton Dickinson	510(k) clearance for BD FACSLyric Flow Cytometer with integrated BD FACSDuet Sample Preparation System
LabCorp	EUA for RNA extraction method for SARS-CoV-2 testing
Genetron	Breakthrough Device Designation for HCCscreen, blood-based NGS test for early detection of liver cancers
Chembio Diagnostics	Premarket approval for DPP HIV-Syphilis System
DiaSorin	EUA for Liaison SARS-CoV-2 IgM Assay
DiaSorin	Approval for six hepatitis B serology assays
Tempus	EUA for iC SARS-CoV-2 test
Alimetrix	EUA for SARS-CoV-2 RT-PCR Assay
NanoEntek America	EUA for Frend COVID-19 total Ab test
Nirmidas Biotech	EUA for Nirmidas COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit
Centogene	EUA for CentoSure-SARS-CoV-2 RT-PCR Assay
Clear Labs	EUA for Clear Dx SARS-CoV-2, first nanopore sequencing-based test for SARS-CoV-2 with EUA
Quadrant Biosciences	EUA for Clarifi COVID-19 Test Kit
KimForest Enterprise	EUA for SARS-CoV-2 Detection Kit v1
Assure Tech	EUA for Assure COVID-19 IgG/IgM Rapid Test Device, first antibody point of care assay to detect previous SARS-CoV-2 infection with EUA
Vela Diagnostics	EUA for ViroKey SARS-CoV-2 RT-PCR Test v2.0

Manufacturer(s)	Product
GK Pharmaceuticals Contract Manufacturing Operations (GK CMO)	EUA for GK Accu-Right SARS-CoV-2 RT-PCR Kit
Shenzhen New Industries Biomedical Engineering (SNIBE)	EUA for Maglumi 2019-nCoV IgM/IgG test
Accelerate Diagnostics	510(k) clearance for enhancements to Accelerate Pheno system

Genetic Testing: New EMSO Guidelines Address Efficacy of Next Generation Sequencing for Different Cancer Types

The European Society for Medical Oncology (ESMO) recently issued guidelines on use of next-generation sequencing (NGS) for various types of cancer as part of routine clinical practice.
The guidelines also address whether broad-based NGS should replace small panels designed to test a single gene or a group of genes. The ESMO guidelines are the first recommendations from a scientific society on the use of NGS. Their objective is to "unify decision-making about how NGS should be used for patients with metastatic cancer."

The Diagnostic Challenge

NGS is a high throughput technique that uses DNA sequencing technologies capable of deciphering multiple nucleotide sequences at the same time. NGS is used for cancer treatment and its effectiveness depends in large part on tumor type and the efficacy and availability of targeted drugs.

Routine Use of NGS by Cancer Type

The new guidelines, published in *Annals of Oncology*, address the eight cancers responsible for the most deaths worldwide as well as additional cancers for which routine NGS may be justified based on the ESMO Scale for Clinical Actionability of molecular Targets (ESCAT), which ranks molecular targets and their respective treatments on four levels. The authors also considered cost-effectiveness research regarding the use of multigene sequencing.

- **For advanced, non-squamous NSCLC**, the guidelines recommend routine use of RNA- or DNA-based NGS to detect

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New EMSO Guidelines Address Efficacy of Next Generation Sequencing for Different Cancer Types, *from page 7*

mutations and fusions with ESCAT level I matches. Broad-based NGS could also be used routinely to detect alterations with lower than level I matches, but only when specific agreements are made with payors to consider the cost of testing versus small panels.

- **For metastatic breast cancer**, the guidelines say there is "currently no need to perform tumor multigene NGS in the context of daily practice." Somatic testing cannot fully substitute germline testing for actionable BRCA mutations, they explained, and actionable PIK3CA mutations can be tested with polymerase chain reaction (PCR)-based assays instead.
- **For metastatic colorectal cancer**, the guidelines say that PCR and IHC can be used to detect level I mutations in KRAS, NRAS, and BRAF for which targeted treatments have demonstrated efficacy to highlight why routine multigene NGS is not necessary. However, PCR and IHC should be used as an alternative "only if it does not generate extra cost compared to standard techniques."
- **For advanced prostate cancer**, the recommendations support routine NGS to assess somatic BRCA mutations in countries where PARP inhibitors are accessible. In addition, where broad-based testing is used, it should also include testing for AKT inhibitors, DNA repair genes and MSI signature, but broader panels should only be used in cases where payors agree it is cost effective.
- **For metastatic gastric cancer, pancreatic cancer and hepatocellular carcinoma**, the guidelines do not recommend multigene NGS, saying that "cheap standard methods" could be used to detect MSI or NTRK fusion status, for which immune checkpoint inhibitors and TRK inhibitors, respectively, may provide benefit.
- **For metastatic cholangiocarcinoma and ovarian cancer**, routine multigene NGS is recommended based on the presence of level I ESCAT matches, as well as for cancers of unknown primary, despite the absence of level I matches.
- **Other cancers:** The guidelines also recommended NGS for TMB testing in cervical cancer, well- and moderately- differentiated neuroendocrine tumors, salivary cancers, vulvar cancers, and thyroid cancers. Beyond these tumor types, the evidence was not strong enough to justify routine TMB testing.

For tumor-agnostic approvals of several TRK inhibitors for NTRK fusion-positive cancers, the authors recommended that NGS should only be used to detect NTRK fusions, which have a very low incidence, in cancers where the technology is otherwise recommended.

Point of Care: New Low-Cost Sensor Offers Promise Test for Rapid, At Home COVID-19 Testing

Laboratory companies and scientists are working furiously to produce the rapid, point of care testing technology needed to prevent asymptomatic people from spreading SARS-CoV-2. And in a promising new development, researchers from the California Institute for Technology (Caltech) have developed a new type of test that combines multiple kinds of data with a low-cost sensor that could enable rapid in-home diagnosis of a COVID infection in less than 10 minutes. In addition, the multiplexed test uses small volumes of saliva or blood and can be utilized without the involvement of a health care professional.

The Diagnostic Challenge

To contain the spread of COVID-19, it is vital to ensure that people with SARS-CoV-2 stay home. The problem is that those who are infected are often asymptomatic and have no idea that they are exposing others to the virus. While asymptomatic people can always get tested, scarce testing resources are needed to diagnose patients who do exhibit symptoms. Moreover, current COVID-testing technologies generally take hours or days to produce results and require the use of expensive, complex equipment.

Truly effective screening of the asymptomatic would require tests capable of rapidly and accurately identifying infections that people could easily self-administer, like a scanning device that could be used before leaving home to ensure that the COVID-19 coast is clear.

The New Sensor-Based Test

Maybe, just maybe, the new Caltech test will turn out to be the prototype for this solution. A team of scientists that has previously developed wireless sensors capable of monitoring conditions such as gout and stress levels via the detection of extremely low levels of specific compounds in blood, saliva, or sweat, carried out the research in the laboratory of **Wei Gao**, assistant professor in the Andrew and Peggy Cherng Department of Medical Engineering at Caltech.

Gao's sensors are made of graphene, a sheet-like form of carbon. A plastic sheet etched with a laser generates a 3D graphene structure with tiny pores. Those pores create a large amount of surface area on the sensor, which makes it sensitive enough to detect, with high accuracy, compounds that are only present in very small amounts. The new version of the sensor, which is called the SARS-CoV-2 RapidPlex, contains antibodies and proteins that allow it to detect the presence of the virus itself; antibodies created by the body to fight the virus; and chemical markers of inflammation, which indicate the severity of the COVID-19 infection.

The device has been tested only in the laboratory thus far with a small

New Low-Cost Sensor Offers Promise Test for Rapid, At Home COVID-19 Testing, *from page 7*

number of blood and saliva samples obtained from individuals who have tested positive or negative for COVID-19. While preliminary results indicate that the sensor is highly accurate, the developers caution that larger-scale tests must still be performed.

Takeaway

Although exciting, the new scanner test will take at least a year to roll off the pipeline. With the pilot study completed, the next step will be to test how long the sensors last with regular use, and then begin testing them with hospitalized COVID-19 patients. After the in-hospital testing is completed, the researchers will have to evaluate the suitability of the tests for in-home use. Of course, once all of the testing is completed, the device will have to receive regulatory approval from the U.S. Food and Drug Administration before it is available for widespread use at home. The developers hope to be able to begin testing for in-home use sometime next year.

Testing Trends: Total Shipments of Molecular COVID-19 Tests Top 200 Million Mark

As of October 16, total U.S. shipments of COVID-19 molecular diagnostic tests have topped the 200 million mark, according to the AdvaMed COVID-19 Diagnostic Supply Registry (Registry). On average, diagnostics companies are shipping, over 1.4 million molecular tests every day. Registry data also show that approximately 121 million COVID-19 molecular tests have been administered.

The AdvaMed Registry

Since the pandemic began, federal and state government response actions have been impaired by the lack of widely available national data on COVID-19 testing and supplies has been a problem impairing since the pandemic began. On July 21, with that problem in mind, the Advanced Medical Technology Association (AdvaMed) launched a national COVID-19 diagnostic supply registry compiling information from diagnostic companies with publicly available daily test data. The Registry provides weekly state and national updates on the number of molecular and serology (antibody) tests shipped in the U.S. AdvaMed and AdvaMedDx, the association's diagnostics division, developed the Registry in partnership with 13 commercial diagnostics manufacturers:

- Abbott;
- Becton Dickinson;
- bioMérieux;
- Bio-Rad;

- Beckman Coulter;
- Cepheid;
- Hologic;
- Ortho Clinical Diagnostics;
- QIAGEN;
- Roche Diagnostics;
- Sekisui Diagnostics;
- Siemens Healthineers; and
- Thermo Fisher Scientific.

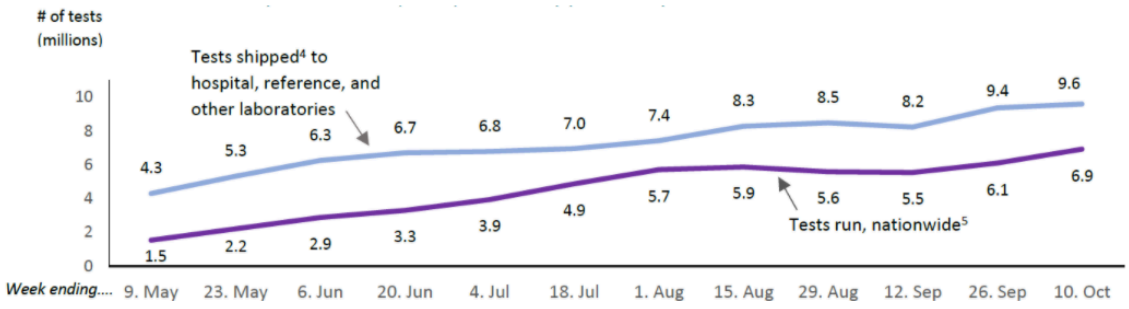
Key Registry Findings

According to the Registry, as of October 16:

- The 13 Registry participants have shipped over 200 million cumulative molecular COVID-19 tests nationwide since March 2020, including approximately 145 million commercial tests and 55 million extraction reagents;
- On a week to week basis, the number of daily molecular tests run increased approximately 5 percent compared to the previous week (October 9), up to an average of approximately 1.1 million tests per day;
- High-quality serology testing authorized by the U.S. Food and Drug Administration remains available at scale with industry capacity to manufacture 100 million tests per month.

Registry participants are also bringing antigen testing to the market with significant manufacturing capacity, the October 16 report notes.

Weekly Molecular (MDx) tests shipped & reported test results nationwide[3]



Source: AdvaMed COVID-19 Diagnostic Supply Registry

Takeaway

"For the past few months, our diagnostics companies have made it clear they'll do whatever it takes to stay ahead of COVID-19 testing demand to help bring this pandemic under control," Scott Whitaker, president and CEO of AdvaMed said in a press release, "200 million molecular tests shipped nationwide since the beginning of the pandemic is a remarkable testament to their commitment to saving lives."

Saliva and Oral Swabs Emerge as Scalable Alternative to Nasopharyngeal SARS-CoV-2 Testing, *from page 1*

The Diagnostic Challenge

There are three things about nasopharyngeal sample collection that impair its viability as a method for broad and widespread testing during the pandemic:

- It is uncomfortable for patients;
- It must be performed by a skilled health professional using appropriate personal protective equipment; and
- It requires swabs and chemicals which are currently in short supply.

As the pandemic spread, researchers began investigating cheaper, simpler alternatives for sample collection, including home collection kits and saliva-based tests.

The Case for Saliva-Based Testing

Among the nearly 200 COVID-19 diagnostic tests to receive Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA), nearly a dozen may be performed on saliva samples provided directly by the patient without the need for a health care professional. Like tests using swabs, saliva tests are based on polymerase chain reaction (PCR) technology, which amplifies small amounts of viral genetic material to facilitate detection. Some of the saliva tests to receive EUA, including assays from Yale and the University of Illinois, simplify the process by eliminating a standard intermediate step: the extraction of viral RNA. Their protocols also do not require viral transport media (VTM), the chemicals used to stabilize the samples after collection.

While nobody disputes that saliva testing is cheaper, simpler and easier on the supply chain, there are concerns about its accuracy as compared to testing on samples obtained by nasopharyngeal swabs. However, evidence is emerging to suggest that COVID-19 saliva-based is at least as reliable and accurate as swab-based testing.

A Yale University study published in The *New England Journal of Medicine* on August 28 found that the Yale saliva test actually detected the SARS-CoV-2 virus more frequently in patients known to have COVID-19, with 81 percent of the tests coming back positive in the first five days of infections, compared to the 71 percent rate got nasopharyngeal tests. The saliva test also detected more copies of the virus's genetic material.

A second study from the University of Ottawa published in the *Annals of Internal Medicine* the very same day was also supportive of saliva testing. The researchers tested nearly 2,000 people who had either mild symptoms of the virus or no symptoms but were at a high risk of infection. Participants collected their own saliva and also underwent the traditional swab test: 34 came back positive in both tests. In 14 cases, the virus was detected in the saliva sample, but not the nasal sample. In 22 cases, the

opposite was true. Although the nasal sample had a slight edge in detecting infections, the researchers concluded that the study findings support the case for use of saliva samples to diagnose SARS-CoV-2.

The Case for Oral Swab-Based Testing

Another alternative testing technique uses specimens collected by oral rather than nasopharyngeal swabs. Respiratory viruses colonize areas inside the nasal cavity and at the back of the throat. Besides the nasopharyngeal approach, nasal samples obtained with shorter and less invasive swabs have proven effective for COVID-19 testing. Unlike nasopharyngeal swabs, patients can self-swab, and the oral swab procedure takes less time to perform than a saliva test. However, unlike saliva tests, oral swab tests generally do require the involvement of a qualified health care professional.

A case study for the effectiveness of oral swab testing comes from the City of Los Angeles, which began using the Curative-Korva SARS-Cov-2 Assay, an oral swab test developed by Korva Labs. More than 10,000 samples have been collected per day since the City first started using the assay in late March (the test received EUA from the FDA on April 17) with Curative's three labs processing the tests.

Takeaway

Eight months into the pandemic, the move toward saliva and oral swab testing is gaining traction, with tens of thousands of people across the country undergoing such testing each day. However, saliva and oral swab tests still represent only a small percentage of the more than 900,000 tests conducted daily on average at the end of September. One reason for the slow adoption is the inherently caution displayed by regulators, payors and clinicians toward new and unproven technologies and understandable predilection and preference for well-established protocols.