



April 22nd, 2020

COVID-19 TOWN HALL

Agenda

- Board of Pharmacy Update
- Legislative Update
- State and National COVID Updates
- COVID-19 Testing
- Q & A

Kam Gandhi

Executive Director
AZ Board of Pharmacy

BOARD OF PHARMACY UPDATE

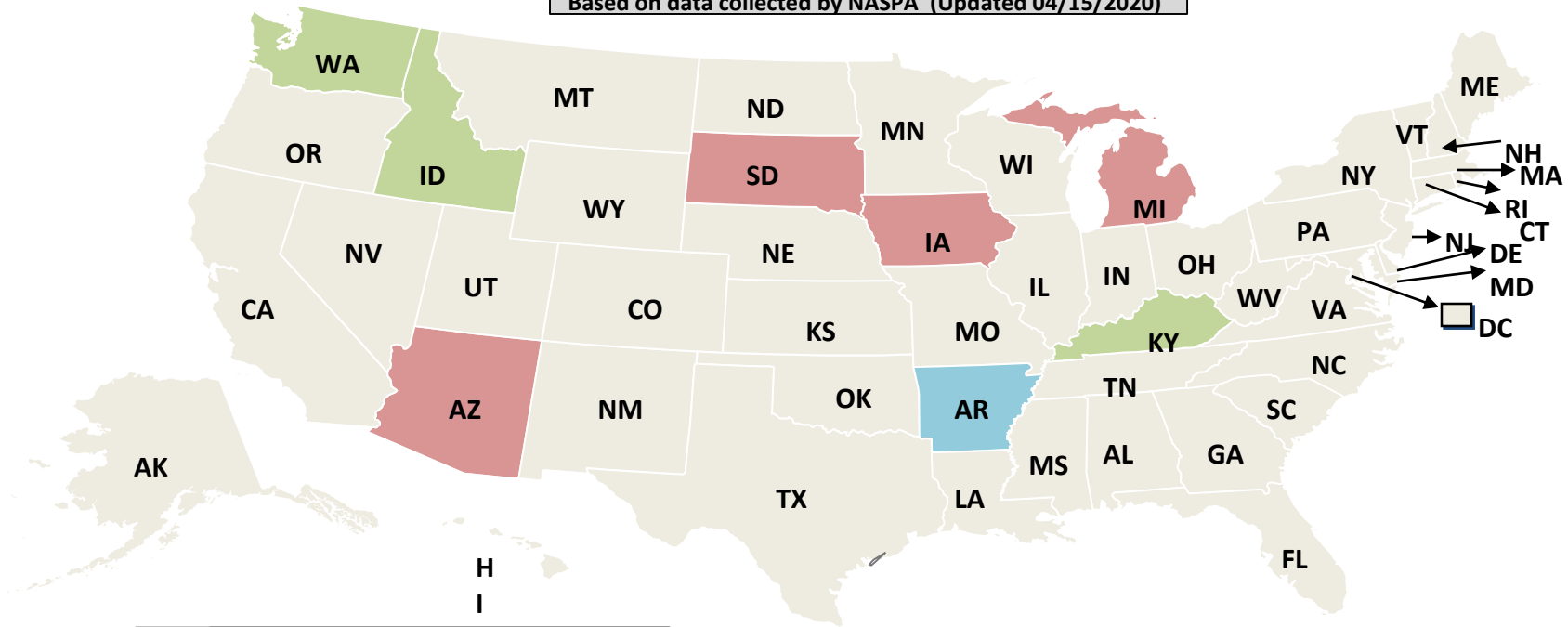
- [FAQ'S](#)
- [Submit ?'s](#)
- COVID Task Force Update

COVID-19: State Comparison

- Therapeutic Interchange
- Compounding of Hand Sanitizer
- Hydroxychloroquine | Chloroquine | Azithromycin

State Policy Map For Therapeutic Interchange

Based on data collected by NASPA (Updated 04/15/2020)

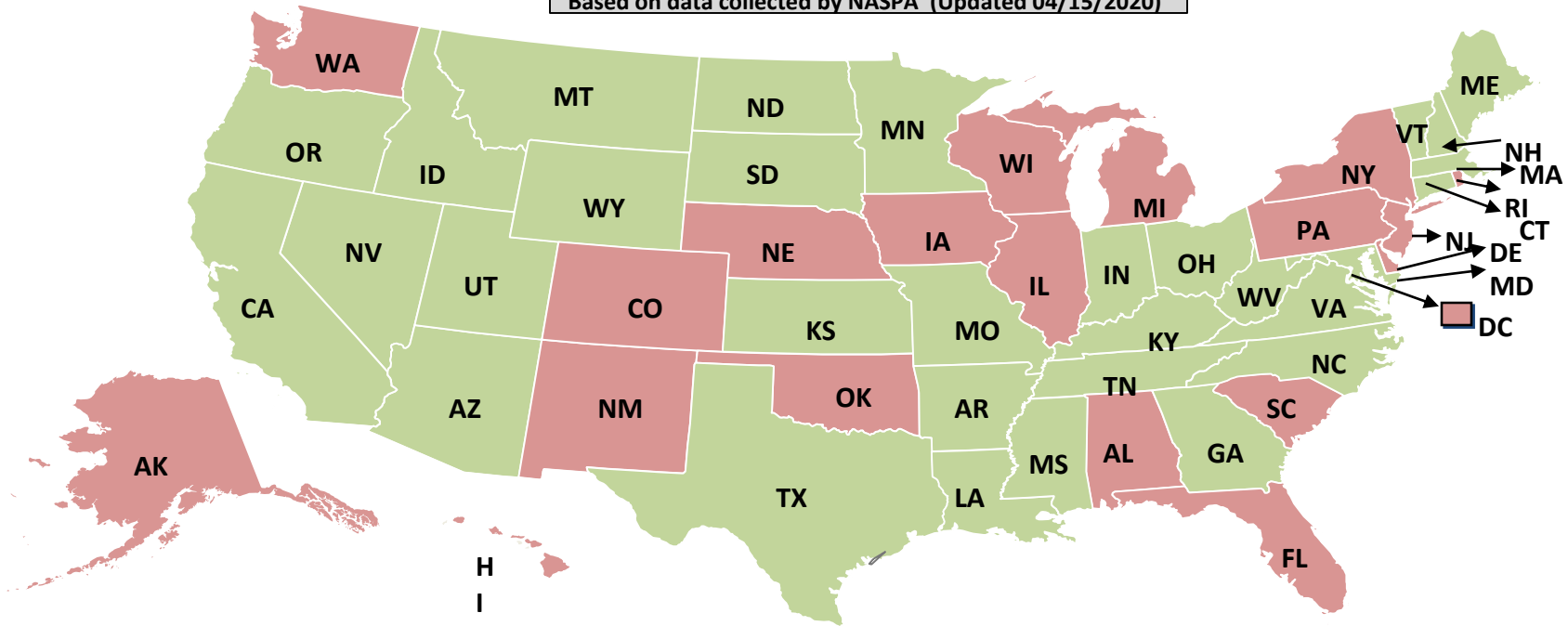


	No Action Taken
	Emergency Authority
	Pre-Existing Authority
	Pre-Existing + Emergency Authority



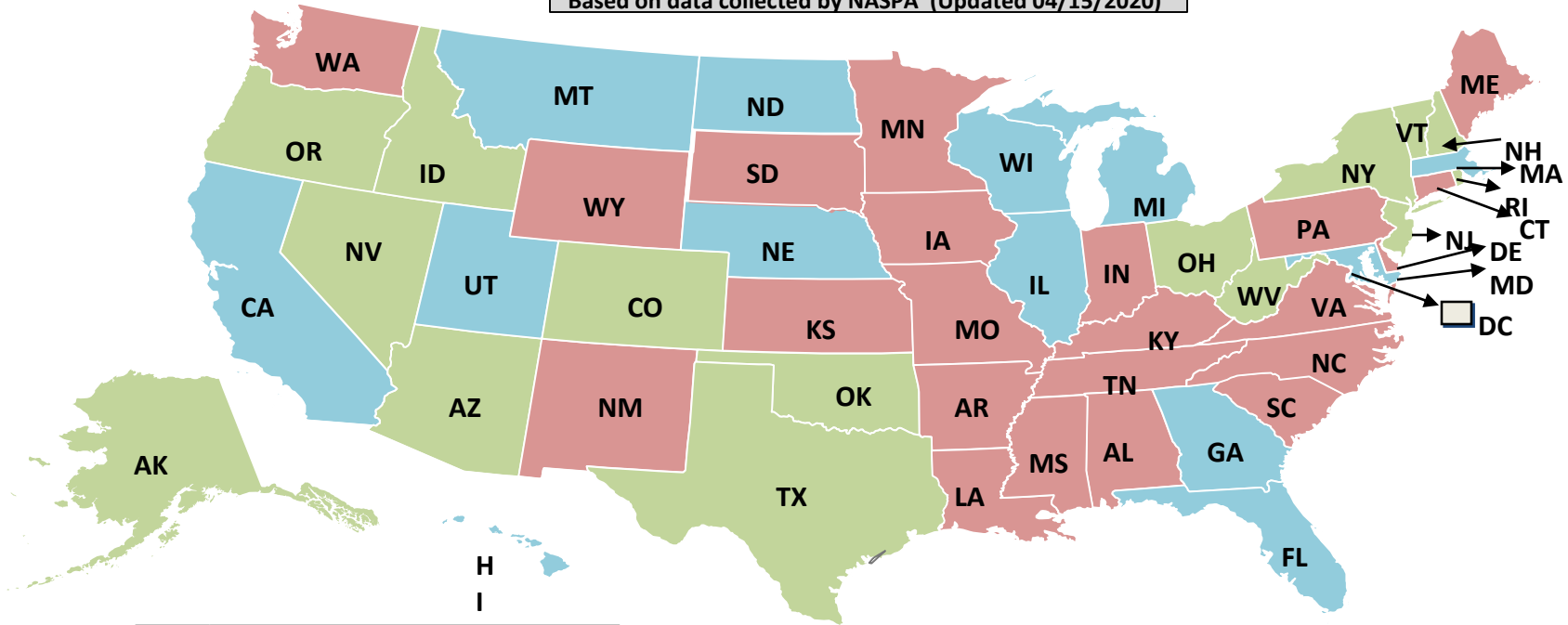
State Policy Map For Compounding of Hand Sanitizer

Based on data collected by NASPA (Updated 04/15/2020)



State Policy Map For Hydroxychloroquine/Chloroquine/Azithromycin

Based on data collected by NASPA (Updated 04/15/2020)



	No Action Taken
	Use Professional Judgement
	Requirements in-place



Jessie Armendt

AzPA Contract
Lobbyist

Legislative Update

LEGISLATURE TO ADJOURN SINE DIE ON MAY 1, CONSIDER SPECIAL SESSION LATER

House and Senate leadership agreed to reconvene the Legislature next week in order to adjourn *sine die* by [May 1](#), Shope told our reporter. That date would fall immediately after the official conclusion of Ducey's stay-at-home order, the point at which federal guidelines about social distancing and gathering in groups of ten or more are theoretically lifted. "Most of the issues we have in front of us now are budget and fiscal related," Shope said. "If we don't have the answers we need until the first of June, there's no reason for us to be there any longer." He's not expecting any business from the first half of the session to be on the agenda. Rather, lawmakers will convene and someone will make a motion to adjourn - "ceremonial as it is," Shope said. Then, legislative leadership will look to convene in a special session in order to balance the state's books over the summer. "It's an excellent idea, I think we need to all continue to do what we're doing ... we're flattening the curve by staying close to home," Fernandez, who confirmed Shope's account, said. She said lawmakers will have a more accurate picture of the state's finances by the summer, at which time they can consider passing further aid packages. Shope said lawmakers will have to be physically present for the purposes of attendance, but will likely be able to vote on the motion remotely.

State Budget Update

- Until late March, the state's economy was strong and revenues were up 8.1% over the prior year
- Finance Advisory Committee (FAC) anticipates the COVID-19 pandemic will reduce FY 2020 4th quarter revenues by 24% and projects that the state will face a \$1.1 billion shortfall by the end of FY 2021 (with a margin of error of \$500 million in either direction).
- Due to lags in both TPT data and income tax data, we likely won't have a full picture of the economic impact until late May or early June - FAC will meet again in June prior to the end of the fiscal year.

Proposed State or Regional Gating Criteria

(Satisfy Before Proceeding to Phased Opening)

SYMPTOMS

Downward trajectory of influenza-like illnesses (ILI) reported within a 14-day period

AND

Downward trajectory of covid-like syndromic cases reported within a 14-day period

CASES

Downward trajectory of documented cases within a 14-day period

OR

Downward trajectory of positive tests as a percent of total tests within a 14-day period (flat or increasing volume of tests)

HOSPITALS

Treat all patients without crisis care

AND

Robust testing program in place for at-risk healthcare workers, including emerging antibody testing

*State and local officials may need to tailor the application of these criteria to local circumstances (e.g., metropolitan areas that have suffered severe COVID outbreaks, rural and suburban areas where outbreaks have not occurred or have been mild). Additionally, where appropriate, Governors should work on a regional basis to satisfy these criteria and to progress through the phases outlined below.

<https://apps.npr.org/documents/document.html?id=6840714-Guidelines>

Core State Preparedness Responsibilities

TESTING & CONTACT TRACING

- ✓ Ability to quickly set up safe and efficient screening and testing sites for symptomatic individuals and trace contacts of COVID+ results
- ✓ Ability to test Syndromic/ILI-indicated persons for COVID and trace contacts of COVID+ results
- ✓ Ensure sentinel surveillance sites are screening for asymptomatic cases and contacts for COVID+ results are traced (sites operate at locations that serve older individuals, lower-income Americans, racial minorities, and Native Americans)

HEALTHCARE SYSTEM CAPACITY

- ✓ Ability to quickly and independently supply sufficient Personal Protective Equipment and critical medical equipment to handle dramatic surge in need
- ✓ Ability to surge ICU capacity

PLANS

- ✓ Protect the health and safety of workers in critical industries
- ✓ Protect the health and safety of those living and working in high-risk facilities (e.g., senior care facilities)
- ✓ Protect employees and users of mass transit
- ✓ Advise citizens regarding protocols for social distancing and face coverings
- ✓ Monitor conditions and immediately take steps to limit and mitigate any rebounds or outbreaks by restarting a phase or returning to an earlier phase, depending on severity

Guidelines for All Phases: Employers

Develop and implement appropriate policies, in accordance with Federal, State, and local regulations and guidance, and informed by industry best practices, regarding:

- ✓ Social distancing and protective equipment
- ✓ Temperature checks
- ✓ Testing, isolating, and contact tracing
- ✓ Sanitation
- ✓ Use and disinfection of common and high-traffic areas
- ✓ Business travel

Monitor workforce for indicative symptoms. Do not allow symptomatic people to physically return to work until cleared by a medical provider.

Develop and implement policies and procedures for workforce contact tracing following employee COVID+ test.

Phased Opening Criteria

- **Phase 1:** Vulnerable individuals should continue to shelter in place. Other individuals may begin to venture out in public in groups of no more than 10 people. Telework continues to be encouraged. Large venues (sit-down dining, movie theaters, sporting venues, places of worship) can operate under strict physical distancing protocols. Elective surgeries can resume and gyms can open if they adhere to strict physical distancing and sanitation protocols.
- **Phase 2:** Vulnerable individuals should continue to shelter in place. Other individuals should avoid congregating in groups of more than 50 people. Non-essential travel can resume. Schools can reopen. Large venues can operate under moderate physical distancing protocols. Bars may operate with diminished standing-room occupancy.
- **Phase 3:** Vulnerable adults can resume public interactions, but should practice physical distancing. Worksites can resume unrestricted staffing. Visits to senior care facilities and hospitals can resume. Large venues can operate under limited physical distancing protocols. Bars may operate with increased standing room occupancy.

KELLY FINE

Executive Director
AzPA

Updated Healthcare Facility Guidance

- **Actively screen everyone for fever and symptoms of COVID-19 before they enter the healthcare facility.**
- **To protect others in case of asymptomatic or pre-symptomatic transmission, everyone entering a healthcare facility (e.g., healthcare personnel, patients, visitors) should wear a mask or cloth face covering, regardless of symptoms.**
 - HCP should wear a surgical grade face mask; non-HCP can wear a cloth face covering

Updated 4-20-20: https://www.maricopa.gov/DocumentCenter/View/58541/HCF_Guidance

PLEASE REMEMBER TO ENFORCE SICK POLICIES!

Table. Clinical Course and Outcomes of Health Care Personnel With Confirmed SARS-CoV-2 Infection—King County, Washington

	No. (%)		
	Total health care personnel (N = 48)	Onset with fever, cough, shortness of breath, or sore throat (n = 40 [83.3%])	Onset without fever, cough, shortness of breath, or sore throat (n = 8 [16.7%])
Initial symptoms			
Cough	24 (50.0)	24 (60.0)	0
Fever ^a	20 (41.7)	20 (50.0)	0
Myalgias	17 (35.4)	15 (37.5)	2 (25.0)
Headache	8 (16.7)	7 (17.5)	1 (12.5)
Chills	7 (14.6)	5 (12.5)	2 (25.0)
Sore throat	7 (14.6)	7 (17.5)	0
Coryza	6 (12.5)	4 (10.0)	2 (25.0)
Shortness of breath	5 (10.4)	5 (12.5)	0
Malaise	5 (10.4)	3 (7.5)	2 (25.0)
Diarrhea	3 (6.3)	3 (7.5)	0
Voice hoarseness	2 (4.2)	1 (2.5)	1 (12.5)
Anorexia	1 (2.1)	1 (2.5)	0
Nausea/vomiting	1 (2.1)	1 (2.5)	0
Abdominal pain	1 (2.1)	0	1 (12.5)

Make sure your fever/respiratory symptom screening system for healthcare personnel is in place and working

Please reinforce that NO ONE should work with respiratory symptoms

Fever alone is not a good screening tool, so it is important to use symptom screening!

<https://jamanetwork.com/journals/jama/fullarticle/2764953>

Update: New Healthcare Facility Guidance

- Updated isolation and quarantine recommendations when a patient is transferred to a lower acuity care setting, based on Governor's Executive Order 2020-22.
- Patients/Residents who tested COVID-19 positive AND require ongoing isolation should be isolated for 14 days after initial admission or readmission to a long-term care facility with COVID-19 isolation precautions.
 - A patient/resident requires ongoing isolation if they have not completed the following isolation duration while in a higher acuity facility:
 - 7 days after their COVID-19 test was collected AND
 - Until they have been free of fever and symptoms of acute infection for 72 hours •
- Patients/Residents with unknown COVID-19 testing should be quarantined in their rooms using COVID-19 isolation precautions for 14 days after admission or readmission to a long-term care facility from an acute care facility.

CDC'S Updates Guidance for Pharmacists and Pharmacy Technicians in Community Pharmacies

- **Everyone entering the pharmacy should wear a face covering, regardless of symptoms.**
 - Exclusions include: young children under age 2, anyone who has trouble breathing, or is unconscious, incapacitated or otherwise unable to remove the mask without assistance.
- **Pharmacists and pharmacy technicians should always wear a facemask while they are in the pharmacy for source control.**
- Postpone and reschedule delivery of some routine clinical preventive services, such as adult immunizations, which require face to face encounters.

[CLICK HERE](#)

FDA Releases Guidance for 503A Compounding Pharmacies to Compound Certain Drugs for Hospitalized Patients

- If a hospital cannot find a 503B (outsourcing) to meet its urgent need for COVID treatment drugs, 503A compounding pharmacies that are accustomed to preparing sterile medications, may provide compounded medications to a hospital without a patient-specific prescription.
- FDA does not intend to take action against a pharmacy for compounding a drug that is essentially a copy of a commercially available drug, or for providing a drug to a hospital without obtaining a patient-specific prescription, if all of the following circumstances are present and the other conditions of section 503A of the FD&C Act are met.

Note: FDA states that the State Board of Pharmacy has to adopt the policy

[CLICK HERE](#)

Appendix A: List of Drugs Used for Hospitalized Patients with COVID-19

FDA has identified the following list of drugs for the purposes of the temporary enforcement policies described in this guidance.

Products that are aqueous solutions for injection:

- Cisatracurium besylate
- Dexmedetomidine hydrochloride
- Etomidate
- Fentanyl citrate
- Furosemide
- Hydromorphone hydrochloride
- Ketamine hydrochloride
- Lorazepam
- Midazolam hydrochloride
- Norepinephrine bitartrate
- Rocuronium bromide
- Vancomycin hydrochloride
- Vecuronium bromide

Where is Your Provider Refund?

- All providers who received Medicare fee-for-service reimbursements in 2019, such as pharmacies enrolled as Medicare Part B suppliers, are eligible to receive part of the CARES Act Provider Relief Fund.
- HHS requires signing an attestation form within 30 days of receiving the payment through the HHS portal
 - [CLICK HERE](#)
- If you want to know if your pharmacy is eligible for reimbursement from the provider relief fund, call the United Health Group hotline
 - 1-866-569-3522.
 - UHG is sending funds on behalf of HHS and will look up individual pharmacies by their tax ID number to check eligibility and when they should expect payment.

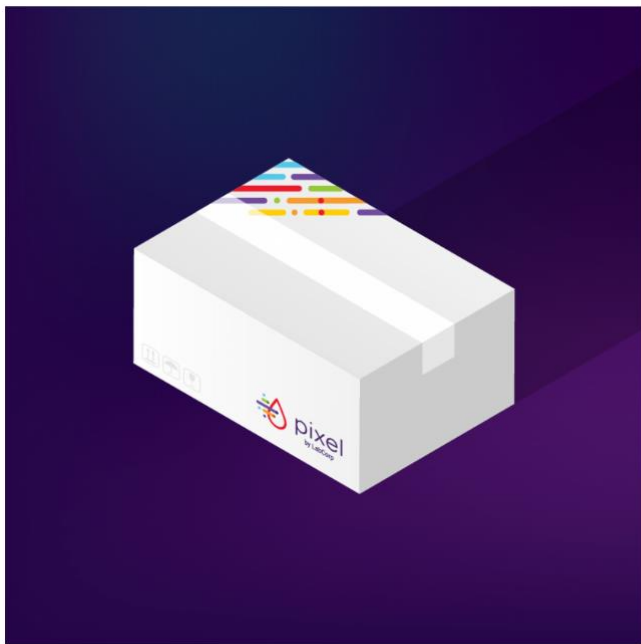
COVID Testing by Pharmacists

What we know so far...

References:

- https://media.pharmacist.com/COVID19/APhACovid-19Demystifying0420_Revised_web.pdf
- <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>
- <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

First-At Home Test Kit Approved



COVID-19 Test (At-Home Kit)

Sample Type:  Nasal Swab

GET STARTED

\$119

Now you can access COVID-19 testing from home.

We'll send you an at-home kit to collect your nasal swab sample and ship it back to our lab. Our lab will test your sample for SARS-CoV-2, the virus that causes coronavirus disease (also called COVID-19), a respiratory illness.

First diagnosed in Wuhan, China in December 2019, COVID-19 has since spread around the globe. When an infected person coughs, sneezes, or exhales air, droplets containing the SARS-CoV-2 virus go into the air and onto surfaces and objects around them. Other people are exposed to the virus by breathing in these droplets or by touching their eyes, nose, or mouth after touching infected surfaces.

* Pixel by LabCorp offers this test and collection kit with an FDA Emergency Use Authorization. This means that while the laboratory performing this test has validation data to support offering this test and the collection kit, neither have been approved or cleared by the FDA. This test has only been authorized by FDA for detection of nucleic acid from SARS-CoV-2 (i.e., the COVID-19 virus), and not for any other virus or pathogen. It is only authorized during the duration of the COVID-19 emergency declaration by federal regulators. LabCorp may modify or cease to offer the test and the test kit upon direction of state or federal regulators in its sole discretion. Please see the [Patient Fact Sheet](#) for additional information.

Types of COVID-19 Testing

Type of Assay	Specimen Type in SARS-CoV-2	Typical Time for Analysis	Notes
Molecular assays Example: reverse-transcriptase polymerase chain reaction (RT-PCR)	Respiratory	A few hours to 2 days	<ul style="list-style-type: none">• Gold standard for sensitivity• Must be analyzed in a certified laboratory• Detects pathogen presence
Rapid molecular assays Example: rapid RT-PCR (RT-qPCR or rRT-PCR)	Respiratory	15-30 minutes	<ul style="list-style-type: none">• Can be conducted at point-of-care• Detects pathogen presence
Serology assays Examples: lateral flow assay, enzyme-linked immunosorbent assay (ELISA), neutralization ("neut") assay	Blood	10 minutes to 5 days	<ul style="list-style-type: none">• Can be conducted at point-of-care• Detects antibodies to determine active infection (IgM) vs. established infection or acquired immunity (IgG)

Greatest number of specimens have been collected by nasopharyngeal swab. On March 24, the CDC made changes to allow for self-collection of nasal and nasal turbinate swabs as an alternative to nasopharyngeal swabs. [CLICK HERE](#)

FDA COVID Test Authorization Process

How does FDA authorize COVID-19 tests?

FDA's [Policy for Diagnostic Tests for Coronavirus Disease-2019](#) "describes policies intended to help rapidly expand testing capacity by facilitating the development and use of SARS-CoV-2 diagnostic tests during the public health emergency." There are three main paths for COVID-19 tests to being "approved" for use:

- Obtaining an emergency use authorization (EUA) from the FDA
- Developing the test under the [authorities of the State](#), in which the laboratory operates, and the State takes responsibility for, COVID-19 testing by laboratories in its State
- Using serological testing without an EUA

The policies and guidance above do not apply to [home-based tests](#) and self-collection of samples to be sent to laboratories. Manufacturers of those tests should work directly with FDA early in the development process.

[FDA EUA and FAQ](#)

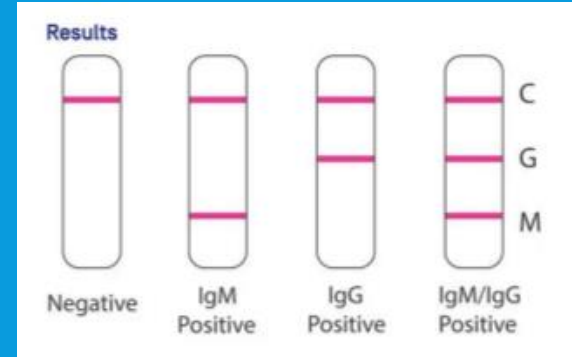
NOTE: EUA does not mean
FDA approved

Diagnostic test with EUA's and Can Be Provided in a Pharmacy

Diagnostic Test (Manufacturer)	Diagnostic Method	Patient Care Setting Instrument Required	Specimen Collected via		
			Nasopharyngeal	Nasal	Throat
<u>ID NOW COVID-19</u> (Abbott)	Molecular	ID NOW Instrument	Swab	Swab	Swab
<u>Accula SARS-Cov-2 Test</u> (Mesa Biotech Inc.)	Molecular	Accula Dock or Silaris Dock	—	Swab	Swab
<u>Xpert Xpress SARS-CoV-2 test</u> (Cepheid)	RT-PCR	GeneXpert Dx and GeneXpert Infinity Systems	Swab	Wash/ Aspirate	—

Serology Testing

- Many tests are available:
 - Some operating under EUA from FDA
 - None are FDA-approved
 - **None are CLIA waived**
- Unknown cross-reactivity
- Unknown correlation with immunity
- Useful for population-level studies, but less for individual clinical and infection control decisions



Clinical Laboratory Improvement Amendments (CLIA)

- CLIA regulations establish quality standards for lab testing performed on specimens from humans, such as blood, body fluid, and tissue for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health
- FDA, CMS, and CDC are jointly responsible for CLIA test
- How to obtain a CLIA certificate of waiver: [CLICK HERE](#)

\$180- Certificate is good for 2 years

Testing Criteria

- Healthcare professionals should prioritize testing among three specific groups until sufficient and consistent PPE, testing supplies and capacity are widely available:
 - Healthcare workers, first responders, and employer identified critical infrastructure personnel* with COVID-19 symptoms
 - Individuals living in congregate settings with symptoms of COVID-19
 - Individuals hospitalized with respiratory symptom
- Healthy individuals do not require testing. These individuals should practice social-distancing and follow the recommendations of their local and state public health authorities.
- Follow Arizona Department of Environmental Quality and appropriate state and federal laws for biohazard waste disposal.
- Report all COVID test results to ADHS

[AzPA Website](#) Updated Regularly



ATTENTION

Information on this web page is updated multiple times a day. Check back frequently for the most up to date information.

COVID-19 Hotline	+
COVID-19 Testing - Information for Pharmacists	+
Board of Pharmacy Updates	+
Emergency Statutes Executive Orders	+
DEA Guidance [Controlled Substance]	+
State Resources State Testing Sites	+
National Resources	+
Personal Protective Equipment (PPE)	+
FDA Guidance Compounding & Drug Shortages	+
PBM Insurance Concessions	+
CE Clinical Information	+
Staffing Shortage	+
News Press Releases Updates	+

Questions?