

COVID-19 TOWN HALL

May 20th, 2020

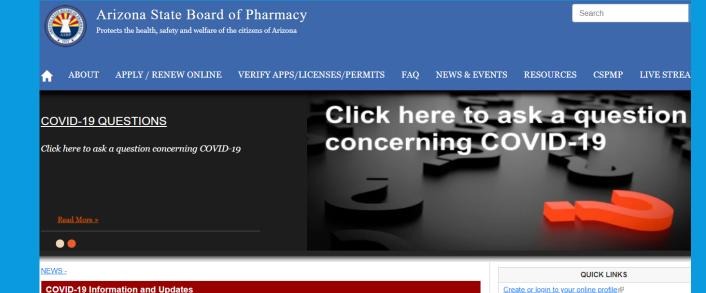


# **Board of Pharmacy Update**

Kam Gandhi Executive Director | AZ Board of Pharmacy

## **BOARD OF PHARMACY UPDATE**

<u>FAO'S</u><u>Submit ?'s</u>



Submit COVID-19 Questions

<u>COVID-19 FAQs</u> updated 4/23/20 (as situations progress, the FAQ will continue to change and be revised). Please check the ASBP website for updates.

Governor Ducey's Executive Order - Expanding Access to Pharmacies @ (see updated FAQs @)

Create or login to your online profile@ Apply for license/permit online Verify apps/licenses/permits Change your Address / Employment / PIC@ Submit a Complaint Submit Suspicious Activity Report@ Board Meetinos

# State and National Updates

Kelly Fine Executive Director | Arizona Pharmacy Association



433

#### ARIZONA DEPARTMENT OF HEALTH SERVICES

Health and Wellness for All Arizonans

1,888

97

46

HOME AUDIENCES TOPICS DIVISIONS A-Z INDEX Summary Show case counts or population rates in the map below? Number of Number of Cases • Cases Deaths Select a county to filter the other numbers. Deaths will not be shown for counties with fewer than three deaths. 14,566 704 Number of New Cases Number of New Deaths reported today\* reported today\* 396 18 943 262 Rate of cases, per 100,000 Rate of fatalities, per 1,320 1,023 100,000 population population 269 202.6 9.79 22 38 Total COVID-19 PCR Tests New PCR Tests reported 3 today\* 720 20

 Total COVID-19 PCR Tests
 New PCR Tests reported today\*
 PCR Percent Positive\*\*

 161,571
 5,098
 6.9%

 Total COVID-19 Serology
 New Serology Tests reported today\*
 Serology Percent Positive\*\*

 59,041
 2,730
 3.1%

\*Counts of new cases, deaths, and numbers tested reflect increases in the total numbers compared to the previous day.

\*\*Percent positive is the number of people with a positive test result, out of all people with COVID-19 testing completed in AZ.

ENHANCED BY Google

Number of

COVID-19 Tests

220,612

Number of New Tests

reported today\*

7,828

Total Percent Positive\*\*

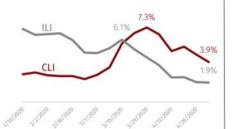
5.9%

# **Returning Stronger**

Data show Arizona is ready for a gradual and phased-in return.

#### DECLINING SYMPTOMS

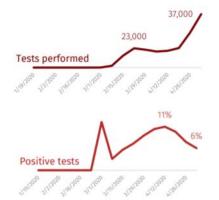
Hospital visits for COVID-like Illness (CLI) & Influenza-like Illness (ILI) are declining.





#### DECLINING PERCENTAGE OF POSITIVE TESTS

As the number of COVID-19 diagnostic tests has increased, the percentage of positive tests has decreased.



#### TREAT ALL PATIENTS WITHOUT CRISIS CARE

PHASE 1

- 1,405 healthcare providers with adequate PPE, including 51 hospitals
- Adequate hospital beds, ICU beds and ventilators

#### ROBUST TESTING FOR AT-RISK HEALTHCARE WORKERS

- 51 hospitals attesting to a robust testing plan
- Implementing COVID-19 testing for residents and staff of 147 long-term care facilities
- Tens of thousands of serology tests reported to ADHS

## **ADHS Standing Order**

This standing order is issued by Dr. Cara Christ, MD MS (NP #1639369036), Director of the Arizona Department of Health Services. This standing order authorizes any licensed pharmacist, as per guidance by Health and Human Services, to order and administer (or oversee the administration by trained personnel) a SARS-CoV-2 RT-PCR test for any individual in accordance with the conditions of this order.

#### PATIENT ELIGIBILITY

The following criteria are required for a pharmacist at a testing location to administer and collect a SARS-CoV-2 RT-PCR test by this standing order:

Individual who is concerned that he or she has been exposed to and infected with COVID-19

#### AND

Individual who has signed a consent and voluntary isolation agreement (or parent/guardian, if patient cannot legally consent)

#### PLAN OF CARE

A licensed pharmacist/trained personnel operating at a pharmacy or testing location may collect a nasopharyngeal swab or other appropriate clinical specimen and order a SARS-CoV-2 RT-PCR.

### What does this mean?



STANDING ORDER FOR COVID-19 TESTING LOCATIONS LABORATORY TEST: SARS-CoV-2 RT-PCR

This standing order is issued by Dr. Cara Christ, MD MX (NP #1639369036), Director of the Arizona Department of Health Services. This standing order authorizes any licensed pharmacist, as per guidance by Health and Human Services, to order and administer (or oversee the administration by trained personnel) a SARS-CoV-2 RT-PCR test for any individual in accordance with the conditions of this order.

#### PATIENT ELIGIBILITY

The following criteria are required for a pharmacist at a testing location to administer and collect a SARS-CoV-2 RT-PCR test by this standing order:

- Individual who is concerned that he or she has been exposed to and infected with COVID-19
- AND

Individual who has signed a consent and voluntary isolation agreement (or parent/guardian, if patient cannot legally consent)

#### PLAN OF CARE

A licensed pharmacist/trained personnel operating at a pharmacy or testing location may collect a nasopharyngeal swab or other appropriate clinical specimen and order a SARS-CoV-2 RT-PCR.

- A. Preparation to collect a nasopharyngeal swab:
  - Ensure correct testing materials: (1) Sterile Dacron/nylon swab with an aluminum or plastic shaft (cotton swabs with wooden shafts are not recommended); (1) Viral transport media tube with 1-3mL of sterile viral transport medium.
  - Ensure appropriate personal protective equipment for medical provider: gloves, gowns, surgical mask (or respirator) and eye
    protection (goggles or face shield).
- B. Instructions to collect a nasopharyngeal swab:
  - 1. By medical provider / trained personnel:
    - Tilt patient's head back 70 degrees.
    - Insert swab into nostril parallel to the palate. Leave the swab in place for a few seconds to absorb secretions.
    - Slowly remove swab while rotating it.
    - Place tip of swab into sterile viral transport media tube and snap/cut off the applicator stick.
  - 2. By patient: Follow manufacturer-specific instructions for specimen collection.
- C. Instructions to process clinical specimens:
  - Store specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70°C or below.
  - Process specimens in accordance with national biological safety regulations, procedures as listed under the CDC Emergency Authorization Agreement, and the supervising Arizona healthcare facility or pharmacy.

NOTE: Pharmacies should have access to medical personnel to assess and respond should a patient need medical attention. NOTE: Processes to collect other appropriate clinical specimens should follow test manufacturer instructions. NOTE: tensenewn medical services should be activated if a patient appears toxic, is struzgling to breathe, or moribund.

#### FOLLOW-UP

Test results should be reported to the patient within one week of the testing unit's receipt of the test result.
 A positive result requires continued in-home isolation per local health department recommendations.

2. Results should be reported to the Arizona Department of Health Services, as required by Arizona Administrative Code, R9-6-202.

Cara Christ, MD MS, Director of Arizona Department of Health Services Effective Date: 5/15/2020; Expiration Date: 6/30/2020

Douglas A. Ducey | Governor Cara M. Christ, MD, MS | Director

150 North 18th Avenue, Suite 500, Phoenix, AZ 85007-3247 P | 602-542-1025 F | 602-542-0883 W | azhealth.gov Health and Wellness for all Arizonans

## **HHS-More Guidance**



#### DEPARTMENT OF HEALTH & HUMAN SERVICES

- The US Health and Human Services (HHS) issued an advisory opinion yesterday concluding that licensed pharmacists may order and administer COVID-19 tests.
- This confirms the Administration's intent and confidence in pharmacists to provide expanded and widespread testing capacity for Americans across the entire country.
- We are still evaluating the opinion and how this impacts pharmacists' payment and billing for COVID-19 tests.
- <u>At this time we do know</u>:
  - You will need a CLIA Waiver
  - NPI number (good idea if you plan to continue to do POC tests)
  - You may need to apply as Independent Clinical Lab through Medicare



## Yet Another Update!

- The House of Representatives reconvene on Tuesday, May 19<sup>th</sup>
  - Note: Bills cannot be amended because any SBs that get amended in the House have to go back to the Senate for final read and the Senate has indicated that they will not vote bills (other than perhaps the liability protection issue or a few third reads they may have ready to go).
- At this time, the Senate does not plan to reconvene this week but that is subject to change.

## House of Representative - Guidelines

PLEASE NOTE: PPE (masks) is required in committee hearing rooms for members, staff, and guests.

Upon entering the building, you will see signage conveying the following messages: **BY ENTERING THE HOUSE OF REPRESENTATIVES BUILDING, YOU ARE AGREEING TO ABIDE BY THE HOUSE'S CDC-BASED GUIDELINES. YOU MAY BE ASKED TO LEAVE IF YOU FAIL TO ABIDE BY THE GUIDELINES.** 

#### **STAY SAFE AND HEALTHY**

- PROTECT YOURSELF & OTHERS FROM THE SPREAD OF COVID-19. PLEASE FOLLOW THESE HOUSE OF REPRESENTATIVES SAFETY GUIDELINES:
  - If you are feeling sick, please do not enter the building. (Everyone will have their temperature taken upon entry)
  - PPE is expected to be worn by everyone. (PPE is available by request)
  - Strict social distancing is required. (Maintain six feet apart from others)
  - Only 2 people may enter an elevator at any one time
  - Wash your hands with soap and/or use hand sanitizer regularly
  - Cover your cough and sneeze and avoid touching your face

## Emerging Condition: Possible Kawasaki Diseaselike Syndrome Associated with COVID-19

A **pediatric multi-system inflammatory syndrome** has recently been reported in the UK and NYC that may be linked to COVID-19.

 Clinical features of this syndrome have been noted to include features of Kawasaki disease or shock; persistent fever and elevated inflammatory markers such as CRP and troponin have been seen among affected patients. Many of these children have tested positive either for COVID-19 or for its antibodies.

#### If the above-described inflammatory syndrome is suspected, Arizona providers should immediately:

- **Refer patients to a specialist**. (pediatric infectious disease, rheumatology, and/or critical care) Early diagnosis and treatment of patients meeting full or partial criteria for Kawasaki disease is critical to preventing end-organ damage and other long-term complications. Patients meeting criteria for Kawasaki disease should be treated with intravenous immunoglobulin and aspirin.
- **Consider COVID-19 testing**. Many pediatric patients with this syndrome did not show respiratory symptoms, yet tested positive for COVID-19 or its antibodies.
- **Report suspected cases of Kawasaki Disease-like Syndrome to <u>local public health</u>. Real-time surveillance of this is critical to public health understanding and recommendations.**

## **Update: Residency Licensure Requirements**

Q: My incoming resident is having difficulty scheduling licensing exams. Test dates are already scheduled through September 2020. Is the Commission on Credentialing going to consider any actions to assist incoming residents who are having difficulty testing?

A: The Commission on Credentialing and ASHP Board of Directors approved a temporary waiver and extension of the licensure requirement for residents until January 1, 2021. This temporary waiver is for the requirement that residents complete at least two-thirds (2/3) of the residency year as a licensed pharmacist. This waiver is only for the 2020-2021 residency year.

**PLEASE NOTE**: Incoming residents are expected to schedule and take all required licensing exams at the earliest date possible.

# FDA Warns About Possible Accuracy Concerns with Abbott ID NOW POC Test

- The FDA has received 15 adverse event reports about the Abbott ID NOW device that suggest some users are receiving inaccurate negative results. The agency is reviewing these reports.
- This test can still be used and can correctly identify many positive cases in minutes. Negative results may need to be confirmed with a high-sensitivity authorized molecular test.
- Abbott has agreed to conduct post-market studies for the ID NOW device that each will include at least 150 COVID-19 positive patients in a variety of clinical settings. The FDA will continue to review interim data on an ongoing basis.



## **FDA Clears Standalone At-Home Collection Kit**

#### COVID-19 Test Home Collection Kit

Diagnose whether you are infected with SARS-CoV-2. The Everlywell COVID-19 Test Home Collection Kit and our lab partners have received Emergency Use Authorization from the FDA. After an online screening, you can collect your sample and send it for processing to a certified lab for secure digital results within days. A telehealth consult is available to guide you through your next steps.

#### Measures

Presence or absence of RNA from SARS-CoV-2 virus

#### **Collection Method**

§ Self-collected nasal swab

#### Available results in

3-5 days from purchase (overnight shipping to the lab is included)



Before purchasing this test, you must complete an eligibility questionnaire developed in accordance with the Centers for Disease Control and Prevention (CDC) recommendations.

#### COVID-19 Test Home Collection Kit \$109

**Check Availability** 

#### **CLICK HERE**

FDA Updates Temporary Policy Regarding Non-Standard PPE Practices for Pharmacy Compounders During the COVID-19 Public Health Emergency

- On May 14<sup>th</sup> the FDA issued an update to its guidance for pharmacy compounders that experience shortages, due to the COVID-19 public health emergency, of the (PPE) they typically use to compound sterile drugs.
- The FDA clarified that drugs can be compounded in a segregated compounding area that is not in a cleanroom, when the following BUD are utilized:
  - Up to 12 hours for product stored at room temp
  - Up to 24 hours for refrigerated products

#### <u>CLICK HERE</u>

## COVID-19 Event Risk Assessment Planning Tool

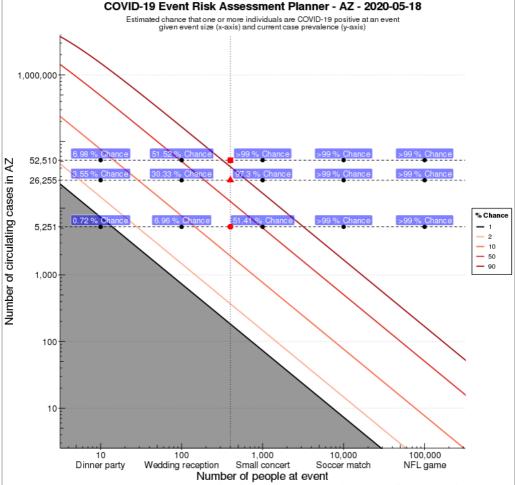
The horizontal dotted lines with risk estimates are based on real-time COVID19 surveillance data. They represent estimates given:

- Current reported incidence [CI] (●)
- 5 times the current incidence (▲)
- 10 times the current incidence (■)

These estimates help understand the effects of potential under-testing and reporting of COVID19 incidence.

#### **CLICK HERE**

Chande, A.T., Gussler, W., Harris, M., Rishishwar, L., Jordan, I.K., and Weitz, J.S. 'Interactive COVID-19 Event Risk Assessment Planning Tool', URL http://covid1grisk.biosci.gatech.edu/



@CC-BY-4.0 Chande, A.T., Gussler, W., Harris, M., Rishishwar, L., Jordan, I.K., and Weitz, J.S. 'Interactive COVID-19 Event Risk Assessment Planning Tool', URL http://covid19risk.biosci.gatech.edu/ Data updated on and risk estimates made: 2020-05-18

Real-time COVID19 data comes from the COVID Tracking Project: https://covidtracking.com/ap

US 2019 population estimate data comes from the US Census: https://www.census.gov/data/abiestime-series/demo.popest/2010s-state-tobai.html

## Initial Covid-19 Vaccine Results Are Positive

- Preliminary results from the first human study of Moderna Inc.'s experimental coronavirus vaccine (code-named mRNA-1273) show the vaccine induced an immune response in some of the healthy volunteers who were vaccinated. In addition, the vaccine appears to be generally safe and well-tolerated.
- FDA recently gave Moderna permission to launch the second phase of testing, and the company hopes to start the final phase in July. If the vaccine proves to work safely in subsequent tests, it could be ready for emergency use as early as this fall.

#### <u>CLICK HERE</u>

## AzPA COVID19 Testing Training Program

#### Part 1 covers:

- Video 1 | Intro
- Video 2 | CLIA
- Video 3 | Types of Tests (updated 5-12-20)
- Video 4 | Patient Assessment
- Video 5 | Specimen Collection
- Video 6 | POC tests (updated 5-12-20)
- Video 7 | Biohazard Waste
- Video 8 | Reporting Results
- Video 9 | Other Considerations

Part 2 will cover Billing in more detail once we have all of the info!

Get CLIA WAIVER!

## PHARMACIST-

Reaister

ADMINISTERED COVID-19 TESTING CE PROGRAM

## **Questions**?