April 15, 2020
COVID-19 Update

Sponsored by Kansas Pharmacists Association

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Agenda

- Introduction
- State Action Update
- Testing
  - Types of Tests
  - FDA Emergency Use Authorizations (EUAs)
  - HHS Guidance on Pharmacists Testing
  - Tests Available Now
  - CLIA Waived Tests and Getting CLIA Waived Designation
- Questions - Moderated
- Open Discussion - Moderated

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State and Federal Resources

- Please visit our website https://kansaspharmacistsassociation.wildapricot.org/COVID-19/ to view a list of resources and the latest information from:
  - KDHE
  - The CDC
  - US Department of Labor
  - The White House
  - OSHA
  - World Health Organization
  - US Food and Drug Administration
  - CMS
  - National Institutes of Health
  - National Institute of Allergies and Infectious Disease
  - USP

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State Action Update

- Safer-at-Home order extended to May 3, 2020
- Waiting on feedback from CMS on delivery fee

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Testing – Types of Tests (Swabs)

- PCR
  - Nasal or throat swab test
  - Best when used before or during symptomatic stage
  - Very specific
  - Easily detectible within 7-10 days of illness
  - Usually cannot be performed in a provider's office
- Antigen
  - Nasal or throat swab
  - Not reliable until symptomatic
  - Most reliable within 6-10 days of illness
  - Can be performed in a provider's office

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Testing – Types of Tests (Blood)

- Antibody
  - Blood sample
  - Looks for immunity response
  - IgM is most reliable after 10 – 14 days of infection
  - IgG is most reliable after 21 – 30 days of infection
  - Should be performed on asymptomatic patients
    - 7 days after symptoms subside or never symptomatic individuals
  - Can be venipuncture or finger stick, depending on test
  - Looking at these tests to make behavior recommendations
    - Return to work
    - Social modifications

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Testing – FDA EUAs

- One way FDA helps enable access to medical countermeasures (MCMs), such as in vitro diagnostic (IVD) tests, is through Emergency Use Authorizations (EUAs). An EUA allows FDA to authorize use of an unapproved MCM, in anticipation of a potential emergency or during an actual emergency involving a chemical, biological, radiological, or nuclear agent, or emerging infectious disease, if criteria in section 564 of the Federal Food, Drug, and Cosmetic Act are met.
- To date 34 tests have received EUA, 1 of those tests is serological

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Testing – FDA EUAs

- When FDA authorizes a COVID-19 test for POC under a EUA, does that mean it is CLIA waived?
  - Yes. We note that the term point of care in the EUAs may include settings such as hospitals, physician offices, urgent care, outreach clinics, and temporary patient care settings that have appropriately trained personnel to perform the test and are operating under a CLIA Certificate of Waiver or Certificate of Compliance. These terms generally do not apply to home specimen collection or at home testing unless otherwise specified.

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Testing – FDA EUAs

- When tests are offered prior to or without an EUA, what is their CLIA designation?
  - Tests that fall in the above category are not FDA authorized and have not received a CLIA categorization. Therefore, in accordance with CLIA, these tests are considered high complexity by default until or unless they are deemed appropriate, through EUA authorization or general FDA review.

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Testing – FDA EUAs

- Are antibody, or serology, tests used to diagnose SARS-CoV-2 infection?
  - FDA is not aware of any antibody test that has been validated for diagnosis. Based on the underlying scientific principals of antibody tests, the FDA does not expect an antibody test can be shown to definitively diagnose or exclude SARS-CoV-2.

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Testing – FDA EUAs

- All tests that receive an EUA authorization must include information to the patient including the following:
  - This test has not been FDA cleared or approved;
  - This test has been authorized by FDA under an EUA for use by authorized laboratories;
  - This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
  - This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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HHS Guidance on Pharmacists Testing

- April 8, 2020
- Office of Assistant Secretary for Health wants to expand testing for COVID-19
- Recognizes pharmacy as accessible provider
- Authorizes under the Public Readiness and Emergency Preparedness Act (PREP):
  - Order and authorization by pharmacists serology tests authorized by FDA
  - Pharmacists qualified as "covered persons" under PREP
  - Immunity for acting in good faith

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Available Tests

- 34 EUA authorized tests
- 33 are nasal and throat swabs
- 1 is serology
  - Venipuncture draw
- Total of 3 are considered point of care
  - 2 nasal/throat
  - 1 serology
  - All require moderate and high complexity labs

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CLIA Waived Tests and Designation

How do I enroll in or apply to the CLIA program?

- You can enroll your laboratory in the CLIA program by completing an application (Form CMS-116) available on the CMS CLIA website
- Send your completed application to:

  KANSAS HEALTH & ENVIRONMENT CLIA Laboratory Certification

  6810 SE Dwight Street

  Topeka, KS 66620
- Additionally, check with KDHE for any other state-specific requirements

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CLIA Waived Tests and Designation

- If you are wanting to receive a CLIA waiver for a COVID-19 test you must be able to identify which test and company you are requesting the waiver for on your application
- Currently no waiver are being approved without this information

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QUESTIONS

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DISCUSSION

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