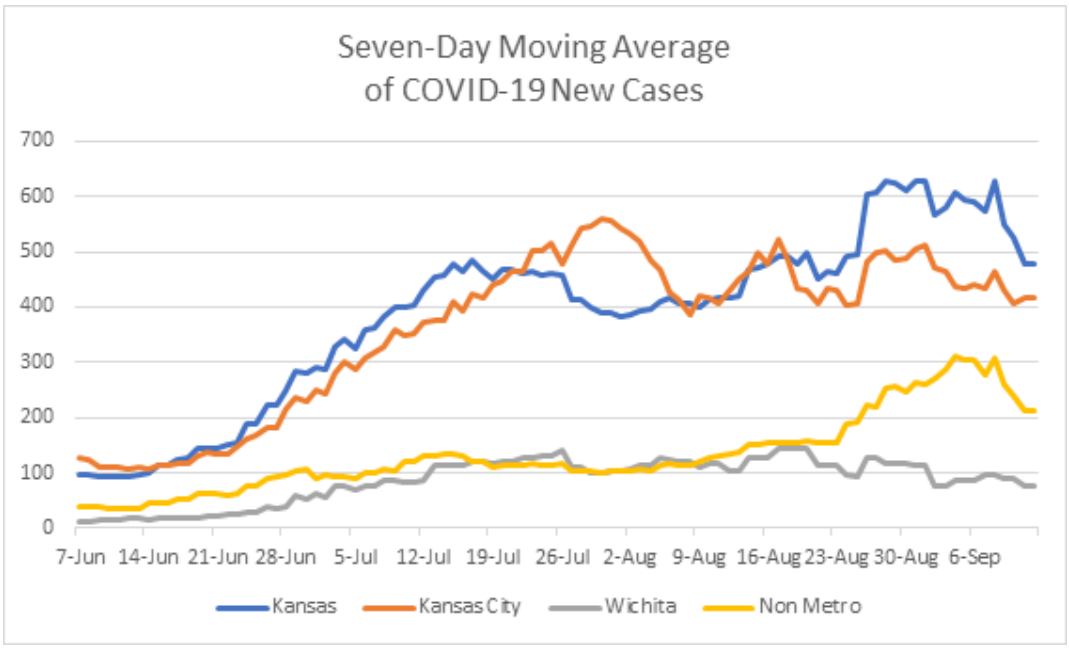
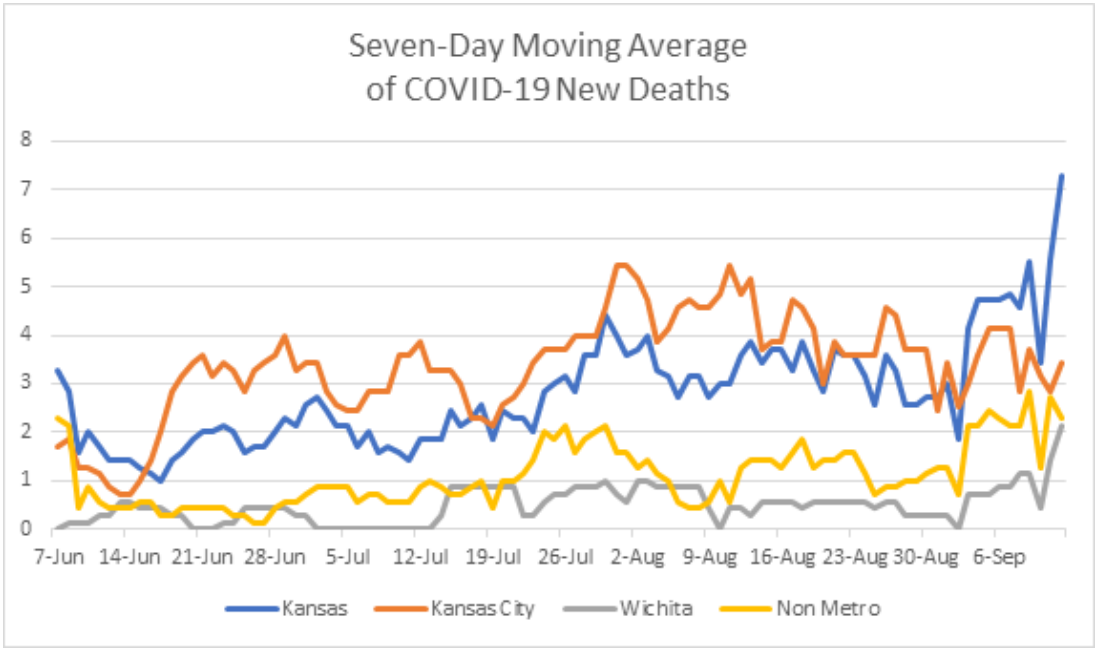
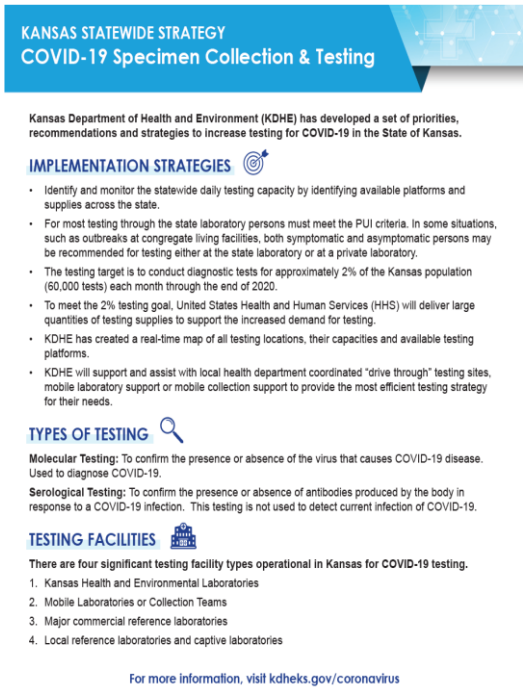
# KHA/Care Collaborative Statewide Covid19 Call






# Testing for Covid-19

- CDC guidance remains to test
  - Those symptomatic
  - Known exposure if less than 6 ft for more than 15 min
  - Those recommended by their provider
- KDHE Testing Strategy – 2% of population



KANSAS STATEWIDE STRATEGY

COVID-19 Specimen Collection & Testing

**Kansas Department of Health and Environment (KDHE) has developed a set of priorities, recommendations and strategies to increase testing for COVID-19 in the State of Kansas.**

IMPLEMENTATION STRATEGIES

- Identify and monitor the statewide daily testing capacity by identifying available platforms and supplies across the state.
- For most testing through the state laboratory persons must meet the PUI criteria. In some situations, such as outbreaks at congregate living facilities, both symptomatic and asymptomatic persons may be recommended for testing either at the state laboratory or at a private laboratory.
- The testing target is to conduct diagnostic tests for approximately 2% of the Kansas population (60,000 tests) each month through the end of 2020.
- To meet the 2% testing goal, United States Health and Human Services (HHS) will deliver large quantities of testing supplies to support the increased demand for testing.
- KDHE has created a real-time map of all testing locations, their capacities and available testing platforms.
- KDHE will support and assist with local health department coordinated "drive through" testing sites, mobile laboratory support or mobile collection support to provide the most efficient testing strategy for their needs.

TYPES OF TESTING

**Molecular Testing:** To confirm the presence or absence of the virus that causes COVID-19 disease. Used to diagnose COVID-19.

**Serological Testing:** To confirm the presence or absence of antibodies produced by the body in response to a COVID-19 infection. This testing is not used to detect current infection of COVID-19.

TESTING FACILITIES

**There are four significant testing facility types operational in Kansas for COVID-19 testing.**

1. Kansas Health and Environmental Laboratories
2. Mobile Laboratories or Collection Teams
3. Major commercial reference laboratories
4. Local reference laboratories and captive laboratories

For more information, visit kdheks.gov/coronavirus

# Testing for Covid-19

- Diagnostic tests for current infection
  - Molecular tests (genetic material) and antigen testing (protein fragments)
    - Reported rate of false negatives for molecular - low as 2% and as high as 37% and for antigen, false negative rates as high as 50%, which is why antigen tests are not favored by the FDA as a single test for active infection.
    - Antigen testing requires confirmation with molecular testing
    - Pooled Saliva testing – 95% specific. collection easier, no stabilizing medium required, and no cold transport required, and helps in saving supplies. Good for Surveillance.
      - Sensitivity reduces by 12-15% with larger pooled testing relative to individual testing -↑ False Neg
      - When the prevalence is 3% or more, therefore, smaller pools of 5 will result in the optimal number of tests overall. But with lower prevalence, larger pool sizes of 10 or 20 will reduce the number of tests required
      - Researchers report that a prevalence of 0.5%, just over 1,300 tests would be enough to cover a population of 10,000 people.
      - This would mean saving over $260,000 by pooled testing vs. individual testing, given that tests typically cost $30 each, while still identifying 43-50 infections

# Testing for Covid-19

- Diagnostic tests for past exposure
  - Serology Testing
    - SARS-CoV-2 serology tests cannot be used to definitively determine if a patient has developed protective immunity.
    - SARS-CoV-2 serology testing should not be used to diagnose acute or recent COVID-19.
  - Types of Antibody Testing are broadly classified to detect either binding or neutralizing antibodies
  - Binding antibody detection –These tests use purified proteins of SARS-CoV-2, not live virus, and can be performed in lower biosafety level laboratories (e.g., BSL-2)
  - Neutralizing antibody detection: **FDA has not yet authorized the use of neutralization tests for SARS-CoV-2**
  - Currently, there is no substantive performance advantage of assays whether they test for IgG, IgM and IgG, or total antibody

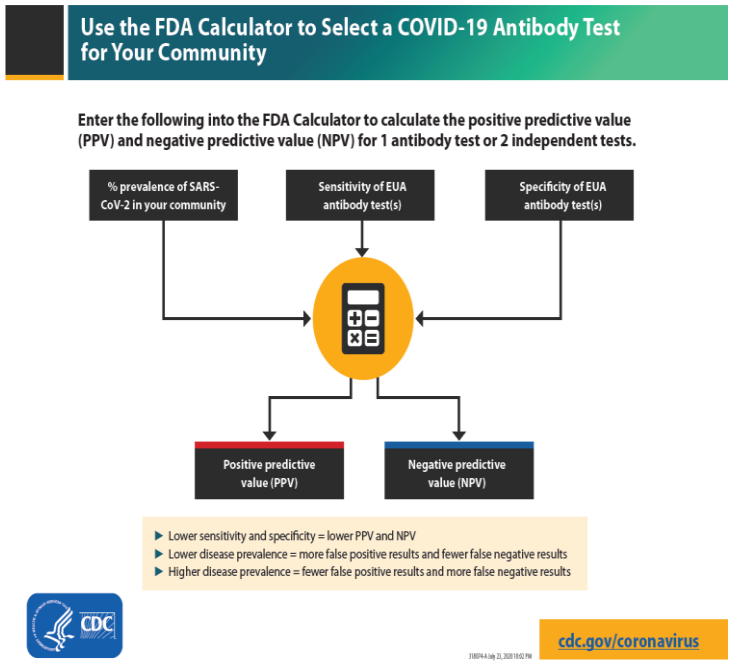
# Final CDC Guidance on Serology Testing Use

- Recommendations for persons who test positive for anti-SARS-CoV-2 antibodies
- The presence of anti-SARS-CoV-2 antibodies indicates a previous infection and possibly at least some degree of immunity or protection against future SARS-CoV-2 infection.
  - However, until the durability and duration of immunity are established, it cannot be assumed that individuals who test positive for SARS-CoV-2 antibodies, including total antibody, IgM, IgG, or IgA, are protected from future infection.
- Asymptomatic persons who test positive by serologic testing without recent history of a COVID-19 confirmed or compatible illness have a low likelihood of active infection and should follow general recommendations to prevent infection with SARS-CoV-2. They should continue with normal activities, including work.
- Persons who have had a COVID-19 compatible or confirmed illness should follow previous guidance regarding when to resume normal activities, including work, regardless of the presence of antibodies.
- There should be no change in clinical practice or use of (PPE) by health care workers and first responders who test positive for SARS-CoV-2 antibody.

https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

## Determining Test to Use

- https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/fda-calculator.pdf




## Remdesivir

- On August 28, 2020, the FDA broadened Emergency Use Authorization (EUA) for remdesivir to Include All Hospitalized Patients for Treatment of COVID-19

"Perplexingly different study outcomes reported"

- May 2020 when first EUA given:

Two RCTs compared clinical benefit of a 10-day course of remdesivir with a placebo. The first trial, conducted in Wuhan, China, didn't find a benefit but had enrolled only 237 patients and may have been underpowered.

# Remdesivir

- US National Institutes of Health study involving 1,063 patients found that patients given remdesivir for 10 days recovered 4 days sooner than those given a placebo, but there was no significant difference in death rate between those who received remdesivir (7.1%) or placebo (11.9%) (hazard ratio, 0.70; 95% CI, 0.47 to 1.04)
- Follow-up on the first study
  - RCT - Effect of Remdesivir vs Standard Care on Clinical Status at 11 Days in Patients With Moderate COVID-19; CD Spinner, et al. JAMA. 2020;324(11):1048-1057
  - Findings - Among patients with moderate COVID-19, those randomized to a 10-day course of remdesivir did not have a statistically significant difference in clinical status compared with standard care at 11 days after initiation of treatment. Patients randomized to a 5-day course of remdesivir had a statistically significant difference in clinical status compared with standard care, but the difference was of uncertain clinical importance.

# Convalescent Plasma

- Mayo-led national Expanded Access Program (EAP)

Effect of Convalescent Plasma on Hospitalized Patients with COVID-19: Initial Three-Month Experience (pre-print so not peer reviewed)

- Design: Open-label, Multi-center (0ver 2800 facilities in US and territories
- Participants: Adult participants enrolled and transfused under the purview of the US Convalescent Plasma EAP program between April 4 and July 4, 2020 who were hospitalized with (or at risk of) severe or life threatening acute COVID-19 respiratory syndrome.
- Intervention: Transfusion of at least one unit of human COVID-19 convalescent plasma using standard transfusion guidelines at any time during hospitalization.
- Convalescent plasma was donated by recently-recovered COVID-19 survivors, and the antibody levels in the units collected were unknown at the time of transfusion.
- Main Outcomes and Measures: Seven and thirty-day mortality.

https://www.medrxiv.org/content/10.1101/2020.08.12.20169359v1 Last Accessed 9/22/2020

# Convalescent Plasma -continued

- Results:
  - 35,322 transfused patients with heterogeneous demographic and clinical characteristics.
  - This cohort included a high proportion of critically-ill patients, with 52.3% in the intensive care unit (ICU) and 27.5% receiving mechanical ventilation at the time of plasma transfusion
  - **Timing Important:**
    - 7 day mortality rate was 8.7% [95% CI 8.3%-9.2%] in patients transfused within 3 days of COVID-19 diagnosis but 11.9% [11.4%-12.2%] in patients transfused 4 or more days after diagnosis ($p<0.001$)
  - **Concentration of IgG Important**: a gradient of mortality was seen in relation to IgG antibody levels in the transfused plasma
    - high IgG plasma seven-day mortality was 8.9% (6.8%, 11.7%); for recipients of medium IgG plasma mortality was 11.6% (10.3%, 13.1%); and for recipients of low IgG plasma mortality was 13.7% (11.1%, 16.8%) ($p=0.048$).

# Status of the Vaccine

- One coronavirus vaccine has been approved.
  - Sputnik V – formerly known as Gam-COVID-Vac and developed by the Gamaleya Research Institute in Moscow – was approved by the Ministry of Health of the Russian Federation on 11 August.
- The US government has chosen three vaccine candidates to fund for Phase 3 trials under Operation Warp Speed: Moderna's mRNA-1273, The University of Oxford and AstraZeneca's AZD1222, and Pfizer and BioNTech's BNT162
- https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker