### Daily Overview
- This working group will provide daily evidence updates to healthcare providers, hospitals leadership, policymakers and the public on issues related to the coronavirus pandemic.
- The Daily COVID-19 Digest includes information about:
  - (A) Pandemic Status
  - (B) Face Masks
  - (C) Tracking, Anticipating Spread and Hospitalizations
  - (D) Pharmacologic Treatment of COVID-19
  - (E) Vaccine development
  - (F) Relevant Government Actions
  - (G) Other Relevant Developments

### Key Highlights
- **On August 28, 2020,** the [FDA broadened Emergency Use Authorization (EUA) for remdesivir](https://www.fda.gov/Drugs/ApprovalInformationbyProduct/ApprovedDrugs) to Include All Hospitalized Patients for Treatment of COVID-19
- **By August 31, 2020,** 519 clusters have been identified in KS, of which 153 remains active. New clusters contribute to the increased numbers of cases in KS. Clusters are associated with private companies, aggregate living including long-term care facilities, food processing facilities, large gatherings including religious gatherings, correctional facilities, schools/childcare, sports and college and universities.
- We are experiencing a prolonged fluctuating plateau. However, with the increase in daily reported cases, we move from low to high numbers. Close monitoring of COVID-related infections, hospitalizations and deaths remains critical over the next weeks.
- Based on the best available evidence to date, until a sufficient medical intervention is able to be deployed broadly or a vaccine is developed it remains likely over the longer term that COVID-19 will persist in our community to varying degrees that will require continued management.
A. Pandemic Status

Pandemic Status (as of September 1st, 2020)

<table>
<thead>
<tr>
<th>Location</th>
<th>Confirmed cases</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>The University of Kansas Health System*</td>
<td>4,614</td>
<td>50</td>
</tr>
<tr>
<td>Johnson county</td>
<td>8,362</td>
<td>118</td>
</tr>
<tr>
<td>Sedgwick county</td>
<td>6,970</td>
<td>50</td>
</tr>
<tr>
<td>Wyandotte county</td>
<td>5,987</td>
<td>114</td>
</tr>
<tr>
<td>Ford county</td>
<td>2,262</td>
<td>10</td>
</tr>
<tr>
<td>Shawnee county</td>
<td>2,199</td>
<td>22</td>
</tr>
<tr>
<td>Finney county</td>
<td>1,896</td>
<td>12</td>
</tr>
<tr>
<td>Leavenworth county</td>
<td>1,677</td>
<td>9</td>
</tr>
<tr>
<td>Douglas county</td>
<td>1,473</td>
<td>8</td>
</tr>
<tr>
<td>Seward county</td>
<td>1,377</td>
<td>4</td>
</tr>
<tr>
<td>Riley county</td>
<td>1,045</td>
<td>6</td>
</tr>
<tr>
<td>Lyon county</td>
<td>878</td>
<td>17</td>
</tr>
<tr>
<td>Reno county</td>
<td>755</td>
<td>1</td>
</tr>
<tr>
<td>Crawford county</td>
<td>686</td>
<td>3</td>
</tr>
<tr>
<td>Saline county</td>
<td>503</td>
<td>9</td>
</tr>
<tr>
<td>Jackson/KS State</td>
<td>43,280</td>
<td>461</td>
</tr>
<tr>
<td>MO State</td>
<td>88,805</td>
<td>1,697</td>
</tr>
<tr>
<td>USA</td>
<td>6,242,895</td>
<td>189,063</td>
</tr>
<tr>
<td>Global</td>
<td>25,749,642</td>
<td>857,015</td>
</tr>
</tbody>
</table>

*TUKHS had a total of 866 hospital admissions

B. Face Masks and Physical distancing

There is increasing interest in evaluating data around mask mandate policies. As noted below, the evidence that masks reduce droplet spread is compelling, but this may or may not be reflected in analyses of mask mandate policies for a variety of reasons.

1. Mask mandates do not necessarily result in changing in behavior of mask wearing or ensure proper mask wearing, particularly in high spread, large group settings and small gatherings within social networks.

2. A definitive answer to the effectiveness of mask mandate policies requires establishing an accurate counterfactual for what would have happened in the absence of the mask mandate. This is difficult because the local nature of the virus spread and mask compliance make comparisons of mandate and non-mandate challenging and potentially problematic. Facts that should be considered, and properly adjusted for, as we evaluate evidence assessing mask mandates include:
   a. Mask mandate areas tend to have denser populations.
   b. Mask mandate areas tend to have reported cases earlier and be further in the disease process.
   c. Mask mandate areas tend to have had increase in case counts at the time mask policies were implemented.
   d. There is no reliable information on mask compliance across locations.
   e. New cases are heavily influenced by a number of factors including virus spread, testing policies, testing supplies, mass testing events, and preferences for testing in the resident population.
There is a wide range of scientific evidence assessing the impact of face masks on controlling the pandemic and reducing the transmission of the virus. While assessing each body of evidence may leave us with some uncertainty, the totality of evidence is convincing. Wearing face masks is associated with a large reduction of the risk of infection without causing harm. Apparently, the level of protection a mask provides, to the wearers and to the people around them, depends on the type of mask and whether you are wearing it properly.

- **Evidence from basic science** and lab setting confirms that even loose-fitting surgical masks blocked almost all the contagious droplet the wearers breathed out and even some infectious aerosols (tiny particles that can linger in the air).
- **Multiple studies** support that asymptomatic or pre-symptomatic patients may have similar viral loads and shedding compared to those who are symptomatic. This is one of the major challenges in controlling the pandemic and universal mask wearing would help decrease transmission from those who are not aware that they have the infection.
- Individual level evidence showing that **even in the same household**, where everyone was wearing face masks indoors as a precaution before they knew anyone was sick, the risk of transmission was cut by 79%. In another report, masks helped protect 140 customers who were exposed to infected barbers which can be translated into a very large effect when we consider how contagious SARS-Cov2 is.
- A **meta-analysis of 173 studies** provided evidence that at least 1 meter physical distancing are associated with a large reduction in infection, and distance of 2 meters might be more effective. The meta-analysis results also support that wearing face masks could result in large reduction in risk of infection of 85% (with 95% confidence interval (66-93%) and that eye protection could infer additional benefit.
- **Population level data** showing that not wearing a face mask is correlated with increase number of deaths in 22 countries. Additionally, the finding of a study reporting on natural experiment of states mandating masks in the United Stated showed that requiring face masks use in public is associated with a decline in the daily COVID-19 growth rate by 0.9 to 2.0 percentage-points in 1–5, to 21+ days after signing the orders, respectively
- Multiple **models** and **modeling** studies suggesting that adhering to near universal wearing of masks saves thousands of lives in the United States and around the world.

The effect of physical distancing on the number of contacts and the extent of the infection

The basic rate of infection spread depends on (a) the period of infectiousness (approx. 14 days); (b) the number of close contacts a person has, and (c) the likelihood of transmission of the virus to a susceptible person with each contact. The primary goal of physical distancing is to reduce the effective rate of infection by reducing the number of contacts each person has. There is incomplete understanding of how physical distancing efforts have influenced the number of close contacts the average individual has.

### C. Tracking, Anticipating Spread and Hospitalizations

**Clusters update:** On August 31, 2020, there were 519 clusters (153 active) with 10,325 cases, 627 hospitalizations and 290 deaths [reported in KS](#)

<table>
<thead>
<tr>
<th>Cluster</th>
<th>Cases</th>
<th>Hospitalizations</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>163 Private companies (38 active)</td>
<td>1,201</td>
<td>74</td>
<td>8</td>
</tr>
<tr>
<td>137 Long-term care facilities (48 active)</td>
<td>1,864</td>
<td>313</td>
<td>229</td>
</tr>
<tr>
<td>84 Gatherings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 45 Private Events (16 active)</td>
<td>304</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td>• 19 Religious Gatherings (7 active)</td>
<td>201</td>
<td>53</td>
<td>13</td>
</tr>
<tr>
<td>• 13 Bars/Restaurants (3 active)</td>
<td>267</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>• 2 Camps (1 active)</td>
<td>42</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
• 1 Fairs or Festivals (1 active)  
• 4 travel (0 active)  

### 17 Food processing/meatpacking plants (8 active)
3,427  106  19

### 25 Group homes (7 active)
221  17  5

### 25 Healthcare facilities (11 active)
214  13  5

### 16 Correctional facilities (8 active)
2,098  19  6

### 14 Childcare (3 active)
50  0  0

### 5 School (4 active)
38  2  0

### 14 Sports (5 active)
106  0  0

### 19 College or University (18 active)
257  1  0

**Projected local spread:** As of September 1st, 2020 the updated predictions based on a variety of widely used models for COVID-19 pandemics suggest that:

- **We are experiencing a prolonged fluctuating plateau.** However, with the increase in daily reported cases, we moved from low to high numbers and we are consistently observing an increase in the number of cases. We are likely to have a slower and more prolonged downward trend and could experience other “peaks” in the future.

- It remains critical to follow closely the number of new cases in different metro areas and assess their effect on hospitalization and deaths over the next weeks especially with re-opening plans in effect.

- Surveillance of cases, hospitalizations, and deaths is essential to ensure early identification of another “peak” and understand the effect of behavioral and policy effects on disease spread. COVID-19 related death is the most robustly reported data point but is a lagging indicator of about 4-6 weeks after any change in behavior. Hospitalizations are also lagging indicators of disease spread.

- No matter what model we use, however, it is very unlikely that we will reach healthcare capacity at the state level.
driven prediction is determined by existing data from other states and locations that are ahead of KS in regard to the pandemic. A major limitation of using this model is that we cannot forecast the effects of events (e.g. Memorial Day) that happen concurrently across locations.

D. Pharmacologic Treatment of COVID-19

- On August 28, 2020, the FDA broadened Emergency Use Authorization (EUA) for remdesivir to include all hospitalized patients for treatment of COVID-19.
- On August 23, 2020, the FDA issued an Emergency Use Authorization (EUA) for COVID-19 convalescent plasma to treat patients with severe disease requiring hospitalization.
- On July 30, 2020, the British Medical Journal published a living systematic review and network meta-analysis summarizing the evidence from all trials assessing medications that have been evaluated as a treatment of COVID19. As a living review this publication will be updated to include new trials as their data becomes available.
- On June 15, 2020, the FDA revoked its Emergency Use Authorization (EUA) for use of chloroquine phosphate and hydroxychloroquine sulfate to treat patients with COVID-19 based on review of data from new studies including randomized trials.
- On June 15, 2020, the FDA issues warning against use of hydroxychloroquine/Chloroquine and remdesivir and updated its fact sheet for health care providers due to concerns about decreasing efficacy of the antiviral medication with the concurrent use.
- On May 1, 2020, the FDA issued an Emergency Use Authorization (EUA) for Remdesivir to treat hospitalized patients with severe COVID-19.
- On April 24, 2020, the FDA issues a warning for use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems.
- On April 3, 2020, the FDA approved plans for nationwide trials of the convalescent plasma and hyperimmune globulin.
- On March 27, 2020, FDA approved compassionate use of convalescent plasma for serious or immediately life-threatening COVID-19 infections under a single patient emergency Investigational New Drug authorization.
- There are >1000 clinical trials worldwide of various regimen from the list above. Interactive figures and raw data of all COVID19 trials.
- SOLIDARITY trial: (Remdesivir; Lopinavir/Ritonavir; Lopinavir/Ritonavir with Interferon beta-1a; and chloroquine or Hydroxychloroquine) Large global 4-arm randomized clinical trial launched by the WHO on 3/20/2020 with a sample size of 10,000 hospitalized patients.
- DISCOVERY: French add-on study to SOLIDARITY with 3200 participants in France, with a similar design and drug regimen as SOLIDARITY.
- U.S. Clinical Trials: a large number of actively recruiting clinical trials using sarilumab, nitric oxide gas inhalation, remdesivir, hydroxychloroquine, monoclonal antibodies from convalescent serum or lopinavir-ritonavir combination.
- A registry of clinical trials can be found on the WHO and clinicaltrials.gov websites.

E. Vaccine development

- Many vaccines (>135) are under development (see New York Times tracker for brief lay overview). The digest will review vaccines that are thought likely to have immediate or future relevance, rather than comprehensively evaluate all vaccinations.
Messenger RNA (mRNA)-based vaccine mRNA-1273, sponsored by Moderna, published the results of their Phase 1 trial in the New England Journal of Medicine on July 14, 2020. The open-label, dose-response trial, comprising an initial vaccination followed by a booster 28 days later induced an immune response in all 15 participants. Common adverse effects included fatigue, chills, headache, myalgia, and pain. Phase II trials are underway.

The vaccine being developed in association with AstraZeneca and the University of Oxford – a chimpanzee adenovirus-vectored vaccine (ChAdOx1 nCoV-19) directed against the SARS-CoV-2 spike protein – reported a combined Phase 1/2 in the Lancet on July 20, 2020. In this single-blind trial of 1077 individuals, vaccination was associated with development of neutralizing antibodies and T-cell response. There were no serious adverse events, with the most common adverse effects including pain, fever, chills, myalgia, headache and malaise. Phase 2/3 (England) and Phase 3 (Brazil, South Africa) are underway.

F. Relevant legislative actions

As part of ongoing efforts to limit the spread of COVID-19:

- On June 29, 2020, Governor Laura Kelly announced a new Statewide mandate requiring residents to wear face masks going into effect July 3rd 2020.
- On June 26, 2020, Mayor Quinton Lucas announced a new citywide mandate requiring residents to wear face masks which went into effect June 29, 2020.
- Due to increase in COVID-19 cases, Wyandotte County will delay moving to phase 4 of its Ad Astra plan until Monday, July 6, at the earliest.
- On June 5, 2020, Governor Laura Kelly recommended most counties advance to phase 3 of the Ad Astra reopening plan. Under Phase 3 of the Ad Astra plan, gathering limits are recommended at 45 or fewer people. None essential travel can resume under phase 3.
- On May 26th, Governor Kelly vetoed a bill that limited power, signed a new state disaster declaration, lifted statewide order and returned control to counties and called a special session of the Kansas Legislature.
- On May 14, 2020, Governor Laura Kelly announced a new “1.5” phase in KS, effective May 18th, which continues reopening efforts while preserving some data-driven restrictions necessary to prevent community transmission of COVID-19.
- On April 30, 2020, Governor Laura Kelly announced that the statewide "Safer-at-Home" order will lift Monday May 4, 2020, followed by a phased-in approach to reopening the state.
- On April 30, 2020, Johnson County, KS, announced extending the stay-at-home order through Sunday, May 10. A phased re-opening of businesses in the county is set to begin May 11.
- On April 30, 2020, Mayor Quinton Lucas announced the city’s new 10/10/10 Plan which will be set to motion on May 15. Under this plan, businesses may open with 10% of building occupancy (or 10 persons, whichever is greater). Customers remaining inside a business for more than 10 minutes will be required to provide their contact information, to support contact tracing.
- On April 28,2020, President Trump signed an executive order invoking the Defense Protection Act to keep meat processing plants open.
G. Other Relevant Developments

Social impact

- Decision makers are commonly using the positive test percent to assess reopening decisions. This measure is being used as a proxy for COVID-19 spread in the community. However, it is essential to highlight that several variables influence how useful test percent is as a metric for these purposes.
  1. The test positive percent (daily, weekly, etc.) does not provide any guidance on the actual number of cases or cases relative to population (e.g. one positive test out of 10 total tests generates the same rate as 10 positives out of 100 tests or 100 positives out of 1,000 tests).
  2. Rolling averages should be based on the sum of positive results and tests over the entire average period to avoid arbitrarily putting heavy emphasis on time periods with small numbers of test reporting (e.g. Day 1: 10 positives out of 100 (10%), Day 2: 1 positive out of 2 (50%) – average using daily data = 30%, average using the sum of data: 11% which is likely to lead to very different decisions).
  3. Large testing events can skew results in a way that might not be reflective of the population (e.g. testing 10,000 returning students to a College or University will likely produce around 150 positives for a rate of 1.5%, if the resident community had 100 tests with 10 positives for a 10% rate, the calculated positive rate using all tests would be 1.6%).
  4. There is considerable variation over time in several factors that can substantially influence the positive test rate including general virus spread in the community, testing policies (e.g. testing only symptomatic people), the availability of testing supplies and personnel, and mass testing events.

- On July 31, 2020, The Lancet public health published a prospective observational study which compared the risk of testing positive for COVID-19 among (1) front-line healthcare workers in the US and UK against (2) the general population. Even after adjusting for differences in demographics, health status and likelihood of being tested for COVID-19, front-line healthcare workers were at three times the risk of testing positive for COVID-19 than the general population (adjusted hazard ratio [HR] 3.40, 95% CI 3.37-3.43). A pre-specified secondary analysis showed that inadequate PPE and PPE re-use both substantially increased the likelihood of infection relative to adequate PPE use (HR for inadequate PPE 1.32, 95% CI 1.10-1.57; HR for PPE re-use 1.46, 95% CI 1.21-1.76). Data regarding PPE re-use in this study should be interpreted with caution, however, as PPE disinfection protocols for PPE reuse were not yet widely implemented during the study period.

- The Association of American Medical colleges (AAMC) published a road map to Reset the Nation’s Approach to the Pandemic includes 11 evidence-based actions — both immediate and long-term.

- Kansas Department of Aging and disability Services (KDADS) publishes recommendations about phased re-opening of Long-term care facilities in KS.

- People’s behavior does not always correlate with restriction and re-opening policies. Reported mobility data provides insight into this issue. Different sources report on mobility data that can be tracked at a country, state and county level.

- The Center for Disease Control (CDC) issues reopening guidance for cleaning and disinfecting public spaces, workplaces, businesses, schools, and homes.

- The CDC and Occupational Safety and Health Administration (OSHA) issued Interim Guidance for the meat and poultry processing workers and employers.

- New clusters are contributing to the increased numbers of cases in the state mainly in the food processing industry, long-term care facilities, religious gatherings and a correctional facility.

- Data suggests racial/ethnic and socioeconomic disparities affecting the case detection and fatality rates of patients with COVID-19.

- On April 3, 2020, the CDC recommended wearing cloth face coverings in public settings where other social distancing measures are difficult to maintain, especially in areas of significant community-based transmission. This recommendation is meant to address the high rates of asymptomatic patients in the
community who may be able to spread the virus. Wearing a face mask in a community setting does not protect the wearer from acquiring infection. Understanding of the transmission risk associated with wearing a face mask remains incomplete; however, COVID-19 is thought to spread mainly through close contact from person-to-person in respiratory droplets from someone who is infected.

Testing

- On August 18, 2020, the Infectious Disease Society of America (IDSA) published COVID-19 serology guidelines.
- By August 31st, 2020, FDA pulled 114 COVID-19 serology tests that are not following guidance. A list of these tests can be found under the FAQs on Testing for SARS-CoV-2.
- On June 26 2020, a new Cochrane systematic review was published summarizing evidence about antibody testing for COVID19.
- Kansas Department of Health and Environment (KDHE) has developed a set of priorities, recommendations and strategies to increase testing for COVID-19 in KS. Additionally, an interactive map summarize available testing sites in KS.
- On May 9, 2020, the Food and Drug Administration (FDA) issues and Emergency Use Authorization (EUA) for the first COVID-19 Antigen test. The Antigen test is very specific, so when the results are positive it is confirmatory of having COVID-19. However, the test is not sensitive and has a high rate of false negative results, so a negative test cannot rule out having COVID-19.
- On May 4, 2020, the Food and Drug Administration (FDA) raises standards and issues new guidance about tests including antibody testing during the pandemic. Tests have to meet standards for quality and accuracy. This development is an effort to control the influx of > 100 commercial coronavirus antibody tests on the marker without full review.
- On April 1, 2020, the FDA issued an Emergency Use Authorization (EUA) for a qualitative test for the detection of IgM and IgG antibodies against SARS-CoV-2. When evaluating the available data, serologic testing appears promising to advance the knowledge about diagnosis and immunology of COVID-19. However, it may not be ready for wide use among the public yet, for several reasons:
  - There are a multitude of different antibody tests for COVID-19 with variable performance. Tests vary in the viral antigen(s) they target. It is not yet clear which antibody responses, if any, are protective or sustained.
  - The antibody response in infected patients remains largely unknown, and the clinical values of antibody testing have not been fully demonstrated.
A "positive" test is exceptionally difficult to interpret because the performance of these tests is not well known. For some assays both sensitivity and specificity may be poor, or at the very least undefined.

Some FDA-authorized COVID-19 antibody tests are estimated to have 96-98% specificity, which would mean that a positive test result is more likely to be a false-positive result than a true positive result in low prevalence area like KS.

Update
This is a living document. Information in this document will need to be revised and updated in the near future. We will conduct ongoing reviews of the available evidence and continuously monitor the data to determine if information require modification. Based on the rapidly evolving nature of this pandemic, information will likely need to be updated daily. This document is not intended to establish clinical practice guidelines or the standard of care. Physicians should exercise their own clinical judgement in the care of individual patients.

References
Appendix 1

SARS-CoV-2 is spread via respiratory droplets from talking, coughing, sneezing, and close contact with symptomatic individuals. Procedures like surgery, endoscopy or bronchoscopy can also lead to aerosolization and subsequent airborne transmission.\(^1\) Human-to-human transmission can occur from unknown infected persons (e.g. asymptomatic carriers or individuals with mild symptoms) as well as individuals with virus shedding during the pre-incubation period before symptoms develop.\(^2\) Data related to the spread of SARS-CoV-2 in the early phase of the pandemic have confirmed that healthcare personnel are at higher risk of infection than the general population.\(^3,4\) Several types of PPE are available and summarized below. The WHO has issued guidance on the use of PPE, following a three-pronged strategy: (1) minimize the need for PPE, (2) ensure PPE use is rational and appropriate, and (3) coordinate PPE supply chain management mechanisms.\(^5\) WHO has developed recommendations for PPE use.\(^5\) KUHS Infection Prevention has developed similar, parallel, recommendations.

**Personal protective equipment (PPE) for health care personal and patients in the hospital**

PPE for healthcare personnel is needed to protect both individual providers and the healthcare system itself. Inadequate PPE supply may result in shortage of healthcare personnel due to infection and/or quarantine. Infected healthcare personnel may also act as a vector for transmission to patients. Hospitals and healthcare systems, including the University of Kansas Health System, face challenges in projecting PPE requirements and availability. Projections of future health system PPE use follow projections for total number of persons under investigation (PUIs) or contracts hospitalized, and ICU patients, emphasizing the urgency of reliable projections.

**Information needed to make informed projections about the required PPE during the pandemic**

- Reports of number of patients hospitalized, admitted to the ICU and requiring mechanical ventilation (available from data about hospitalized patients)
- Estimates of forecast of number of patients hospitalized, admitted to the ICU and requiring mechanical ventilation with best- and worst-estimate of when the peak will occur (best and worst-case scenarios)
- Historic utilization of PPE per isolated patient (available from data about hospitalized patients)
- PPE required per COVID-19 positive/suspected patient (available from data about hospitalized patients)
- Historical hospital market share, and projections of whether this is expected to remain stable throughout the course of COVID-19 surge
- Expected number and severity of cases in a specific hospital (both total and per week)
- Period of time that social distancing/community mitigation strategies must remain in place to manage the outbreak

**Types of PPE**

<table>
<thead>
<tr>
<th>PPE</th>
<th>Use</th>
<th>Pros and Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical or medical masks</td>
<td>- Droplet precautions-block large particles (&gt;5 μm)</td>
<td>- Widely available&lt;br&gt;- Does not require fit testing&lt;br&gt;- Cannot be re-used</td>
</tr>
<tr>
<td>N95 mask respirator</td>
<td>- Filter at least 95% of aerosols (&lt;5 μm) and droplet-size (&gt;5μm) particles</td>
<td>- Requires fit testing&lt;br&gt;- Can be used for an extended period and re-sterilized</td>
</tr>
</tbody>
</table>
| Powered Air-Purifying Respirator (PAPRs) | - Provide high level protection from common airborne viruses that exceed N95 face masks | - Does not require fit testing  
- Provides head and neck protection  
- Can be re-used by the same healthcare provider |
|---|---|---|
| Gloves | - Does not require fit testing  
- Cannot be reused | --- |
| Gowns | - Does not require fit testing | --- |