COVID-19 Vaccine Breakthrough Cases

Guidance when Suspecting COVID-19 Vaccine Breakthrough Cases

The Kansas Department of Health and Environment (KDHE) is working to identify cases of COVID-19 in persons who have completed an FDA-authorized COVID-19 vaccine series, also known as vaccine breakthrough cases. The objectives of these investigations are to identify trends or clustering in patient characteristics, the administered vaccine, and the infecting virus.

Case Definition

U.S. resident who has SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected ≥14 days after completing an FDA-authorized COVID-19 vaccine series.

Action Items

- 1. Request to hold any remaining specimen(s) from the positive COVID-19 test (respiratory specimen, RNA extract, or viral isolate).
- 2. Consult with KDHE Epidemiology at 877-427-7317 or kdhe.epihotline@ks.gov and be prepared to report on the following:
 - a. Laboratory results, including RT-PCR cycle threshold (Ct) values if available
 - b. COVID-19 vaccination history (including dates of administration)
 - c. Clinical presentation and outcome
- 3. If requested to submit a specimen to the Kansas Health and Environmental Laboratories (KHEL), follow these shipping and handling requirements:
 - a. Store the specimen at 2 8°C up to 3 days from date of collection.
 - b. Transport specimen with a frozen ice pack coolant. If there is a delay in shipment (>3 days from date of collection) store specimens at -70°C or lower until delivered to the KHEL on dry ice.
 - c. Submit each specimen with a completed COVID-19 Whole Genome Sequencing Specimen Submission Form.
 - i. In the comments section, indicate that specimen is for "Vaccine Breakthrough".

If specimen/s are available and patient meets case definition, KHEL will attempt to sequence the SARS-CoV-2 genome and identify the strain of the virus.

Questions

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Lee A. Norman, M.D., Secretary

Laura Kelly, Governor

As the COVID-19 pandemic continues, surveillance of the circulating strains of SARS-CoV-2 is vital to holding the line. Kansas Health and Environmental Laboratories (KHEL) performs whole-genome sequencing (WGS) on up to 300 SARS-CoV-2 specimens each week.

To help with this surveillance activity KDHE invites laboratories and clinicians to send samples for sequencing that meet any of the following criteria:

- Potential COVID re-infection (documented with testing)
- Any COVID-19 infection acquired after recent overseas travel
- Any infection that tested negative and later tested positive during same sickness
- Any infection that meets vaccine breakthrough criteria
- Any atypical infection or response
- Any samples that indicated an "S-gene dropout" during initial PCR testing

If PCR was performed on the samples then data about the viral load (measured by Ct value) should be considered. If the sample has low viral load (high Ct value for most tests) then sequencing may not be possible due to inadequate viral RNA extracted from the sample. KHEL typically sequences specimens with a Ct of 30 or lower, which indicates there are enough viral particles present for WGS analysis. If an extracted RNA sample is not available, then KDHE will have to first perform PCR to evaluate viral content in the sample.

For samples being submitted for WGS, we ask that you please fill out a COVID-19 Whole Genome Sequencing Specimen Submission Form for each specimen that is submitted for WGS only. Providing these data with your specimen submission will allow KHEL to provide the Epidemiology team with the data needed to conduct timely contact tracing. We thank you for your continued partnership in the battle against COVID-19.