## **Testing Frequently Asked Questions**

- My test has an abnormal flag, what does this mean? The normal value for a COVID test is "not detected." If a test is "detected" then the result is considered "abnormal" because it is outside of the established normal reference range for the test.
- 2. What is a Ct value? The Ct value (Cycle Threshold) indicates the number of cycles the instrument goes through in order to detect the virus that causes COVID. The test interpretation of "not detected" or "detected" is based on Ct values. Detection of viral targets means that you have the virus. The Ct value required for a positive result is defined by the manufacturer of each test and approved by the FDA. Labs cannot deviate from the Ct values determined by the manufacturer.
- 3. What does a low Ct value mean? What does a high Ct value mean? A low Ct value is considered to indicate a higher number of viral particles in the patient sample. A high Ct value is considered to indicate a lower number of viral particles in the patient sample. Ct values may not indicate if person is able to give the virus to others or if the disease will be severe in a given individual.
- 4. Some test results have a value for the S and E gene. What do these results mean? The S and E genes are specific to the virus (SARS-CoV-2) that causes COVID-19. Detection of these viral targets means that you have COVID. The values listed with the targets are the Cycle Threshold (Ct), which refers to the number of times the S and E gene targets are amplified in order to be detected. The test interpretation of "not detected" or "detected" is based on these values.
- 5. My positive (detected) test has a comment stating, "A Ct value of 37-45 indicates that SARS-CoV-2 viral particles are present, but near the limit of detection. Results should be correlated with clinical observations and repeat testing should be considered if necessary." What does this mean? This means if the reported S and E gene Ct values are between 37-45 you should discuss your results with your medical provider because you may have a very low number of viral particles. Your medical provider can evaluate your symptoms along with the COVID test result to determine whether your test should be repeated.
- 6. **My test result was indeterminate, what does that mean?** It means the lab was unable to determine with confidence if the virus is present in the specimen submitted. There are a number of reasons why a test can be indeterminate. The most common reason is when a specimen generates an error on all COVID testing instruments attempted indicating there is an interfering substance of unknown type in the specimen or the test result is only positive for 1 of the 2 genes in the test. When this happens, the test is resulted as indeterminate and the provider is encouraged to order repeat testing.

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- 7. **Do the recent CDC changes to COVID testing impact our testing?** The CDC's removal of their test, CDC 2019-nCoV RT-PCR, does not impact our testing since we did not implement this specific test method at Kootenai Health. The FDA EUA fact sheets for each of our testing methods are included in the notes section with each test result at Kootenai Health.
- 8. **Do we run multiplex testing?** Multiplex means that the test looks for multiple viruses in one test. Multiplex respiratory testing may be ordered by your provider. The doctor may choose to run a multiplex test for RSV, influenza, and SARS-CoV-2 (COVID). They may also order a single test for other viruses.
- 9. Can the vaccine cause a positive polymerase chain reaction (PCR) result? Our tests look for viral particles from the virus. Each test method at Kootenai Health has a slightly different approach to testing, but they each look for a component of the virus that is unique to SARS-CoV-2. The vaccines developed for COVID do not contain the test targets; therefore, it will NOT cause false positive PCR result because the patient is vaccinated.
- 10. How do we know if someone has the Delta variant? At this time, Kootenai Health does not have in-house ability to determine SARS-CoV-2 variants. Kootenai Health sends a random selection of positive tests, including suspected vaccine breakthrough cases, to the Idaho State Lab for variant surveillance. The samples sent to the state are not tracked with individual patient information. Rather the specimens are specific by region only. The latest data from the state indicates the Delta variant is by far the most common strain. Based on this information, it is likely almost all of the cases we are seeing are Delta variant.
- 11. Who do I contact regarding my COVID-19 result? Contact your doctor and/or ordering provider if you have questions regarding your COVID test result interpretation.