

FYR Diagnostics Omicron (B.1.1.529) Update – *December 1, 2021*

FYR Diagnostics' Pandemic Response Taskforce:

FYR's Missoula-based team is comprised of numerous researchers and operations specialists who are actively monitoring SARS-CoV-2 variants and their impact on our region. FYR maintains close contact with state and federal officials and actively collaborates with the Montana Department of Public Health and Human Services.

FYR's taskforce is actively monitoring the various developments related to SARS-CoV-2, including Omicron's potential impact on transmissibility, severity of disease, effectiveness of vaccines, and effectiveness of testing (both PCR and rapid antigen tests, along with effectiveness of specific viral gene detection, sequencing methodologies, etc.). Due to the significant and unprecedented number of mutations throughout the genome, FYR has various concerns that it has not had with past variants – the team will provide updates as it continues to monitor and research the mutations.

How is FYR responding to Omicron and other emerging Variants of Concern?

FYR is well equipped to rapidly monitor and respond to changes in the SARS-CoV-2 virus that could impact testing and sequencing capabilities. Throughout the pandemic, FYR has actively monitored all SARS-CoV-2 variants of concern, with a recent focus on Omicron (B.1.1.529). The team has real-time alerts setup to receive and review the most up-to-date information regarding variants.

FYR has been actively sequencing its own COVID positive samples and samples provided on behalf of the state of Montana Department of Public Health and Human Services (DPHHS).

The team uses advanced next generation sequencing (NGS) technology to monitor for variants of concern from confirmed COVID-positive samples. FYR has not detected any Omicron (B.1.1.529) in Montana to-date. The FYR team is actively sequencing and monitoring for Omicron and other upcoming variants of concern and will report if and when Omicron is detected in the state of Montana. To more rapidly detect Omicron in positive COVID samples, FYR is also re-deploying its PCR-based variant screening methodology to quickly identify potential Omicron samples to prioritize for sequencing. Since the current guidance is to sequence approximately 10-15% of positive COVID samples, FYR can use the screening method to ensure that samples that are likely Omicron are sequenced. In addition, FYR has already doubled its sequencing capacity and will continue to do so as demand increases.

Each day, FYR's Pandemic Response Taskforce monitors the following:

- Monitoring WHO, CDC, FDA, scientific literature, and other announcements related to variants of concern impact on transmissibility, severity of disease, effectiveness of vaccines, surveillance with sequencing, and effectiveness of testing (both PCR and rapid antigen testing methodologies)
- Viral gene detection effectiveness with PCR based on novel mutations in emerging variants
- Local, State, Federal, and Worldwide variant spread and variant-specific risk factors

What is Omicron (B.1.1.529)?

Omicron is the newest SARS-CoV-2 variant of concern (VOC) classified by the WHO on November 26, 2021. Omicron was first identified in Botswana on November 11 and has quickly spread to other regions of Southern Africa and has now been detected around the globe. Omicron is not a derivative of the current dominant variant, Delta. It is instead a derivative from an Alpha-like variant that likely continued to evolve over time in an immunocompromised patient with a chronic infection.

Omicron has the highest number of mutations in its genome compared to any other variants that have emerged thus far, which has led to the rapid response to understand the way this variant behaves. In the spike protein alone, there are 32 mutations in Omicron. Comparatively, Delta only has 9 mutations in the spike protein. While studies are still ongoing, the number and combination of mutations is concerning since they can potentially increase transmissibility, evasion of our immune-response, vaccine resistance, and severity of disease. However, more mutations do not necessarily mean more severe disease, and lab studies and real-world data over the next few weeks will ultimately dictate the impact that these mutations have on the disease.

Where is Omicron (B.1.1.529)?

Omicron has been detected in the United Kingdom, Australia, Hong Kong, Botswana, Italy, Canada, Belgium, Austria, Netherlands, Sweden, Botswana, Czech Republic, Brazil, Israel, India, Portugal, Spain, Japan, Saudi Arabia, South Korea, and the list of countries with known detections is growing. Community spread in some of these countries has also been confirmed. Omicron has not been detected by FYR in Montana yet, but the first case has been detected in the United States in California as of December 1, 2021. FYR will keep the community updated on new developments related to emerging variants in our region.

Will Omicron be effectively detected by current PCR and antigen testing?

Data is still being generated regarding current Point-of-Care testing and antigen testing effectiveness for Omicron. Due to the extremely large number of mutations present in Omicron, particularly in the spike protein, there is an increased chance that these tests may have reduced effectiveness or not work at all.

FYR has a robust testing pipeline with multi-target redundancy to detect three different regions of the SARS-CoV-2 genome. This enables FYR to detect variants of concern that may not be detected by single-target tests. After analyzing the mutations in Omicron, the FYR PCR test is fully capable of detecting the Omicron variant.

FYR has and continues to implement backup testing plans and workflows to accommodate variants of concern that could potentially circumvent current testing methodologies. FYR is committed to rapid response and monitoring of this and future pandemics.

Will current vaccines work well against Omicron?

Our team is actively monitoring the various developments and reports related to how Omicron impacts vaccine efficacy. Not enough real-world data yet to know if current vaccines provide adequate protection against Omicron. With that said, the combination of mutations is concerning and any impact of this variant on vaccine efficacy is being studied right now. It will likely be a few more weeks before we truly know how Omicron impacts vaccines. Vaccinated people are getting infected with Omicron but whether there is a greater chance of infection or more severe outcomes is still unknown. Moderna and Pfizer have already begun strategizing for an Omicron-specific booster as concerns grow about the possibility that vaccines have potentially less efficacy against Omicron. FYR defers to the CDC and WHO for guidance related to vaccines.

Contact FYR

FYR Diagnostics Inc
1121 E Broadway St.
Missoula, MT 59802

COVID-19: Covid19@fyrdiagnostics.com

Press: Press@fyrdiagnostics.com

Background on FYR Diagnostics

FYR (pronounced “Fire”) Diagnostics is a Montana-based company focused on developing and commercializing novel technology for diagnostics and testing in human health, life sciences, and agriculture. FYR Diagnostics is currently developing diagnostic solutions for cancers, neurological disorders, agricultural diseases, and neonatal-associated syndromes.

Thanks to support from the State of Montana, FYR’s [partnership with the State Lab](#) has increased statewide COVID-19 testing capacity and reduced the time patients must wait to receive results. For more information, visit fyrdiagnostics.com.

Disclaimer

FYR Diagnostics does not make any representation or warranties with respect to the accuracy, applicability, fitness, or completeness of the above content and/or any associated materials, collectively (“Materials”). FYR Diagnostics assumes no responsibility for errors or omissions in the contents of the Materials. FYR Diagnostics hereby disclaims any and all liability to any party for any direct, indirect, implied, punitive, special, incidental, or other consequential damages arising directly or indirectly from any use of the Materials, which is provided as is, and without warranties. Please seek advice from your healthcare provider regarding your personal healthcare questions.