

Tracking the Emergence of Sars-Cov-2 Variants of Concern in Vaccinated and Unvaccinated Patients

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Introduction: Emerging infectious organisms, such as SARS-CoV-2, create public health crises that demand real-time tracking and ongoing surveillance of new variants to monitor changes in transmissibility, virulence, and effectiveness of vaccines. Aegis Sciences BioPharma Laboratory has sequenced over 250,000 RT-PCR-confirmed SARS-CoV-2 positive specimens from patients across the United States and Puerto Rico and evaluated the emergence, community spread, and dominance of variants of concern (VOC) in vaccinated and unvaccinated individuals.

Methods: Through a collaboration with Walgreens, Aegis Sciences BioPharma Laboratory performs COVID-19 testing on patient specimens from all over the United States. Patients schedule appointments via an online portal, submit health data and vaccination status for physician review, and perform socially-distanced, self-collections from the Walgreens pharmacy drive-through while being observed by a trained clinical team member. SARS-CoV-2 positive specimens with an average cycle threshold (Ct) value of <30 were selected for sequencing based on their state's testing volume and overall population statistics. SARS-CoV-2 genome sequencing and lineage analysis was performed via an optimized workflow using the Illumina® COVIDSeq RUO Kits with the NovaSeq 6000 sequencer and the Illumina® DRAGEN COVID Lineage Application. The prevalence and spread of variants of concern was evaluated in both vaccinated and unvaccinated patients.

Results: Since March 2021, Aegis has submitted over 250,000 sequences from COVID-19 positive patient specimens to the GISAID database, including 437 unique SARS-CoV-2 lineages. Starting in May, the patient's vaccination status was captured to help monitor vaccine effectiveness and compare variant spread in vaccinated versus unvaccinated individuals. In total, 170,019 patient specimens with a vaccination status have been sequenced. From March to May 2021, Alpha (B.1.1.7) cases increased from 8% to 66%. At Alpha's peak (May to Mid-June), the average rate of breakthrough cases neared 10% of total sequenced samples. In early June, Delta (B.617.2) cases accounted for only 3% of samples but quickly rose to 60% while Alpha declined from 38% to 6%. From July to November 2021, Delta and its sub-lineages (AY) have dominated and accounted for >90% of all cases with an average breakthrough rate of ~30% overall. In early August, Delta's AY sublineages emerged and have since become more prevalent than their B.617.2 parent lineage. Of note, AY.25 (33.54%), AY.44 (37.69%), and AY.39 (36.79%) also have increased vaccine breakthrough rates with the highest breakthrough rate in AY.103 (41.36%).

Conclusions: Monitoring viral variant trends and epidemiology through community surveillance programs is critical during a public health crisis. The data generated through these collaborations is vital to tracking viral evolution and understanding changes in transmissibility, virulence, and vaccine effectiveness. Aegis' sequencing and analysis of >250,000 SARS CoV-2 specimens will continue to contribute to our understanding of COVID-19 for years to come.