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Short Communication

Detection of SARS-CoV-2 variants by multiple diagnostic assays

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Introduction: The emergence of SARS-CoV-2 Variants of Concern (VOC) and Variants Being Monitored (VBM) have presented additional clinical and public health concerns regarding potential virus transmissibility, disease severity, and immune evasion. It is imperative that diagnostic assays can detect all such variants, and since commercial oligo sequences are commonly not available, empirical testing may be necessary to confirm this. To confirm the sensitivity of the SARS-CoV-2 assays used at the Wadsworth Center for the detection of VOC and VBM, relevant specimens were selected from the specimen archive and tested in the various platforms.

Materials and Methods: Patient respiratory specimens submitted from clinical laboratories across the state were selected; three samples per variant were chosen to account for inter assay and variant reproducibility. The four molecular diagnostic platforms for SARS-CoV-2 currently in use at our facility were examined.

Results: A total of 64 specimens were tested, representing 2 VOC, 8 VBM and 4 other variants circulating in New York State. For certain samples, original Ct values provided by sample submitters were much higher, or lower, than those obtained from this study. The investigation of submitter testing platforms, with consideration of the assay’s viral targets, confirmed the differences in Ct were not variant specific.

Conclusions: It was demonstrated that the diagnostic methods investigated in this study detected all the variants tested. Because of the continual evolution of the virus, it is vital to monitor new variants as they emerge for the ability of molecular diagnostic methods to detect them with acceptable sensitivity.

1. Introduction

The 2019 Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) pandemic spread globally, and the virus has now acquired mutations that impact virulence, transmission, and immune protection. In December of 2020, the SARS-CoV-2 variant B.1.1.7, subsequently designated Alpha, that originally emerged in the UK in September 2020 and quickly became the dominant variant in Europe, was detected in the US. This variant has 23 mutations, including several in the spike gene associated with increased transmissibility [1].

The Center for Disease Control and Prevention (CDC) has classified SARS-CoV-2 variants into three categories: Variant of Interest (VOI), Variant of Concern (VOC), and Variant of High Consequence (VHC), generally characterized as variants associated with reduced efficacy of treatment or vaccine prevention, increased transmissibility and more severe disease [2]. These classifications have changed as the pandemic has progressed and on September 21, 2021 a new class of Variants Being Monitored (VBM) was added. [2]

It is vital for patient care and public health surveillance and response, that diagnostic platforms detect all SARS-CoV-2 variants with high levels of sensitivity and specificity. Information on the performance of diagnostic assays with regard to the detection of variants is scarce but two independent single point mutations have been reported to reduce the detection sensitivity for the N2 target of at least one commonly used assay [3]. While constant review of sequence data may assist in identifying mutations that could be problematic for diagnostic detection, sequence information for commercial assays is commonly unavailable for detailed analysis and empirical testing is always reassuring to confirm that assay sensitivity has not been impaired. Therefore, to ensure accurate detection on all testing platforms used at this laboratory, we tested a representative set of specimens containing all available variants of SARS-CoV-2 from the laboratory’s archives.