



### **Testing Update: SARS-CoV-2 Variant of Concern Screening and Impact on COVID-19 Diagnostic Molecular Testing Performance**

**February 18, 2021**

#### **Audience**

Healthcare providers assessing patients for COVID-19 infection and other Dynacare clients in Ontario.

#### **Overview**

In late 2020, novel variants of SARS-CoV-2 ('COVID-19 virus') were detected in the United Kingdom, South Africa, and Brazil. These variants of concern (VOC), designated as **UK Variant** or 'Variant of Concern 202012/01' (VOC-202012/01, or lineage B.1.1.7), **South African Variant** (Variant 501Y.V2, or lineage B.1.351), and **Brazilian Variant** (P.1 lineage) are more transmissible than wild-type SARS-CoV-2 virus due to novel adaptive mutations in the viral genome. The purpose of this Partner Update is to address the emergence of SARS-CoV-2 variants, their potential impact to COVID-19 diagnostic molecular tests offered by Dynacare, and to outline the testing strategy for variants at Dynacare.

#### **COVID-19 Diagnostic Molecular Testing at Dynacare**

Dynacare uses four assays for the detection of SARS-CoV-2 RNA in clinical samples, including i) Thermo Fisher TaqPath COVID-19 Combo Kit, ii) Hologic Aptima SARS-CoV-2, iii) Roche cobas SARS-CoV-2, and iv) Abbott RealTime SARS-CoV-2. Each of these assays target multiple regions of the SARS-CoV-2 genome to increase both the sensitivity and specificity for COVID-19 diagnosis in patient clinical samples. All four tests are Health Canada approved and as such must meet strict

regulatory quality and patient safety requirements for clinical use, including the continuous monitoring of ongoing acceptable performance.

### **Impact of Known Variants of Concern on SARS-CoV-2 Diagnostic Molecular Tests Offered by Dynacare**

There is no evidence to suggest that any currently circulating variants will impact the accuracy or performance of COVID-19 diagnostic molecular tests offered by Dynacare. However, a mutation within the S gene of the UK Variant can result in a negative result for the S gene target when using the Thermo Fisher TaqPath COVID-19 Combo Kit test, referred to as 'S gene dropout'. The occurrence of 'S gene dropout' does not impact the overall performance of this assay (i.e. will not result in an overall false-negative result) since two additional targets (N gene and *orf1-ab*) would continue to be detected. At this time, the test manufacturer is not recommending any testing adaptations or other changes in response to 'S gene dropout'. This phenomenon is not observed in the South African or Brazilian Variants and there is no additional impact to any remaining Dynacare tests.

### **Screening and Reporting of SARS-CoV-2 Variants at Dynacare**

As of February 18<sup>th</sup>, 2021, Dynacare will automatically test all SARS-CoV-2 positive samples with Ct values  $\leq 35$  for the presence of N501Y mutations associated with VOCs. Samples that are positive using this screening test will be referred to Public Health Ontario Laboratory (PHOL) for confirmatory testing and VOC sub-grouping (i.e., UK, South African, Brazilian, or other novel VOC characterization). In addition, a random subset of samples that test negative for variants using the Dynacare screening test will be forwarded to PHOL for reference VOC testing in an attempt to detect potential novel variants.

Submitters will be notified that their client's sample has been forwarded to PHOL through a comment included on the Dynacare report and they will also receive both the results of the Dynacare variant screening test and PHOL confirmatory test (for samples that were submitted to PHOL). Importantly, the turn-around time of PHOL confirmatory testing may be up to 14 days from sample receipt.

Clients with who currently receive their COVID-19 molecular diagnostic test results through a Dynacare interface will receive both the variant screen results and VOC confirmatory test results by fax. All other reporting to the public health unit (PHU) and Ontario Laboratory



Information System (OLIS) will be conducted by Dynacare for variant screen tests and by PHOL for VOC confirmatory testing.

### **Measures in Place to Detect and Mitigate the Risk of Emerging Variants of Concern**

Viruses including SARS-CoV-2 are constantly changing. The performance of any testing method that relies on detecting specific viral sequences could potentially be impacted by a new variant; thus, it is important to remain vigilant in monitoring trends in test performance and emergence of new variants. To this end, Dynacare staff are in frequent communication with test manufacturers to keep apprised of the impact of variants on test performance as new information becomes available. In addition, our scientific staff are engaged with public health agencies and actively reviewing emerging literature, including post-market reports and public database updates, in order to prospectively assess the potential impact of emerging variants on test performance. Dynacare has additional quality systems in place to track testing metrics as an early indicator for potential issues with test performance should they arise.