Re: Response to request for information on the impact of new SARS-CoV-2 variants of epidemiological interest recently reported in the UK, South Africa, and Brazil on the performance of SARS-CoV-2 molecular IVD test kits designed, developed, and manufactured by Co-diagnostics, Inc. (Salt Lake City, USA)

New SARS-CoV-2 variants of epidemiological interest have been recently reported (CDC, 2021):

- 20H/501Y.V2 or B.1.351 reported in South Africa (GISAID, 2021).
- P.1 or 20J/501Y.V3 reported in Brazil (Faria, et al., 2021).

The new variants have been reported in December 2020 and January 2021. Some variants, including N501Y, have been has been associated with an increase in transmissivity of COVID-19 (Public Health England, 2020) (CDC, 2021) (GISAID, 2020). Other possible identified candidates for differences in transmissivity include the following: deletion 69-70, deletion 145, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H (GISAID, 2020).

The Genomics UK Consortium that identified the VOC-202012/01 variant also identified 17 mutations characteristic of the B.1.1.7 lineage of this variant (see list of mutations on Figure 1) (Virological, 2020). None of those mutations are near the binding targets of the markers in gene RdRp and gene E that are used either separately or multiplexed in the Company’s suite of COVID-19 diagnostics.

More information about the epidemiological relevance of the South African and Brazilian mutations are currently being investigated by the scientific community. The Figure 2 shows a list of existing clades of the SARS-CoV-2 being studied by the public consortiums.
All three new variants of epidemiological interest have been sequenced and known mutations in the S-gene have been reported (GISAID, 2021).

According to CoDx’s Risk Assessment, since none of the molecular test kits intended for the detection of SARS-CoV-2 developed by Co-Diagnostics, Inc. contain CoPrimers™ (primers and probes) that target the S-gene, there is no reason to believe that these variants will affect the performance of these tests. All CoDx’s SARS-CoV-2 test kits are expected to detect 20I/501Y.V1, 20H/501Y.V2, and 20J/501Y.V3 at the same sensitivity level as other variants of SARS-CoV-2.

On 8-Jan-2021 the US FDA published a report on the impact of the UK variant in the EUA-authorized molecular tests in the US, including COVID-K-001 (EUA-authorized). Their analysis concluded that since molecular tests are specific to the targeted region, mutations outside the targeted region will not impact the performance of such primers and probes (U.S. FDA, 2021).
REFERENCES


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