

## **Hyris System (Interim Order- CE IVD): Monitoring update regarding SARS-CoV-2 novel variants**

Mutations of SARS-CoV-2 have been observed globally. Some of them are innocuous, while others may give the virus a selective advantage. Based on a risk assessment by major authorities involved in the fight against the spread of COVID-19, such as WHO<sup>i</sup>, ECDC<sup>ii</sup>, CDC<sup>iii</sup>, these mutations are identified as Variants of Concern and monitored.

The updated list of the Variants of Concern emerged so far is:

- United Kingdom variant known as VOC 202012/01<sup>iv</sup>
- South Africa variant known as 501Y.V2<sup>v</sup>
- Brazil variant known as 484 K.V2<sup>vi</sup>
- Indian variant known as B.1.617<sup>vii</sup>
- Californian variants known as B.1.429 and B.1.427<sup>viii</sup>

Hyris is monitoring the surveillance data and has performed routine in silico analysis of SARS-CoV-2 sequences (from GISAID database: <https://www.gisaid.org/>) in order to safeguard both public health and the quality of the product, by assessing their potential impact on inclusivity and performance characteristics.

All sequences investigated showed no variations from the reference sequence of SARS-CoV-2 in the oligonucleotides annealing sites. These include all the Variants of Concern mentioned above.

Coverage of the Hyris System (bCUBE, bKIT, bAPP) is currently 100% based on in silico analysis. Accordingly, no variations on assay performances are expected.

Disclaimer: this Document has been developed by Hyris Ltd as a meaningful update to be provided to Hyris customers using the bKITS in the 'Hyris Virus Finder' family; more specifically:

- bKTE-SCV2.01 SARS-CoV-2 Environmental
- bKTH-SCV2.02 Virus Finder COVID-19

Please note that it is still your laboratory's or trained resources' responsibility to validate any test according to your country's existing laws.

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