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To whom it may concerns,

December 3rd, 2021

Product update regarding detection of omicron SARS-CoV-2 variant (B.1.1.529) with the ViraSpec Covid-19 test from Aegirbio AB.

The omicron variant (B.1.1.529) originally detected in South Africa has now been found worldwide and appears to be spreading rapidly in many countries. This variant contains a large number of mutations in the spike protein and a smaller number of mutations in the nucleocapsid (N) protein. While much research is ongoing into the role of these mutations in increased transmissibility and virulence, preliminary indications are that our current rapid antigen test will detect this variant because the mutations in the N protein do not occur in the epitopes recognized by the antibodies used in the test.

This is consistent with announcements by other leading medical research groups, including the German Society for Immunology (DGfI), that "According to current knowledge, the common PCR methods...can also detect the omicron variant. **Rapid antigen tests should also be suitable**". The US FDA also recently stated that, "On preliminary review, we believe high-volume polymerase chain reaction (PCR) and antigen (rapid) tests widely used in the U.S. show low likelihood of being impacted and continue to work. However, the FDA will continue to closely review and adjust course as needed".

Studies to confirm these statements for the ViraSpec Covid-19 antigen test will be performed as soon as reference material is available.



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