

Product Bulletin

Date: 30 November 2021

To: Whom it may concern,

RE: Detection of new SARS-CoV-2 variant (B.1.1.529) using the Sienna COVID-19 Antigen Rapid Test Cassette

In November 2021, a new SARS-CoV-2 variant (B.1.1.529) was identified in South Africa. Key mutations include 34 mutations on the spike protein of the virus, where 15 mutations occurs in the RBD of the spike protein. Despite the significant mutation on the spike protein and its significant potential to influence this variant's immune escape and transmissibility, based on preliminary analysis, it is estimated that the Sienna COVID-19 Antigen Rapid Test Cassette will still be able to detect the new variant.

The Sienna COVID-19 Antigen Rapid Test is a qualitative, lateral flow immunoassay for the detection of the nucleocapsid protein of SARS-CoV-2. Comparing the mutations that occur on the nucleocapsid protein of the new variant Omicron (B.1.1.529) : P13L, E31del, R32del, S33del, R203K and G204R and the epitopes (the part of the antigen that binds to the antibody) of the antibodies used on the test, it was determined that all 6 mutations are outside the epitopes of the antibodies used in the test. This indicates that the binding of the antibodies and the antigen will likely not be affected, therefore, the risk of the new variant not being detected by the Sienna COVID-19 Antigen Rapid Test is low.

In addition, according to the statement issued by the Society of Virology (Gfv) and German Society for Immunology (DGfI), on 28th November 2021 (<https://g-f-v.org/en/ad-hoc-stellungnahme-schnelles-politisches-handeln/>), "According to current knowledge, the common PCR methods for detecting SARS-CoV-2 can also detect the omicron variant. Rapid antigen tests should also be suitable. The extent to which this is true is currently under review."

As standard reference materials become available, Salofa Oy will conduct wet-testing to confirm the ability of the test to detect the new SARS-CoV-2 variant (B1.1.529).

Yours Sincerely,



Christoffer Riska
Vice President Regulatory Affairs, Quality Assurance

