November 29, 2021

Re: Simplexa™ COVID-19 Direct assay performance is NOT impacted by the Omicron SARS-CoV-2 variant
Dear Valued Customer,

The purpose of this letter is to provide an update on the additional variants that have been analyzed for their performance impact on the Simplexa™ COVID-19 Direct test. This notification is a follow up from our letter emailed on August 18, 2021. We can confirm that in addition to those SARS-CoV-2 variants previously confirmed, no performance impact is expected for Mu (B.1.621) and Omicron (B.1.1.529) variants.

The DiaSorin Molecular R&D team's *in silico* evaluation of SARS-CoV-2 variants impact on the Simpexa™ COVID-19 Direct assay is summarized in the table below. The conclusion of the evaluation was that none of the mutations in the Spike (S) or ORF1ab regions characterizing these variants occur in the primer or probe target regions used by the Simplexa™ COVID-19 Direct assay. Thus, the performance is not impacted by the presence of these variants in patient samples.

WHO Label	Alpha	Beta	Gamma	Delta	Epsilon	Zeta	Eta	Iota	Kappa	Lambda	Mu	Omicron
Pango Lineage	B.1.1.7	B.1.351 B.1.351.2 B. 1.351.3	P.1	B.1.617.2	B.1.427 B.1.429	P.2	B.1.525	B.1.526	B.1.617.1	C.37	B.1.621	B.1.1.529
Impact on performance of Simplexa™ COVID-19 Direct	None	None	None	None	None	None	None	None	None	None	None	None

DiaSorin Molecular will continue to monitor the SARS-CoV-2 variants deposited in the reference databases (NCBI and GISAID EpiCoV™). The Simplexa™ COVID-19 Direct assay primers and probes will be analyzed against these databases to evaluate any mutations that may impact the primer and/or probe binding. We expect that our monitoring approach will provide you with an additional level of confidence in the performance of the Simplexa™ COVID-19 Direct assay.

Should you have any additional questions, please do not hesitate to reach out to your local representative or to myself.

Best regards,

Ayaz Majid, Ph.D.
Director, Product Management