



August 10, 2022

**Re: Simplexa™ COVID-19 Direct, Simplexa™ SARS-CoV-2 Variants Direct (RUO), and Simplexa™ COVID-19 & Flu A/B Direct assay performances are NOT impacted by the Omicron SARS-CoV-2 variant sublineages BA.2.12.1, BA.4, BA.5, and BA.2.75**

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, Simplexa™ SARS-CoV-2 Variants Direct (RUO)\*, and Simplexa™ COVID-19 & Flu A/B Direct test kits. This notification is a follow up from our letter emailed on May 27, 2022. We can confirm that in addition to those SARS-CoV-2 variants previously confirmed, no performance impact is expected for the Omicron BA.2.12.1, BA.4, BA.5, and BA.2.75 subvariants of concern.

The DiaSorin Molecular R&D team’s *in silico* evaluation of SARS-CoV-2 variants impact on the Simplexa™ COVID-19 Direct, Simplexa™ SARS-CoV-2 Variants Direct (RUO), and Simplexa™ COVID-19 & Flu A/B Direct assays 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 these assays. Thus, the performance is not expected to be impacted by the presence of these variants in patient samples.

WHO Label	Alpha	Beta	Gamma	Delta	Epsilon	Zeta	Eta	Iota	Kappa	Lambda	Mu	Omicron
<b>Pango Lineage</b>	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 BA.2 BA.2.12.1 BA.4 BA.5 BA.2.75
<b>Impact on performance of Simplexa™ COVID-19 Direct or Simplexa™ COVID-19 &amp; Flu A/B Direct or Simplexa™ SARS-CoV-2 Variants Direct (RUO)</b>	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 GISAID EpiCoV™ reference database. The Simplexa™ COVID-19 Direct, Simplexa™ SARS-CoV-2 Variants Direct (RUO), and Simplexa™ COVID-19 & Flu A/B 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, Simplexa™ SARS-CoV-2 Variants Direct (RUO), and Simplexa™ COVID-19 & Flu A/B Direct assays. 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

\*For Research Use Only. Not for use in diagnostic procedures.