DiaSorin Molecular

June 8, 2021

**Re: Simplexa™ COVID-19 Direct assay performance is NOT impacted by new SARS-CoV-2 variants, including India variants**

Dear Valued Customer,

DiaSorin Molecular continues to monitor and evaluate potential performance impacts of SARS-CoV-2 variants on the Simplexa™ COVID-19 Direct assay. This notification is an update to our letter emailed in March 2021. We can confirm that, in addition to those previously confirmed, no performance impact is expected from the India SARS-CoV-2 Variants (Pango lineage: B.1.617, B.1.617.1, B.1.617.2, B.1.617.3).

The DiaSorin Molecular R&D team conducted an extensive *in silico* evaluation of the variants which are summarized in the table below. It was concluded that none of the mutations characterizing these variants occur in the primer or probe target regions used by the Simplexa™ COVID-19 Direct assay and performance is not impacted by the presence of these variants in potential patient samples.

| **Variant Strain (Pango Lineage)** | 20I/501Y.V1, VOC 202012/01, (B.1.1.7) | 20H/501Y.V2 (B.1.351) | 20J/501Y.V3 (P.1) | CAL.20C (B.1.427/B.1.429) | B.1.526 | B.1.617, B.1.617.1, B.1.617.2, B.1.617.3 |
|---|---|---|---|---|---|---|
| **Country of First Detection** | United Kingdom | South Africa | Brazil | California, U.S.A. | New York, U.S.A. | India |
| **Spike Protein Mutations** | Deletion 69-70 HV, deletion 144, N501Y, A570D, D614G, P681H, T716I, S982A, and D1118H | L18F, D80A, D215G, R246I K417N, E484K, N501Y, D614G and A701V | L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, H655Y and T1027I | S13I, W152C and L452R | L5F, T95I, D253G, E484K or S477N , D614G, and A701V | L452R, E484Q, D614G, G142D, E154K, P681R, Q1071H, T19R, 156del, 157del, R158G, T478K, D950N |
| **ORF1ab Mutations** | T1001I, A1708D, I2230T and deletion 3675-3677 SGF | T265I, K1655N and K3353R | S1188L, K1795Q, del3675-3677 SGF, E5662D | I4205V and D1183Y | - | - |
| **Impact on performance of Simplexa™ COVID-19 Direct** | None | None | None | None | None | None |

DiaSorin Molecular will continue to monitor and analyze 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 checked 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.

To differentiate variants, we now have the Simplexa™ SARS-CoV-2 Variants Direct (RUO) assay (MOL4350) which is for research use only and allows for the detection and differentiation of key mutations associated with SARS-CoV-2 variants in circulation.

Should you have any additional questions, please do not hesitate to reach out to your regional Scientific Affairs team member or to me.

Best regards,

Ayaz Majid, Ph.D.
Senior Product Manager, Respiratory Portfolio