



NEWS RELEASE

FOR IMMEDIATE RELEASE

DiaSorin Molecular Releases an Assay for Rapid Identification of Mutations Associated with Circulating Variants of SARS-CoV-2, including the India B.1.617

Cypress, Calif. (May 21, 2021) – DiaSorin Molecular LLC announced today that it has released the Simplexa™ SARS-CoV-2 Variants Direct assay (RUO) to enable detection and discrimination of four SARS-CoV-2 mutations associated with circulating virus variants without requiring upfront RNA extraction. The assay helps to streamline and speed-up the pre-selection process of positive samples that need further sequencing, maximizing the effectiveness of monitoring programs for the spread of concerning variants.

The Simplexa SARS-CoV-2 Variants Direct is a Research Use Only assay and is not for use in diagnostics procedures. The assay allows for the *in vitro* qualitative differential detection of the mutations N501Y, E484K, E484Q, and L452R directly from nasopharyngeal and nasal swab specimens from individuals previously diagnosed with COVID-19. These mutations are present in potential variants of clinical interest including those that were isolated in the United Kingdom (B.1.1.7), South Africa (B.1.351), Brazil/Japan (P.1 and P.2), New York (B.1.526/B.1.526.1), California (B.1.427/B.1.429), Nigeria (B.1.525) and India (B.1.617/B.1.617.1/ B.1.617.2/B.1.617.3). The kit format consists of pre-aliquoted reagents that are ready for use while leveraging Direct Amplification Disc technology and the melting curve capabilities of the LIAISON® MDX.

During the course of the COVID-19 pandemic, new genetic variants of SARS-CoV-2 have spread rapidly across the globe creating concern as to their infectivity, transmissibility, and the impact on current vaccines or available immunotherapy. The availability of affordable molecular solutions that can be easily implemented and provide



quick results will facilitate and increase the ability to monitor the spread of variants by streamlining laboratory workflows.

“The ability to identify potential SARS-CoV-2 variants in positive samples is of national and global importance in the continuous effort to monitor, track, and fight against SARS-CoV-2 variants,” said John Gerace, president of DiaSorin Molecular. “We are proud to continually develop products that meet the evolving needs of laboratories around the globe during this time.”

About DiaSorin Molecular

DiaSorin Molecular LLC manufactures and distributes innovative molecular diagnostic products for hospital and reference laboratories. The company’s products help laboratories consolidate their testing, streamline processes and increase efficiency. DiaSorin Molecular’s Simplexa molecular diagnostic kits are designed for use on the company’s versatile LIAISON MDX platform. The company provides service and support solutions for its kits and instruments through a global network of offices and distributors. DiaSorin Molecular also markets a range of ASRs (analyte-specific reagents) for use in lab-developed tests.

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