GENOMTEC

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Press release

For immediate release

Genetic tests Genomtec SARS-CoV-2 Duo Kit (Cat. no.: GA00B) and Direct-RT-LAMP Kit (Cat. no.: GA00C) detect multiple virus lineages

Wroclaw, Poland – 24th of June 2021 - **Genomtec SA, a medical technology company specialising in the isothermal clinical diagnostic technology, both in the POCT and also rapid genetic laboratory tests. As part of our standard product surveillance and assurance strategy, and also due to growing concerns on ability of IVD tests to recognize newly appearing SARS-CoV-2 variants, Genomtec conducted bioinformatic (in-silico) as well as the wet lab analysis of its products, Genomtec® SARS-CoV-2 EvaGreen® RT-LAMP CE-IVD Duo Kit (RT-LAMP Duo) and Genomtec® SARS-CoV-2 EvaGreen® Direct-RT-LAMP CE-IVD Kit (Direct).**

RT-LAMP Duo and Direct Kits' reliability in recognition of identified SARS-CoV-2 significant variants, among them the Breton that has the potential to escape standard RT-PCR testing analysis from swab-based samples, has been fully confirmed. Recognition of multiple variants by the RT-LAMP Duo and Direct Kit is important to ensure public health safety where accurate testing against multiple types of SARS-CoV-2 variants of concern is absolutely crucial in sustaining efforts against pandemic surviliance.

Methodology:
The in-silico analysis was performed by analyzing the NCBI reference sequence of SARS-CoV-2 (NC_045512.2) together with below mentioned whole genome sequences of specific strains deposited in GISAID database EpiCoV:

Accession number	Variant	WHO classification
EPI_ISL_723044	B.1.1.7	Alfa
EPI_ISL_825139	B. 1.351	Beta
EPI_ISL_792680	P.1	Gamma
EPI_ISL_2650470	B.1.617.2	Delta
EPI_ISL_2631197	B.1.427/B.1.429	Epsilon
EPI_ISL_2614193	P.2	Zeta
EPI_ISL_1563854	B.1.525	Eta
EPI_ISL_1122452	P.3 (version: 2021-04-01)	Theta
EPI_ISL_2647531	B.1.526	Iota
EPI_ISL_1415353	B.1.617.1	Kappa
EPI_ISL_2536799	C.37	Lambda
EPI_ISL_1259297	Breton (hCoV-19/France/BRE-IPP04233/2021)	N/A

Sequence alignment was performed by utilizing multiple sequence alignment program Clustal Omega (EMBL-EBI) that uses seeded guide trees and HMM profile-profile techniques to generate alignments between three or more genomic sequences. Further visualization of the alignment was performed by using MView (EMBL-EBI).

For further wet-lab analysis fragment-specific sequences different from the reference genomic sequences were utilized, as several of the abovementioned new variants exhibit mutations' similarities in the S and N genes. For this purpose, cDNA for S and N genes specific-fragments where synthetized and after dilution to 1000 copies / µl utilized as a template when setting-up reactions with primer sets utilized in RT-LAMP Duo and Direct Kits.

The above-mentioned steps show that Genomtec® SARS-CoV-2 EvaGreen® RT-LAMP CE-IVD Duo Kit and oraz Genomtec® SARS-CoV-2 EvaGreen® Direct-RT-LAMP CE-IVD Kit successfully detects all of the abovementioned SARS-CoV-2 variants.

Genomtec constantly evaluates how newly emerged SARS-CoV-2 variants might impact assay performance by utilizing both in-silico as well as wet-lab approach in order to assure customers of the high inclusivity of Genomtec® SARS-CoV-2 EvaGreen® RT-LAMP CE-IVD Duo Kit and Genomtec® SARS-CoV-2 EvaGreen® Direct-RT-LAMP CE-IVD Kit among SARS-CoV-2 variants of concern.

Miron Tokarski

CEO, Genomtec SA

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Additional information avaiable at:

Genomtec S.A.
Magdalena Kicińska
+48 604 201 230
m.kicinska@genomtec.com

Genomtec S.A.
Charles Winiarski
+44 7972406384
bkc.winiarski@genomtec.com

About Genomtec S.A.

Genomtec is an innovative medical technology company dedicated to the development and commercialization of a mobile molecular diagnostics platform for detection of various infectious diseases, and also rapid laboratory diagnostic tests used, among others, in the detection of COVID-19 disease caused by the SARS-CoV-2 virus. Manufacturing of Genomtec® SARS-CoV-2 EvaGreen® laboratory tests in RT-LAMP technology is based in Poland, with current EU market authorisation (CE-IVD), and product registration started in other regulatory jurisdictions outside Europe.

The company's flagship project is the Genomtec ID mobile IVD platform. The analyser is uniquely placed among Point-Of-Care (POC) products worldwide. It will allow for a quick and precise clinical molecular analysis outside the standard laboratory setting, without the need to involve qualified laboratory personnel. The system uses microfluidic technology and the proprietary, patent-protected SNAAT® isothermal technology. Appropriate

design of the system enables the process to be carried out in record time, i.e. even in 15 minutes, with the diagnostic parameters equal to, and in some cases exceeding, the quality of PCR laboratory tests.

The development and manufacturing process is executed in close cooperation with international CMO (Contract Manufacturing Organization) companies. According to the assumptions of the Genomtec Management Board, the commercialization of the flagship solution will take place in the first half of 2022.

Genomtec was founded in 2016. The headquarter of Genomtec SA is located in Wroclaw. The company has its offices also in the United Kingdom hiring mostly engineers and designers to commercialize Genomtec ID. The company is listed on Warsaw Stock Exchange in alternative trading system NewConnect since March 17, 2021.
More information: www.genomtec.com