

Press Release

Assay development for SARS-CoV-2 testing successfully completed

Hamburg, February 20th 2020

altona Diagnostics GmbH announced today the launch of the **RealStar® SARS-CoV-2 RT-PCR Kit 1.0***, a real-time RT-PCR based test for the qualitative detection and differentiation of lineage B-betacoronaviruses (B-βCoV) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA.

SARS-CoV-2 (previously 2019-nCoV) is a member of the coronavirus family and the causative agent of coronavirus disease 2019 (COVID-19). First cases of a severe mystery respiratory disease were reported from Wuhan, China, end of December 2019. Since then, the number of COVID-19 cases has increased dramatically in China. Additionally, in more than 25 other countries, exported and locally transmitted COVID-19 cases have been confirmed.

"In recent weeks, we have received numerous inquiries from laboratories around the world for a test for SARS-CoV-2. We developed this kit to provide our customers with a reliable product of high quality so that they can respond to the current outbreak of coronavirus disease", said Dr. Markus Hess, General Manager of altona Diagnostics.

"In order to ensure that the test delivers highly reliable results we sent prototype kits to reference centers where the product was tested and where the functionality even with clinical samples was confirmed." Dr. Leonie Hecht, the responsible R&D Project Manager, added.

Designed as a dual target assay and manufactured according to GMP guidelines the ready-to-use kit allows rapid detection of all lineage B-betacoronaviruses and confirms the presence of SARS-CoV-2 specific RNA in only one reaction. All RealStar® (RT-) PCR kits consist of Master Reagents, Positive Control and an Internal Control. They can be used with a wide range of different real-time PCR instruments.

altona Diagnostics has already developed molecular diagnostic test systems during previous global health crises and made them available very quickly. During the outbreaks of swine flu (H1N1) pdm09, MERS-CoV, Zaire ebolavirus and Zika virus, altona Diagnostics' tests have always been among the earliest available and most widely used in the world.

About altona

altona Diagnostics GmbH is a diagnostics company with currently around 200 employees at its headquarters in Hamburg. Further subsidiaries are located in France, Great Britain, Italy, Canada, the USA, Brazil, Argentina and India. altona Diagnostics is focused on developing, manufacturing and marketing molecular diagnostic test systems for the reliable and specific detection of pathogens related to human infectious diseases. A particular focus of the company lies on the field of emerging diseases. altona Diagnostics is ISO 13485 certified and manufactures its high-quality CE-IVD medical devices according to GMP guidelines.

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