Press Release

altona Diagnostics launches CE-IVD certified RT-PCR test for SARS-CoV-2 detection

Hamburg, April 30th 2020

altona Diagnostics GmbH announced today the launch of the **CE-IVD** marked **RealStar® SARS-CoV-2 RT-PCR Kit 1.0** an *in vitro* diagnostic test, based on real-time PCR technology, for the qualitative detection of lineage B-beta coronavirus (lineage B-βCoV) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. It is intended to be used as an aid for diagnosis in individuals with signs and symptoms of coronavirus disease 2019 (COVID-19) in conjunction with clinical and epidemiological risk factors.

SARS-CoV-2, a member of the coronavirus family, is the causative agent of COVID-19. It is highly contagious, transmitted via aerosols and droplets, and causes acute respiratory infections with flu-like symptoms. Since the first cases of the severe respiratory disease were reported from Wuhan, China, in December 2019, COVID-19 infections have spread rapidly around the world.

The **RealStar® SARS-CoV-2 RT-PCR Kit 1.0** consists of Master Reagents, Positive Control and Internal Control. Designed as a dual target assay the ready-to-use kit allows reliable detection of all lineage B-betacoronaviruses (including SARS-CoV-2) and confirms the presence of SARS-CoV-2 specific RNA in only one reaction.

The assay has been validated at multiple national and international reference laboratories, like for example the Charité - Universitätsmedizin Berlin, Bavarian Health and Food Safety Authority (LGL), the Public Health England (PHE) and National Institute for Infectious Diseases Lazzaro Spallanzani.

The **RealStar® SARS-CoV-2 RT-PCR Kit 1.0** has been validated with human respiratory swabs using the **AltoStar® Purification Kit 1.5** on the **AltoStar® Automation System AM16** for nucleic acid extraction and purification and can be used with a wide range of different real-time PCR instruments.

Furthermore, altona Diagnostics also received **Emergency Use Authorization (EUA)** from the U.S. Food and Drug Administration (FDA) for the **RealStar® SARS-CoV-2 RT-PCR Kit U.S.** whose components are chemically identical with the ones included in the **CE-IVD marked RealStar® SARS-CoV-2 RT-PCR Kit 1.0.** The **RealStar® SARS-CoV-2 RT-PCR Kit U.S.** is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory samples from individuals who are suspected of COVID-19 by their healthcare provider.

“altona Diagnostics was one of the first companies to provide reliable RT-PCR based SARS-CoV-2 detection kits early in the corona crisis. In response to the market requirements, we successfully achieved CE-IVD certification as well as Emergency Use Authorization by the FDA. We also ramped up our production capacity quite significantly and adapted our kit configuration by increasing the number of reactions per kit to 384, to respond to the still growing demand and be able to provide all our customers with the **RealStar® SARS-CoV-2 RT-PCR Kit 1.0**”, said Dr. Markus Hess, General Manager of altona Diagnostics.

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 has 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.

altona Diagnostics is ISO 13485 certified and manufactures its high-quality CE-IVD medical devices according to GMP guidelines.

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