altona Diagnostics receives Emergency Use Authorization for RealStar® MERS-CoV RT-PCR Kit U.S.

Hamburg, July 21, 2015 altona Diagnostics GmbH, a diagnostic company headquartered in Hamburg, Germany, today announced that it received Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) for the RealStar® MERS-CoV RT-PCR Kit U.S.. The real-time Reverse Transcriptase/Polymerase Chain Reaction (rRT-PCR) based nucleic acid test can be used under this authorization as a molecular diagnostic tool for the *in vitro* qualitative detection of RNA from Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in lower respiratory samples (tracheal aspirate/ tracheal secretions) from individuals with signs and symptoms of MERS-CoV infection in conjunction with clinical and/or epidemiological risk factors. The test performance was verified in collaboration with the German Consiliar Laboratory for Coronaviruses at the Institute of Virology, University of Bonn, Germany.

The RealStar®MERS-CoV RT-PCR Kit U.S. is authorized for a workflow consisting of nucleic acid extraction using the QIAamp® Viral RNA Mini Kit (QIAGEN) followed by the amplification and detection of MERS-CoV specific RNA using the RealStar® MERS-CoV RT-PCR Kit U.S. on an ABI Prism® 7500 SDS/Fast SDS (Applied Biosystems), CFX96™ system/Dx Real-Time System or CFX96 Touch™ Deep Well Real-Time PCR Detection System (both from BIO-RAD), LightCycler® 480 Instrument II (Roche), Rotor-Gene® 6000 (Corbett Research), Rotor-Gene® Q 5/6 plex/MDxPlatform (QIAGEN) or VERSANT® kPCR Molecular System AD (Siemens).

The RealStar® MERS-CoV RT-PCR Kit U.S. is for use only under Emergency Use Authorization (EUA) in CLIA High Complexity Laboratories, or by similarly qualified non-U.S. laboratories, by clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. The test has been authorized only for the detection of MERS-CoV and not for any other viruses or pathogens. This test has not been FDA cleared or approved and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of MERS-CoV under section 564(b)(1) of the Federal Food, Drug & Cosmetic Act, 21 U.S.C.§360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

about altona Diagnostics GmbH
altona Diagnostics, founded 2007 in Hamburg, Germany, is focused on the development, approval, manufacturing, and marketing of molecular diagnostic test systems for the detection and quantification of pathogens. altona Diagnostics is a fully integrated diagnostic company. The founders and staff of altona Diagnostics have a broad experience in molecular diagnostics and corresponding technologies. Among other activities, they were among the first to make reliable molecular diagnostic kit systems commercially available during outbreak situations for SARS, avian Flu, swine Flu, EHEC and Ebolavirus. altona Diagnostics is ISO 13485 certified.

Media contact
Petra Kampmann
altona Diagnostics GmbH
Mörkenstraße 12
22767 Hamburg, Germany

P.: +49 (0)40 5480676-0
F.: +49 (0)40 5480676-10
petra.kampmann@altona-diagnostics.com
www.altona-diagnostics.com

EUROPEAN UNION
European Regional
Development Fund