altona Diagnostics receives Emergency Use Authorization for RealStar® Ebolavirus RT-PCR Kit 1.0

Hamburg, November 12, 2014. 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® Ebolavirus RT-PCR Kit 1.0. 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 in CLIA high complexity laboratories for the detection of Ebolavirus specific RNA from human plasma. The rRT-PCR kit detects RNA from *Zaire ebolavirus* (ZEBOV), which is responsible for the current outbreak of Ebola Virus Disease in West Africa, as well as all other human pathogenic Ebolaviruses.

The RealStar® Ebolavirus RT-PCR Kit 1.0 is authorized for a workflow consisting of nucleic acid extraction using the QIAamp® Viral RNA Mini Kit (QIAGEN, Hilden, Germany) followed by the amplification and detection of Ebolavirus specific RNA using the RealStar® Ebolavirus RT-PCR Kit 1.0 on an ABI Prism® 7500 SDS /Fast SDS (Applied Biosystems), LightCycler® 480 Instrument II (Roche) or CFX96™ system/Dx real-time system (Bio-Rad).

The test performance was verified in collaboration with the German National Reference Centre for tropical pathogens, the Bernhard Nocht Institute for Tropical Medicine (BNITM), Hamburg, Germany.

The RealStar® Ebolavirus RT-PCR Kit 1.0 is for use only under Emergency Use Authorization (EUA) in CLIA high complexity laboratories and clinical laboratory personnel who have been trained on authorized instruments. The test has been authorized only for the detection of Ebolavirus species 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 *Zaire ebolavirus* (ZEBOV) under the section 564(b)(1) of the 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 in Europe during outbreak situations for SARS, avian Flu, swine Flu and EHEC. altona Diagnostics is ISO 13485 certified.

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