Press Release

altona Diagnostics receives Emergency Use Authorization from FDA for RealStar® Zika Virus RT-PCR Kit U.S.

Hamburg, 13th of May, 2016.

altona Diagnostics GmbH, a diagnostic company headquartered in Hamburg, Germany, today announced that it received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the RealStar® Zika Virus 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 the Zika virus in human serum or urine (collected alongside a patient-matched serum specimen) from individuals meeting U.S. Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or U.S. CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika virus transmission at the time of travel). The test performance for the use with serum and urine samples was validated by the Institute Pasteur de la Guyane, Cayenne, French Guiana.

The RealStar® Zika Virus 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 Zika virus specific RNA using the RealStar® Zika Virus RT-PCR Kit U.S. on an ABI Prism® 7500 SDS/Fast SDS (Applied Biosystems), CFX96™ Real-Time PCR Detection System or CFX96™ Deep Well Real-Time PCR Detection System (both from BIO-RAD), LightCycler® 480 Instrument II (Roche), Rotor-Gene® 6000 (Corbett Research) or Rotor-Gene® Q 5/6 plex/MDxPlatform (QIAGEN).

The RealStar® Zika Virus RT-PCR Kit U.S. is for use only under Emergency Use Authorization (EUA) in CLIA-certified High Complexity Laboratories in the United States, or by similarly qualified non-U.S. laboratories, by clinical laboratory personnel specifically trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. The test has been authorized only for the detection of Zika virus and diagnosis of Zika virus infection, 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* diagnostic tests for the detection of Zika virus and/or diagnosis of Zika virus infection 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 in 2007 and based in Hamburg, Germany, is focused on developing and manufacturing molecular diagnostic test systems for the detection and quantification of pathogens related to human infectious diseases. Among other activities, altona Diagnostics was one of the first companies to make reliable molecular diagnostic kits commercially available during outbreak situations for SARS, avian Flu, swine Flu, EHEC, MERS, and Ebolavirus. altona Diagnostics is ISO 13485 certified.

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RealStar® (altona Diagnostics GmbH); ABI Prism® (Applied Biosystems); CFX96™ (BIO-RAD); LightCycler® (Roche); Rotor-Gene® (Corbett Research/QIAGEN).