

Press Release

altona Diagnostics' RealStar® Zika Virus RT-PCR Kit 1.0 receives Emergency Use Authorization for Korea

Hamburg, 5th of August, 2016

altona Diagnostics GmbH, a diagnostic company headquartered in Hamburg, Germany, announced that it received Emergency Use Authorization (EUA) from the Korea Centers for Disease Control & Prevention (KCDC) for the RealStar® Zika Virus 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 for the *in vitro* qualitative detection of RNA from the Zika virus in human serum or urine. 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 1.0 is designed 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 1.0 on a Mx 3005P™ QPCR System (Stratagene), VERSANT® kPCR Molecular System AD (Siemens), 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 Platform (QIAGEN).

The RealStar® Zika Virus RT-PCR Kit 1.0 is for use under KCDC Emergency Use Authorization (EUA) in Korean hospitals and commercial labs. The EUA for the RealStar® Zika Virus RT-PCR Kit 1.0 will be effective for one year.

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. altona Diagnostics is ISO 13485 certified and manufactures under GMP guidelines. 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.

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RealStar® (altona Diagnostics GmbH); ABI Prism® (Applied Biosystems); CFX96™ (Bio-Rad); LightCycler® (Roche); Rotor-Gene® (Corbett Research/QIAGEN); Mx 3005P™ (Stratagene); VERSANT® (Siemens); QIAamp® (QIAGEN).

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