19.08.2016 – First Diagnostic Test for Zika virus accepted by WHO

RealStar® Zika Virus RT-PCR Kit 1.0 was listed by WHO as first *in vitro* diagnostic test eligible for procurement agencies and Member States. It was assessed under the Emergency Use Assessment and Listing Procedure (EUAL) - an emergency quality assessment mechanism established by WHO during the 2014 Ebola Virus Disease outbreak. The EUAL procedure was developed to expedite the availability of IVDs needed in public health emergency situations. Such a Public Health Emergency of International Concern has been declared by WHO´s Director General on February 1st 2016. altona Diagnostics´ RealStar® Zika Virus RT-PCR Kit 1.0 allows the qualitative detection of Zika virus specific RNA in human serum or urine after extraction of the viral RNA using QIAGEN´s QIAamp Viral RNA Mini Kit. It was developed and validated for a range of real-time PCR instruments.

The test performance was validated by the Institute Pasteur de la Guyane, Cayenne, French Guiana, and the limit of detection studies have been performed at the Bernhard-Nocht-Institute for Tropical Medicine (BNITM), a WHO Collaborating Centre for Arbovirus and Haemorrhagic Fever Reference and Research.

A public report with additional details about the WHO Emergency Use Assessment and Listing for RealStar® Zika Virus RT-PCR Kit 1.0. can be found at:

http://www.who.int/diagnostics_laboratory/eual-zika-virus/zika/en/

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 cGMP 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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