Press Release

BIONEER Corporation
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BIONEER'S 3-IN–1 TEST FOR ZIKA, DENGUE AND CHIKUNGUNYA IS ELIGIBLE FOR WHO PROCUREMENT

Bioneer Corporation (South Korea) announced that the World Health Organization (WHO) has assessed and today listed *AccuPower®* ZIKV (DENV, CHIKV) Multiplex Real-Time RT-PCR Kit as the first multiplexing *in vitro* diagnostic test eligible for procurement to its agencies and Member States.

With 73 countries and territories around the world reporting mosquito-borne Zika virus transmission, as of 20 October 2016, Zika virus remains a major threat to the global health.

As presenting symptoms of Zika, dengue, and chikungunya infection are similar yet differ significantly in their clinical manifestation, for instance Zika is dangerous among pregnant women, early diagnosis is paramount and a PCR-based definitive diagnostic assay has distinct advantage over immunoassays that show serological cross-reactivity between these pathogens.

AccuPower® ZIKV (DENV, CHIKV) Multiplex Real-Time RT-PCR Kit is a '3-in–1' assay capable of detecting Zika, dengue and/or chikungunya virus infection in a single test, significantly reducing the total sample-to-result run time.

The test was developed to run on Bioneer's *ExiStation™* Universal Molecular Diagnostic System, an integrated molecular diagnostic platform, capable of end-to-end automated process from sample preparation (*ExiPrep™* 16 Dx) to final result (*Exicycler™* 96) for up to 96 samples. This optimal combination of kit and high-throughput instrument yields unprecedented sensitivity that allows detection even at low viral load during convalescent phase of infection.

"We developed *AccuPower®* Zika test with multiplexed ultra-sensitivity to ensure diagnostic accuracy for better health outcomes," said Dr. Han-Oh Park, Founder and CEO of Bioneer Corporation. "It is perhaps the most relevant molecular diagnostic test for Zika, dengue and chikungunya virus infection currently available to global healthcare professionals, and represents our commitment to advancing the global health through innovative solutions at times of global healthcare emergencies."

The kit was assessed under the Emergency Use Assessment and Listing Procedure (EUAL), a mechanism established by WHO and updated on 5 February 2016 to provide procurement agencies and Member States performance assurance for, thus expedite the availability of, the Zika diagnostic products, following the declaration of a Public Health Emergency of International Concern (PHEIC) on microcephaly cases linked to Zika virus.

A public report with additional details about the WHO EUAL for *AccuPower®* ZIKV (DENV, CHIKV) Multiplex Real-Time RT-PCR Kit can be found at http://www.who.int/diagnostics_laboratory/eual-zika-virus/zika/en/