BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Co-Diagnostics gets CE mark for Zika, Dengue, Chikungunya diagnostic test

11 March 2019 | News

Logix Smart™ ZDC Test now available for export from the United States as a CE-marked IVD

Co-Diagnostics, a molecular diagnostics company with a unique, patented platform for the development of molecular diagnostic tests, announced that its Logix Smart™ ZDC Test has obtained CE mark regulatory clearance to be sold as an in vitro diagnostic ("IVD") for the diagnosis of Zika, dengue, and chikungunya in accepting markets, and is now available for purchase from the Company's Utah-based facility.

The Declaration of Conformity for the Logix Smart ZDC test confirms that it meets the Essential Requirements of the European Community's In-Vitro Diagnostic Medical Device Directive (IVDD 98/79/EC), allowing export and sales of the product to commence immediately to markets that accept a CE mark as valid IVD regulatory approval, pending any local product registration requirements.

These markets include several countries across the Caribbean basin and Latin America in which the Company already has distribution agreements in place. Co-Diagnostics expects regulatory approval for such a high-demand test to facilitate the creation of additional sales and distribution opportunities in those areas.

Co-Diagnostics' Logix Smart ZDC Test functions via a single-step reverse transcriptase real-time polymerase chain reaction to identify and differentiate between the viral RNA of Zika, dengue (all 4 serotypes), and chikungunya. The three viruses are spread by the same Aedes mosquitoes and have similar symptoms, including sever fever and joint pain, which has historically led to false diagnoses.