Malaysia's Mediven gets CE-IVD certification for molecular test kits

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Singapore: Malaysia based diagnostic company, Medical Innovation Ventures (Mediven), has received CE-IVD certification for molecular and rapid test kits for infectious diseases including cholera, dengue and influenza.

"Mediven has a key focus in diseases affecting the bottom billion. Fast and early detection of these diseases can make a positive impact in Southeast Asia and other emerging healthcare markets. With these new series of products, Mediven is able to cover major infectious diseases that are relevant to the region. That is a major milestone for us" said Mr Ariff Ismail, executive director, Mediven.

The products with CE-IVD mark include GenoAmp Real-Time RT-PCR kit for detecting both Influenza A and B. The test detects Influenza A serotypes H1N1 and H3N2 and Influenza B from viral RNA in a single tube within about 4 hours.

The dengue tests with CE-IVD marking are point-of-care lateral flow assays developed for the detection of IgG/IgM antibodies and NS1 antigens in the Blood, which are marketed as ProDetect Dengue NS1 Antigen Test, ProDetect Dengue IgG/IgM Antibody Test and ProDetect Dengue Duo NS1 and IgG/IgM Test.

The cholera test, a thermal-stable end point PCR test, requiring no cold chain, is marketed as GenoAmp Cholera Octaplex kit developed for the detection of Vibrio cholerae in human stool. It is designed to amplify seven different genes of V. cholerae simultaneously in a single tube. The test can be performed by simple addition of boiled DNA sample to the tube, followed by automated capillary electrophoresis. It can detect all serogroups O1, O139 and non-O1, non-O139 of V. cholerae; biotypes - El Tor and -Classical; all the Toxin genes; and O139 specific gene.

Mediven recieved BioNexus status in January 2015 by the Malaysian Biotechnology Corporation for technological innovations in the field of IVD.