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Mediven gets CE-IVD mark for molecular diagnosis kits

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Singapore: Medical Innovation Ventures (Mediven), Malaysia based developer and manufacturer of molecular and rapid tests, has received CE-IVD mark for a new set of products that includes molecular and rapid tests for Fecal Occult Blood (FOB), pregnancy, dengue, and tuberculosis. The products have been developed to facilitate rapid and accurate diagnosis of these diseases.

The new rapid tests that received CE-IVD mark are ProDetect FOB Rapid Test (Cassette), ProDetect hCG Pregnancy Rapid Test (Cassette), ProDetect hCG Pregnancy Rapid Test (Strip), and ProDetect Pregnancy Rapid Test (Midstream). The ProDetect FOB Rapid Test is a simple, direct binding immunoassay for the rapid and qualitative determination of human occult blood in feces, while the pregnancy rapid tests detect the presence of hCG in urine during the early stages of pregnancy.

The new CE-IVD molecular tests that are added to Mediven's portfolio are GenoAmp Real-Time RT-PCR test and GenoAmp Endpoint MTB/NTM test. The GenoAmp Real-Time RT-PCR test for dengue is a real-time molecular diagnostic test for the detection and differentiation of serotype 1, serotype 2, serotype 3, and serotype 4 from clinical samples. The GenoAmp Endpoint MTB/NTM test is a thermostabilized PCR test for the detection of Mycobacterium tuberculosis and non-tuberculosis (atypical) mycobacteria (NTM).

Mediven was awarded BioNexus status by the Malaysian Biotechnology Corporation in January 2015 for its technological innovations in the field of IVD. The BioNexus status provides Mediven increased regional market acceptance and recognition. The firm aims to dominate the infectious disease diagnostic markets in developing countries. In March 2016, Mediven received Frost & Sullivan's 2016 Entrepreneurial Company of the Year Award in In Vitro Diagnostics for Infectious Diseases.

"The new addition of CE-IVD marked molecular and rapid tests to our product portfolio underlines our focus on addressing the healthcare issues of the bottom billion. CE marking is a critical activity for us, to as we are committed to provide "state-of-the-art" products that can assist fast, accurate, and affordable diagnosis" said Mr. Ariff Ismail, executive director, Mediven.