

AITbiotech PCR assay gets first-ever CE in S. Asia

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AITbiotech becomes first-ever ASEAN firm to secure CE-IVD certification for molecular diagnostic assays



Singapore: AITbiotech, a leading molecular diagnostic and genomic services provider in Singapore, has secured CE-IVD mark certification for its abTES Flu 4-Plex and abTES MTB real-time PCR assays.

The CE clearance of abTES Flu and MTB qPCR Kits marked a significant milestone for AITbiotech in the year of 2012. The firm also got the ISO 13485:2003 certification (for design, development and manufacturing of medical devices for detection of infectious diseases) in October 2012. AITbiotech is in the process of seeking certification of its several other abTES assays including the multiplex malaria and dengue assays.

According to Dr Masafumi Inoue of Experimental Therapeutics Center, a Singapore A*STAR Research Institute, "This is a historical milestone for Singapore's molecular diagnostics industry. We are very excited that A*STAR's technology has helped Singapore's local SME, AITBiotech break into the international market for molecular diagnostics. Receiving the CE certification for these two made-in-singapore kits is a stamp of international endorsement on our technology and a remarkable testament to the success of our collaboration with the clinicians and the industry to impact public healthcare."

AITbiotech licensed the assays from ASTAR in 2009. It is the first genomic services provider in Asia to secured 13485:2003 certification for its genomic services including oligonucleotides synthesis, capillary sequencing and next generation sequencing (NGS) services in October 2012. It is now the first diagnostic company in the ASEAN region to secure CE Marking for real-time PCR diagnostic assays.

According to CEO Mr Alex Thian, "Securing CE Mark for our assays is crucial to AITbiotech for its goal to be a significant MDx player in Asia as it is a necessary step for product registration in most Asian countries. With the certification AITbiotech will be able to capture this growing MDx markets in Asia."