

AITbiotech gets ISO certificate for genomic services

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Singapore: AITbiotech, a leading genomics service provider in Singapore, has secured ISO 13485:2003 certification, for design, development and manufacturing of IVD medical devices for detection of infectious diseases; and manufacturing of oligonucleotides and sequencing services.

With the certification AITbiotech will be able to obtain CE certification for its multiplex real-time PCR diagnostic test including its 4-plex flu assay, 5-plex Dengue assay, and 4-plex Malaria assay. It will also be able to register its assays in most Asian countries.

AITbiotech 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 services. With this certification, it

will be able to assure customers consistent quality for these services. Its oligonucleotides can be used by medical device manufacturers as well for their manufacturing of diagnostic assays.

Dr Masafumi Inoue from the Experimental Therapeutic Centre Singapore, who is the developer of some of the assays that AITbiotech have licensed, believes that it is a milestone for a local company to achieve ISO13485:2003 certification for manufacturing of IVD medical device.

"Our team is very excited to hear about AITbiotech achieving ISO 13485 certification and its CE-marking plans for its assays. The strong relationship we have with AITbiotech in the past years has synergistically produced the high-quality diagnostic assays. I am confident that AITbiotech will reap more success by bringing more competitive made-in-Singapore assays to the world in the coming years."

According to CEO Alex Thian "Securing the certification 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 and it ensure our assays are of the highest quality. With regard to genomic services, the certification is also important as more and more such services are being used by researchers in the projects to develop diagnostic assays. We see a grow in the diagnostic companies in Asia. With the certification AITbiotech will be able to capture this growing opportunity."