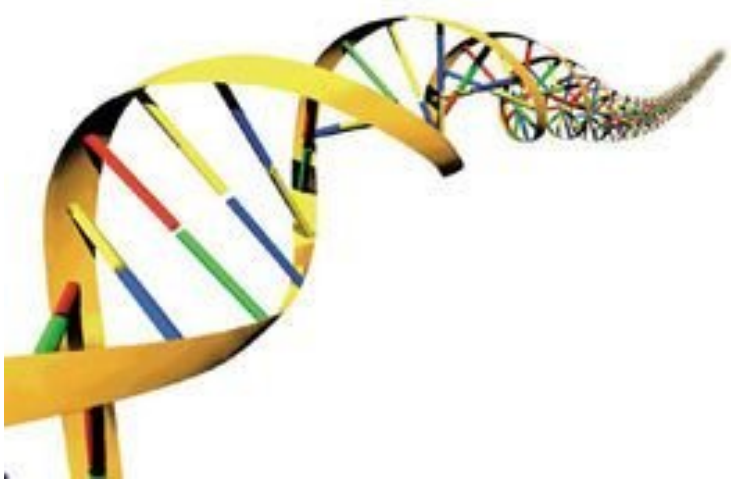
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Life Tech Sanger sequencer gets China SFDA nod

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Singapore:Ã?Â Life Technologies announced that its Applied Biosystems 3500xL Dx Genetic Analyzer has been approved by China's State Food and Drug Administration (SFDA) for clinical diagnostic use in China and the launch of 10 assays from its joint venture with Daan Gene. The development marks a major extension of Life Technologies' capabilities to serve the clinical-end market in China with Sanger-based solutions.Ã?Â

The 3500xL Dx is an automated 24 capillary-based Sanger sequencer designed for a wide range of sequencing applications. It delivers high quality performance, higher throughput and increased productivity for clinical laboratories around the world.

Together with Life Technologies' genetic analyzer 3500 Dx that was approved by SFDA for IVD use in 2011 in China, the 3500 series genetic analyzers are intended for use in a wide range of applications in the process of clinical research, including de novo sequencing and mutational profiling as well as HLA typing. The newly expanded offering of both the 3500 Dx and the 3500xL Dx provides hospitals of all sizes the flexibility they need to meet their unique throughput demands.

Based on the 3500 Dx series platform, 10 assays have been developed or licensed by Guangzhou Life Technologies DaAn Diagnostics, a joint venture that established in 2012 between Life Technologies and Daan Gene of Sun Yat Sen University. These assays will be used for genotypic and drug resistance testing, cancer mutation identification and the prenatal chromosome disorder detection.

Currently, nine out of the ten assays are Research Use Only kits and the other one that can be used in Trisomy 21 prenatal screening for Down syndrome is SFDA registered. The company is currently conducting clinical trials and is actively seeking the SFDA approval for the remaining nine kits.

"The current approval of the 3500xL Dx by SFDA emphasizes Life Technologies' success in pursuing regulatory pathways for our diagnostics laboratory instruments as well as our vision to becoming a global leader in the molecular diagnostics industry," said Mr Ronnie Andrews, president of medical sciences at Life Technologies.

"As in other countries, China is facing the challenges of fighting with infectious diseases like HBV, TB, HCV and HIV, as well as various genetic-based diseases like lung cancer, breast cancer, and ovarian cancers, etc. The early detection and

treatment of these diseases will greatly increase the recovery and survival rate of patients," said Dr Siddhartha Kadia, president, Life Technologies Greater China.
Applied Biosystems Sanger Sequencers supplied the technology that powered the Human Genome Project, and Sanger instruments remain the sequencing "gold-standard" for accuracy, reliability and ease of use. The participation of the sequencing technologies in clinical diagnostics is reshaping the disease treatment paradigm worldwide.

Additional products offered by Life Technologies for the molecular diagnostics lab market in China include: the Applied Biosystem 7500, 7500 Fast Dx, StepOne, StepOne Plus, ViiA7 Dx qPCR series. VeritiÃ?Â Dx Thermal Cycler is in the process of SFDA registration in China.