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ASIA EDITION

Macrogen receives CAP accreditation in two clinical labs in Korea

August 14, 2018 | News

Expected to Expand the Clinical Diagnostics Market in Korea and Accelerate Entry into the Global Market



Macrogen, Inc., a precision medicine biotechnology company has announced that its two next generation sequencing (NGS) clinical laboratories, located in its Seoul headquarters and Bundang Precision Medicine Center, respectively, received the College of American Pathologists (CAP) accreditation.

Macrogen now has three global NGS clinical laboratories with international accreditation, including Macrogen USA, which was CAP-accredited in October 2017.

The CAP Laboratory Accreditation Program is internationally recognized and the largest of its kind, accrediting more than 8,000 laboratories. As part of the program, laboratories undergo an on-site inspection once every two years. Inspectors, who are practicing laboratory professionals, use detailed checklists that reflect the program’s rigorous standards and serve as a guide to assess the laboratory's overall management and operation.

Macrogen was CAP-accredited for genome analysis using NGS. The accreditation qualifies the company to provide genetic testing services that conform to the global standard across its clinical diagnostics business. Such services include Non-Invasive Prenatal Test (NIPT), Cancer Panel, BRCA1/2 Panel, Hereditary Cancer Panel, and Whole Exome Sequencing.

Since 2005, when Macrogen was registered as a genetic testing institution, it has maintained the highest grade in the “Genetic Testing Accuracy Evaluation” by the Korean Institute of Genetic Testing Evaluation. On top of that, in April 2017, “NGS clinical laboratory accreditation” by the Ministry of Food and Drug Safety officially recognized that Macrogen has the outstanding quality management system.

“The CAP-accreditation of our two additional clinical NGS laboratories is the result of our continuing commitment for the highest quality management system,” said Kap-Seok Yang, the CEO of Macrogen. “We consider this accreditation as the recognition of the laboratories’ expertise, transparency, and reliability, and hopefully it will help the company expand its clinical diagnostics and personal genome sequencing services in the Korean market and accelerate entry into the global market.” he added.

Macrogen has continued investments and R&D activities with the aim to expand the use of genome information to the clinical diagnostics and consumer markets based on its global technology leadership in the genome analysis field. It has launched many services ranging from ‘faest™’ (next-generation prenatal genome testing) to the ‘axen™ Cancer Panel’ (a cancer genome testing service based on NGS) and ‘My Genomestory™’ (a personal genome analysis service in the disease prediction and wellness fields). Macrogen, a pioneer in the precision medicine field, is strengthening its foundation for future business by cooperating with major Korean and overseas medical institutions such as the Seoul National University Bundang Hospital, National Cancer Center and many experienced companies in various fields.