

DNA Chip Research, Inc.

[October 28, 2021. Tokyo, JAPAN]

DNA CHIP RESEARCH INC. HAS DEVELOPED A HIGH SENSITIVITY
MULTIPLEX COMPANION DIAGNOSTICS TEST (LUNG CANCER COMPACT
PANEL) TO ANALYZE GENETIC ANOMALY IN LUNG CANCER AND HAS
APPLIED TO THE PMDA FOR PRODUCT APPROVAL.

On October 28, 2021, DNA Chip Research Inc. (President Ryo Matoba) announced that they have developed a high-sensitivity genetic test to detect abnormal (mutated) DNAs in FFPE tissue/Cytology specimen for targeted therapies of lung cancer, and submitted its program, “Lung Cancer CompactPanel Dx Multiplex Companion Diagnostics Test” for approval from Japanese authorities as a medical program. The genetic test can be used as companion diagnostic test in clinical practice after approval.

For the treatment of Non Small Cell Lung Cancer (NSCLC) patients, 7 types of molecular targeted drugs interfering selectively with oncogenic driver mutations (EGFR, ALK, ROS1, MET, BRAF, RET, NTRK) have been currently approved in Japan. Previously, sequential single-plex companion diagnostics test was conducted in clinical settings. However, the number of genes that can be tested using the limited amount of biopsy sample is restricted by sequential singleplex companion diagnostics test. These limitations have been overcome by NGS-based multiplex companion diagnostics test amplifying the multiple genes (or multiple genes) in the same reaction assay. However, there are still several problems for the wide use of NGS panel companion diagnostics. In the case of large panel test designed for profiling testing, only part of the analytical cost can be covered by public health insurance system, and such panel is hardly used for the purpose of companion diagnostics. Moreover, feasibility of multiplex panel is generally low especially with regard to nonsurgical biopsy in Japan. The success rate of currently available multi-companion panel test is influenced by tissue size and tumor cell count. Thus, strict and labor-intensive pathological sample selection is required, and consequently, a considerable fraction of samples is excluded from the test.

To overcome these problems and to meet medical needs unique to Japanese clinical settings, we have developed the highly sensitive companion diagnostics test optimized for lung cancer by focusing on the druggable genes. In the compact panel, the assay is separated by fractionated module components in which amplicon designs and assay conditions have been fully optimized. These optimization and customization enable the high sensitivity, cost merit, and scalability. This test has been developed based on the

research performed at the Nara Institute of Science and Technology (NIST) and the Osaka International Cancer Institute (OICI). We expect the compact panel will help to enhance precision medicine and to deliver optimal drugs as many patients as possible.

DNA Chip Research Inc. was founded in April 1999, specializing in development of DNA microarrays. Since then, we have consistently been engaging in various research projects and services that involve gene analysis and related technologies. To stay on top of this rapidly developing field, we have always engaged ourselves with the latest technology, and our own innovations. We constantly strive to provide exceptional quality of service by consolidating our knowledge on bioinformatics, techniques on automation of sample processing, and nanoscale sample analysis. Currently, our major business is focused on research and development, contract research service, and diagnostic support service.

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