

Thermo Fisher receives reimbursement coverage for Oncomine test

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Thermo Fisher Scientific has announced that its Oncomine Dx Target Test CDx System has received reimbursement coverage from Japan's Ministry of Health, Labour and Welfare and is now commercially available in that country.

The next-generation sequencing (NGS)-based companion diagnostic (CDx) test evaluates patient tumor samples for multiple biomarkers associated with targeted therapies for non-small cell lung cancer (NSCLC).

Japanese cancer patients now have access to a reimbursed NGS test designed to detect multiple key driver genes simultaneously in NSCLC to more quickly determine if they are candidates for one of eight targeted therapies. The CDx biomarkers and therapies include:

- *EGFR* exon 19 deletion mutation and *EGFR* exon 21 L858R mutation – afatinib, gefitinib, erlotinib, osimertinib
- *ALK* fusion gene – alectinib, crizotinib
- *ROS 1* fusion gene – crizotinib
- *BRAF* V600E mutation – Combined therapy of dabrafenib and trametinib

Tumor samples retrieved from NSCLC patients are often limited in quantity, which can pose challenges in the lab. The Oncomine Dx Target Test leverages Thermo Fisher's Ion AmpliSeq technology to overcome this hurdle, enabling testing results to be returned to oncologists using very small amounts of biopsied tumor samples. This reduces the potential for risky second biopsies and unnecessary physical burden to patients.

As an approved CDx system, Oncomine Dx Target Test can now be applied upfront at the initial diagnostic treatment stage for all NSCLC patients in Japan. Since there is no approval condition for the facility requirements, it can be used in all medical facilities where cancer treatment is performed.