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Japan approves Guardant Health's liquid biopsy test for tumour mutation profiling

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Guardant360 CDx is a comprehensive genomic profiling test which utilizes blood samples from patients with advanced solid cancers

The Ministry of Health, Labour and Welfare (MHLW) in Japan has granted regulatory approval of Guardant360 CDx, a liquid biopsy test for tumor mutation profiling, also known as comprehensive genomic profiling (CGP), in patients with advanced solid cancers.

The Guardant360 CDx test was also granted approval as a companion diagnostic to identify patients with microsatellite instability-high (MSI-High) solid tumors who may benefit from Keytruda® (pembrolizumab) and patients with MSI-High advanced colorectal cancer (CRC) who may benefit from Opdivo® (nivolumab).

This regulatory approval has taken on an added significance as CRC is the most commonly diagnosed cancer in Japan. Guardant360 CDx is offered by Guardant Health Japan, a precision oncology company based in Tokyo which is a wholly owned subsidiary of Guardant Health Asia, Middle East & Africa (AMEA).

Additionally, in December 2021, MHLW granted regulatory approval of the Guardant360 CDx liquid biopsy test as a companion diagnostic for identifying patients with metastatic non-small cell lung cancer (NSCLC) who may benefit from treatment with LUMAKRAS™ (sotorasib), a *KRAS* G12C inhibitor developed and manufactured by Amgen.