

FALCO Bio, Promega kit obtains approval in Japan

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Promega Corporation has announced FALCO biosystems of Kyoto, Japan, a core business company of FALCO HOLDINGS, working in collaboration with Promega microsatellite instability (MSI) chemistry and assay design, obtained companion diagnostic approval for FALCO's MSI-IVD from Japan's regulatory agency, the Ministry of Health, Labour and Welfare (MHLW).

The MSI-IVD Kit (FALCO), which detects MSI-High within tumor tissues as a biomarker of DNA repair dysfunction, is the first pan-tumor companion diagnostic test in Japan. Its intended use is to identify patients suitable for treatment with the anti-PD-1 antibody KEYTRUDA (Pembrolizumab).

The FALCO kit detects MSI-High status with DNA isolated only from a patient's tumor tissue, without corresponding submission of a blood sample, using multiplex PCR fragment analysis with Promega designed five mononucleotide repeat markers, which are less susceptible to genetic polymorphisms. The clinical performance study conducted for the kit confirmed the detection capability of MSI-High in 16 different cancer types for stomach, uterine, breast, pancreas, etc. other than colorectal cancer.