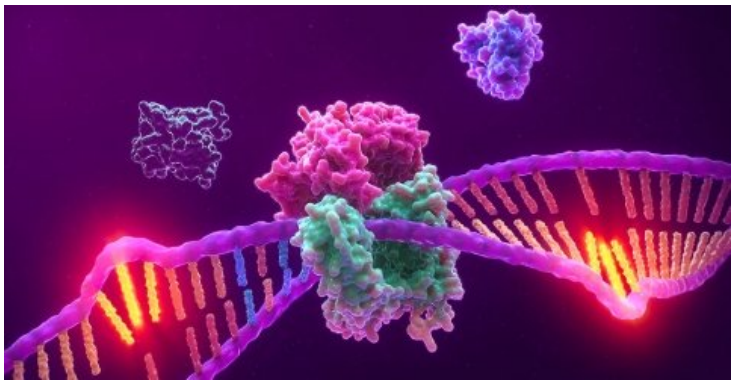
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

# First Promega companion diagnostic receives China's NMPA approval

05 February 2026 | News

**China NMPA approves Promega MSI detection kit as companion diagnostic for KEYTRUDA®**



The National Medical Products Administration (NMPA) has approved the OncoMate® Microsatellite Instability (MSI) Detection Kit as a Class III in vitro diagnostic medical device in China. It is intended for use as a companion diagnostic to identify MSI-High (MSI-H) solid tumour patients for treatment with KEYTRUDA®(pembrolizumab), Merck & Co., Inc., Rahway, NJ, USA's anti-PD-1 therapy. This is the first Promega companion diagnostic to receive NMPA approval.

China continues to face one of the world's highest cancer burdens, with solid tumors representing the vast majority of diagnoses nationwide. Despite advances in oncology care, most patients with advanced solid tumors ultimately progress after first-line therapy, creating a critical need for tools that can guide more effective alternative treatment strategies. The OncoMate® MSI Detection Kit is a PCR-based assay designed to evaluate MSI status in tumor tissue. MSI status can be used to guide treatment decisions and support precision oncology strategies in solid tumors.

The approval was supported through a collaboration with Merck & Co., Inc., Rahway, NJ, USA, which markets KEYTRUDA. The collaboration reflects a shared commitment to improving access to diagnostics that guide therapeutic decision-making.

Promega MSI technology has received additional regulatory approvals in China, the European Union and the United States. OncoMate® MSI Dx Analysis System was recently approved by the FDA as a companion diagnostic designed to identify patients with microsatellite stable (MSS) endometrial carcinoma who may benefit from treatment with KEYTRUDA plus LENVIMA® (Lenvatinib), the orally available multiple receptor tyrosine kinase inhibitor discovered by Eisai.