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# Ventana gets CFDA nod for cancer antibody assay

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**Singapore:** Ventana Medical Systems, which is a member of the Roche Group, received approval for its Ventana ALK (D5F3) Rabbit Monoclonal Primary Antibody assay by the Chinese Food and Drug Administration (CFDA) as a companion diagnostic to aid in the identification of patients for Pfizer's CFDA-approved oncology product Xalkori (crizotinib).

The immunohistochemistry (IHC) assay is designed to identify ALK-positive patients in non-small cell lung cancer (NSCLC) patients. The approval is based on a retrospective study that included 1100 Chinese subjects across three national hospitals where the Ventana assay demonstrated 99.23 percent concordance with Abbott's Vysis ALK Break Apart FISH Probe Kit.

Mr Fatt Heng Wong, GM, Roche Diagnostics China, said that, "I am delighted with the successful product registration of ALK IHC in China. It allows us to offer our customers ALK diagnostic testing in non-small cell lung cancerone of the most prevalent and deadly cancers in Chinaas part of our active pursuit of personalized healthcare initiatives through new innovative products."

The Ventana ALK IHC companion diagnostic assay, available in over 53 countries, provides patients and lab professionals a highly efficient, standardized, and cost effective testing method for the assessment of ALK protein expression. In addition, the Ventana ALK IHC assay is the only CE-marked IVD IHC test with a claim to identify patients eligible for Xalkori treatment. IHC interpretation using brightfield microscopy is widely accessible on over 4,000 Ventana BenchMark XT and GX instruments globally. Immunohistochemistry offers fast interpretation, seamless integration into lab workflow and the ability to archive test results.

In addition to Pfizer, Ventana has worked with more than 45 biopharmaceutical partners over the past decade and is currently engaged in over 150 collaborative projects to develop and commercialize companion diagnostics globally.