

[FDA approves OncoReveal CDx on Illumina MiSeq Dx system](#)

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April 23, 2024—[Pillar Biosciences](#) announced that the FDA has approved the company's premarket approval supplement application for the OncoReveal CDx pan-cancer solid tumor in vitro diagnostic assay. The panel covers 22 clinically relevant genes in one multiplex reaction and has a fully automatable workflow with a sample-to-report time of as little as 48 hours. Up to 46 clinical samples can be batched on a single MiSeq Dx run.

"We are pleased to have expanded the clinical utility of OncoReveal Dx, which was the first FDA PMA-approved multicancer IVD kit launched in the market," Gang Song, founder and executive chairman of Pillar Biosciences, said in a press statement. "In partnership with Illumina, our newest IVD offering, OncoReveal CDx, is a pan-cancer solid tumor IVD that will enable critical diagnostic testing to be performed locally in any NGS lab, whether hospital based or a commercial reference laboratory, running an Illumina MiSeq Dx System."

This approval follows the PMA approval in July 2021 of the company's OncoReveal Dx, which is approved for use on the MiSeq Dx for therapy selection for non-small cell lung cancer and colorectal cancer. The test simultaneously detects clinically relevant mutations in *EGFR* for NSCLC and *KRAS* for CRC.



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