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Datar Cancer Genetics receives landmark US FDA clearance for CellDx-Tissue assay

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Clearance recognises CellDx-Tissue's dual-analyte DNA and RNA workflow across 517 cancer-associated genes



Nashik-based Datar Cancer Genetics (DCG), a global precision oncology company, has announced that its tissue-based comprehensive genomic profiling (CGP) assay for all solid tumours, CelI^{Dx}-Tissue, has been cleared by the US Food and Drug Administration (US FDA).

CelI^{Dx}-Tissue is a qualitative in vitro diagnostic (IVD) test that uses targeted Next-Generation Sequencing (NGS) of DNA and RNA isolated from formalin-fixed paraffin-embedded (FFPE) tumour tissue of patients diagnosed with solid tumors.

The assay analyses 517 cancer-associated genes and is intended to provide information on somatic single nucleotide variants (SNVs), small insertions and deletions (InDels), *ERBB2* gene amplification, and gene fusions involving *ALK, RET* and *ROS1*. CelI^{Dx}-Tissue is a single-site assay performed at Datar Cancer Genetics' CAP- and CLIA-accredited laboratory.

Comprehensive genomic profiling has become a central component of clinical management of solid tumours, supporting clinicians in characterising tumor genomic alterations across a broad spectrum of cancer types.