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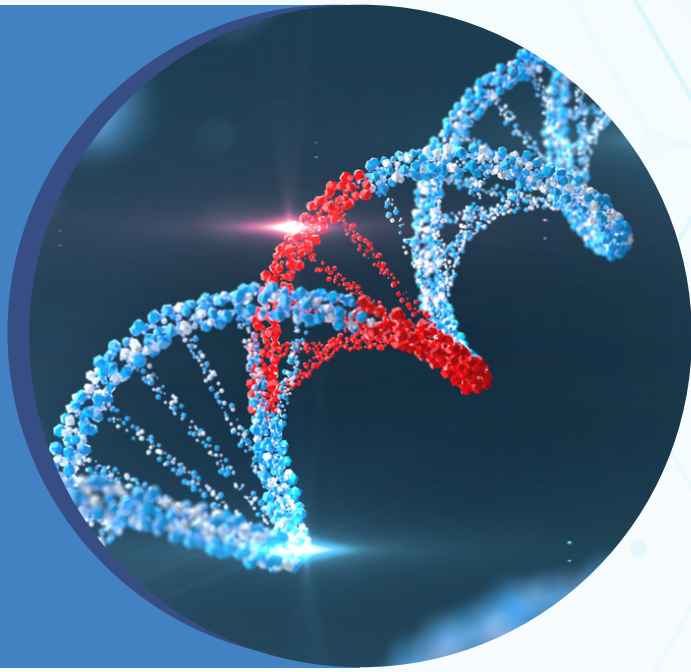
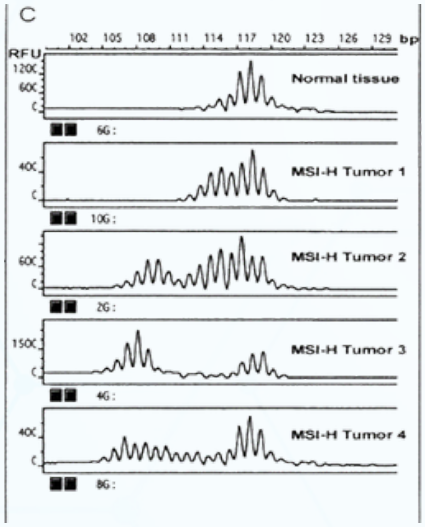
MC-5293

ISO 9001:2015

Uncovering Mutations in Tumor DNA

& providing clinically actionable data for choice of the most optimal treatment





WHAT IS MSI?

Microsatellite instability (MSI) is the condition of genetic hypermutability that results from impaired DNA mismatch repair (MMR). The presence of high levels of MSI (MSI-H) may potentially be predictive of Lynch syndrome, a hereditary condition associated with increased cancer risk across a variety of tumor types including colorectal, gastric, and endometrial cancers. Defects in MMR also result in novel somatic mutations in unrelated loci throughout the genome. These mutations can produce novel immunogenic proteins that can "prime" an immune response to the foreign neoantigens in the tumor.

WHY IT'S IMPORTANT?

- MSI-H tumors are more sensitive to immune checkpoint inhibitor treatments than microsatellite-stable (MSS) tumors. Tumor-based microsatellite instability (MSI) testing, immunohistochemistry (IHC) testing for expression of the MMR proteins, or a measure of Tumor mutational burden are the gold standards for determining eligibility for immune checkpoint blockade therapy. Pembrolizumab (a type of immunotherapy) is approved for the treatment of a relatively wider range of cancer patients, including NSCLC, cervical cancer, gastric cancer, head and neck squamous cell carcinoma (HNSCC), metastatic colorectal cancer, Hodgkin lymphoma, melanoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma and microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancers.
- The National Comprehensive Cancer Network™ (NCCN) guidelines provide recommendations for investigating MSI by PCR and/or MMR by IHC for 15 different cancer types

TECHNIQUE/METHOD

- Molecular examination of microsatellite DNA sequences involves PCR and subsequent fragment analysis of 13 microsatellite markers. For CRC, this typically involves profiling a set of established microsatellite loci, often referred to as the Bethesda set of markers, or the Bethesda panel.
- Mononucleotide markers are more sensitive and specific than the Bethesda dinucleotide markers and thus our fluorescence multiplex assay analyses 13 monomorphic mononucleotide and di nucleotide microsatellite loci.
- Tumour -Normal match not required for testing.

SAMPLE

- FFPE blocks

WHY GENETIC TESTING?

- The latest NCCN guidelines recommend genetic evaluation if younger than age 50 regardless of other test results/ family history.
- The germline MGPT (multigene panel test) strategy is an alternative to tumor and family history-driven selection of patients with CRC for genetic testing because it is more sensitive for identifying individuals with LS and other cancer risk genes than a strategy of selecting for germline testing based on family history and tumor-based criteria.
- Pathogenic variants identified by MGPT are clinically actionable and inform screening and surveillance recommendations the treatment implications for patients with CRC and pathogenic mutations in the Lynch syndrome MMR genes are the best characterized and include response to immune checkpoint inhibitor therapy/programmed death-1 (PD-1) inhibitors.Keytruda (pembrolizumab) is approved for the treatment of any solid tumours that test MSI-H, have progressed after treatment and for which there are no other treatment options.

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BIOSERVE BIOTECHNOLOGIES (INDIA) PVT LTD

Pinnacle Towers, 1st Floor, Plot No.9/17/A&B
Road No.6, IDA, Nacharam, Medchal-Malkagiri Dist.
Hyderabad-500076, Telangana

+91-40 2955 8178/8176
+91 912 122 9283
bioserve.india@reprocell.com
salesindia@reprocell.com
www.bioserve.in

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YOKOHAMA - JAPAN | GLASGOW - UK
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