

Strand® Microsatellite Instability Test (PCR)



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Patient	S. Dilrukshi Vishani Fernando	SampleID	STRAN-2024-56491	Test	Strand MSI by PCR
Gender	Female	Specimen Type	FFPE Block	Type	Full Report
Age	62 Years	Block ID	MO4837 M	Sample Collected	19-Jul-2024
MRN	NA	Tumor Content	75-80%	Sample Received	14-Aug-2024
Clinician	Dr. Mahendra Perera	Specimen Site	Left hemi-colectomy	Report Generated	27-Aug-2024
Hospital	Asiri Surgical Hospital Colombo 5				

Clinical Indication

Colorectal carcinoma

Results

Total microsatellite loci analysed	5
Total microsatellite loci found instable	0
Status of microsatellite instability (MSI)	MSS

Interpretation Summary

This sample has tested negative for microsatellite instability. No microsatellite instability was detected at any of the five loci tested.

Microsatellite instability can result from germline or somatic mutations that cause a functional defect in mismatch repair. This can be primarily due to alterations in the mismatch repair genes MLH1, MSH6, MSH2 or PMS2.

Pembrolizumab is not indicated in this case as it is approved only for the treatment of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) unresectable or metastatic solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options or microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) unresectable or metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. [1]

Dostarlimab is not indicated in this case as it is approved for the treatment of mismatch repair deficient (dMMR) recurrent or advanced solid tumors that have progressed on or following prior treatment and who have no satisfactory alternative treatment options; and mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer in combination with platinum-containing regimen; or as single agent in mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen. [2]

Nivolumab is not indicated in this case as it is approved only for the treatment of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan. [3]

Clinical studies in stage II colon cancer have demonstrated that adjuvant 5-FU therapy significantly improved disease free survival (DFS) in patients with pMMR (MSI-L/MSS) tumors. [4-7]

Clinical correlation is recommended.

References



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1. Keytruda FDA Label - https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125514s024lbl.pdf
2. Jemperli FDA Label - https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761174s006lbl.pdf
3. Opdivo FDA Label - https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125554s055lbl.pdf
4. Benatti P et al. Microsatellite instability and colorectal cancer prognosis. Clin Cancer Res. 2005 Dec 1;11(23):8332-40. Erratum in: Clin Cancer Res. 2006 Jun 15;12(12):3868-9. PubMed PMID: 16322293.
5. Sinicrope FA. DNA mismatch repair and adjuvant chemotherapy in sporadic colon cancer. Nat Rev ClinOncol. 2010 Mar;7(3):174-7. doi: 10.1038/nrclinonc.2009.235. Review. PubMed PMID: 20190798; PubMed Central PMCID: PMC3767984.
6. Sargent DJ et al Defective mismatch repair as a predictive marker for lack of efficacy of fluorouracil-based adjuvant therapy in colon cancer. J Clin Oncol. 2010 Jul 10;28(20):3219-26. doi: 10.1200/JCO.2009.27.1825. Epub 2010 May 24. Erratum in: J Clin Oncol. 2010 Oct 20;28(30):4664. PubMed PMID: 20498393; PubMed Central PMCID: PMC2903323.
7. ASCO Abstract 15S - http://ascopubs.org/doi/abs/10.1200/jco.2008.26.15_suppl.4008

Sample Sufficiency for Testing

A histopathological review of this sample was conducted and the sample was deemed acceptable for testing. It has met our sample acceptance criterion of a minimum 20% tumor content.

Signatures

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Supplementary Section

Test Details

Methodology: Formalin fixed paraffin embedded (FFPE) samples with >20% tumor content were taken for the assay. Genomic DNA was extracted using commercial kits from FFPE sample (Qiagen, USA) and blood (germline sample) (Genfind, USA). The MSI PCR assay was performed using Promega MSI Analysis System, Version 1.2. and MSI amplification was performed as per manufacturer's protocol for 5 mononucleotide repeat marker (NR-21, BAT-26, BAT-25, NR-24, MONO-27) in tumor and germline sample. PCR products were resolved by capillary electrophoresis on the Genetic Analyzer (3500 DX, ThermoScientific, USA). The combination of a four-dye fluorescent system allows for simultaneous amplification and separation of different loci in the assay. The markers were analyzed by using GeneMapper v4.1 software (Applied Biosystems, USA). Results are reported as MSI-high (MSI-H) if 2 or more loci are positive; MSI-low (MSI-L) if 1 locus is positive; microsatellite stable (MSS) if all loci are negative.

Limitations and Disclaimer

As with any laboratory test, there is a small chance that this result may be inaccurate for a procedural reason, such as an error during specimen collection and labelling (incorrect patient identification), an error in processing, data collection or interpretation. Currently available data indicates that technical error rate for analysis involving DNA tests is anywhere between 1-3%. Accurate interpretation of this report is dependent on detailed clinical history of the patient. In the event of unavailability of detailed clinical history, the lab cannot guarantee the accuracy of the interpretation.

End of report

