

MethylTek™-MLH-1 Methylation Test

Q: What is the MethylTek™ MLH-1 test?

A: This test uses patent-pending technology developed by GoPath Labs, specifically designed to analyze MLH-1 hypermethylation for Lynch syndrome.

Q: Why is the MethylTek™ MLH-1 test important?

A: MLH-1 is one of four genes involved in DNA mismatch repair pathway (MMR). Loss of MLH-1 by IHC can be seen in about 15-20% of all CRC patients. About 20% of these patients represent Lynch syndrome/ HNPCC while the rest is sporadic CRC. To distinguish Lynch from sporadic CRC, the key is knowing whether the loss of MLH-1 by IHC is due to hypermethylation of MLH-1 promoter (sporadic) or is caused by germline mutations (Lynch). While both will show 5-FU resistance, finding Lynch syndrome will have significant implications for family members that can be put in early screening programs for CRC and endometrial cancers.

Q: Is MethylTek™ better than others on the market?

A: Yes! MethylTek™ is the only test available in the market that offers quantitative and specific detection of MLH-1 methylation for Lynch syndrome.

Q: Is the BRAF test a good alternative for MethylTek™?

A: Not really. The BRAF gene is only a surrogate marker for MLH-1 methylation and its underlying mechanism is not yet clearly understood. More importantly, about 40% of sporadic MLH-1 deficient CRC would have a negative BRAF mutation.¹ In this case, a direct MLH-1 methylation test is still required to be performed. Opposed to potentially performing two tests (BRAF & methylation), which doubles both cost and TAT, more pathologists recommend ordering MLH-1 Methylation (MethylTek™) directly, when there is IHC loss of MLH-1.

Q: What is the expected Turn Around Time (TAT)?

A: We offer the industry's best TAT, providing results within 3-5 business days in most cases!

Q: When should I order MethylTek™?

A: Order MethylTek™ when your pathologist reports a loss of the MLH-1 gene by IHC, as part of Lynch screening. Alternatively, if MMR IHC is not part of your routine screening process GoPath Labs can help to establish a Lynch program with your Pathology department.

Q: What kind of tissue is needed?

A: While resected cancer tissue is preferred (FFPE - formalin fixed paraffin embedded), biopsies are acceptable as long as sufficient cancer tissue is present. Tissue blocks with 5 blanks at 8 µm, or 10 blanks at 4 µm are required. A request can be made to the Pathology department of your local hospital.

Q: How can I order MethylTek™?

A: This process is very simple! Begin by contacting GoPath Labs via phone or email to request a requisition (see below). Next, send us a tissue block or the appropriate number of blanks with a completed GoPath MolecularDx requisition. Once delivered to GoPath Labs you will be contacted and we will proceed.

Q: How does MethylTek™ reporting work ?

A: MethylTek™ results are reported on a single page with clearly designated areas for diagnosis and interpretation. You can receive reports via fax, or register online to view the reports in *Real Time* at www.gopathlabs.com (Online Reporting).

Q: Who should I contact if I have questions?

A: Experts on this subject are always available for questions and consultation at GoPath Labs. Call our Toll Free number at 855-GOPATH9 or email us at sales@gopathlabs.com to begin today!

References

1. Funkhouser W, Lubin I, Monzon F, Zehnbauer B, Evans J, Ogino S, Nowak J: Relevance, Pathogenesis, and Testing Algorithm for Mismatch Repair-Defective Colorectal Carcinomas. *J Mol Diagn* 2012, 14:91-103