

HOTLINE: Effective November 15, 2021

New Test	3004308	<i>MLH1</i> Promoter Methylation	MLH1 PCR
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Additional Technical Information

Methodology: Real-Time Polymerase Chain Reaction/Fluorescence Resonance Energy Transfer
Performed: **DNA isolation:** Sun-Sat
Assay: Varies
Reported: 7-12 days

Specimen Required: Collect: Tumor tissue. Also acceptable: DNA extracted by CLIA certified lab with corresponding client-circled H&E slide.
Specimen Preparation: **Tumor Tissue:** Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides) Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Extracted DNA: Transport 40 uL DNA with at least 50 ng/uL concentration. (Min: 40 uL) Transport DNA in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Extracted DNA: Refrigerated.
Remarks: Include surgical pathology report.
 If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Unacceptable Conditions: Less than 25 percent tumor. DNA extracted by a non-CLIA lab. DNA extracted without a corresponding circled H&E slide. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
Extracted DNA: Ambient: 1 month; Refrigerated: Indefinitely; Frozen: Indefinitely

Interpretive Data:
 Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

CPT Code(s): 88381; 81288

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.