

Client: Example Client ABC123  
123 Test Drive  
Salt Lake City, UT 84108  
UNITED STATES

Physician: Doctor, Example

**Patient: Patient, Example**

**DOB** 4/29/1965  
**Gender:** Male  
**Patient Identifiers:** 01234567890ABCD, 012345  
**Visit Number (FIN):** 01234567890ABCD  
**Collection Date:** 00/00/0000 00:00

**Microsatellite Instability (MSI) HNPCC/Lynch Syndrome by PCR**

ARUP test code 3004277

Microsatellite Instability Specimen See Note

Microsatellite Interpretation

Stable  
Stable: This patient has a tumor with no detectable instability.  
This result has been reviewed and approved by

H=High, L=Low, \*=Abnormal, C=Critical

**INTERPRETIVE INFORMATION: Microsatellite Instability by PCR**

**CHARACTERISTICS:** This assay is designed to detect microsatellite instability (MSI) at five microsatellite loci. MSI analysis is a screening test for identifying individuals suspected of Lynch syndrome (LS), when they present with colorectal (CRC) or endometrial cancer (or less often another cancer type); however, definitive diagnosis of LS is based on results of germline testing (NCCN Clinical Practice Guidelines in Oncology for Genetic/Familial High-Risk Assessment: Colorectal, www.nccn.org). Additionally, MSI status is a biomarker of treatment response to immunotherapy in many cancer types. For specific treatment recommendations please refer to NCCN Clinical Practice Guidelines in Oncology for a specific cancer type (www.nccn.org).

**METHODOLOGY:** Genomic DNA from a tumor specimen and normal tissue is amplified by PCR for five microsatellite markers: BAT-25, BAT-26, MONO-27, NR-21, and NR-24. Fluorescently labeled products are detected and sized by capillary electrophoresis. Patterns of normal and tumor genotypes are compared for each marker and scored as stable or unstable.

Microsatellite instability-High (MSI-H) indicates a tumor with instability in two or more mononucleotide microsatellite repeats. MSI-H occurs in approximately 90 percent of CRC from individuals with LS, and in 10-15 percent of sporadic CRC.

MSI-Indeterminate indicates a tumor with instability in one of five mononucleotide microsatellite repeats. Since instability in even a single mononucleotide marker can be indicative of a mismatch repair deficient (dMMR) tumor, correlation with evaluation of Mismatch Repair by Immunohistochemistry (ARUP test code 0049302) is recommended.

MSI-Stable (MSS) indicates a lack of microsatellite instability in a tumor. A lack of microsatellite instability would be unusual in CRC from individuals with LS, although it does not completely exclude this possibility. Evaluation of Mismatch Repair by Immunohistochemistry (ARUP test code 0049302) may be helpful in this setting. This interpretation may not apply to tumors other than CRC cancers. The lack of microsatellite instability does not rule out the possibility of other CRC-associated genetic disorders.

**LIMITATIONS:** MSI at markers other than those listed above will not be detected.

**LIMIT OF DETECTION:** 25 percent unstable cells (25 percent tumor content).

**CLINICAL DISCLAIMER:** Results of this test must always be interpreted within the clinical context and other relevant data and should not be used alone for a diagnosis of malignancy. Genetic counseling is recommended.

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.

Microsatellite Marker BAT-26	Stable
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Microsatellite Marker NR-21	Stable
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