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COLARIS®
MLH1, MSH2, MSH6, EPCAM Analysis Results

PHYSICIAN	SPECIMEN		PATIENT	
John Smith, MD	Specimen:	**Blood**	Name:	**Doe, Jane**
Comprehensive Medical Center	Draw date:	**Aug 01, 2010**	Date of Birth:	**April 1, 1492**
1100 Grand Ave	Accession date:	**Aug 02, 2010**	Patient ID:	**000000**
Away, GA 12345	Report Date:	**Aug 12, 2010**	Gender:	**Female**
			Accession #:	**00000000-BLD**
			Requisition #:	**000000**

Test Results and Interpretation

NO MUTATION DETECTED

Test Performed:	Result:	Interpretation:
EPCAM rearrangement analysis	No Mutation Detected	No Mutation Detected
MLH1 sequencing	No Mutation Detected	No Mutation Detected
rearrangement analysis	No Mutation Detected	No Mutation Detected
MSH2 sequencing	No Mutation Detected	No Mutation Detected
*r*earrangement analysis	No Mutation Detected	No Mutation Detected
MSH6 sequencing	No Mutation Detected	No Mutation Detected
rearrangement analysis	No Mutation Detected	No Mutation Detected

Analysis includes sequencing of all exons and adjacent intronic regions and large rearrangement (LR) testing of the MLH1, MSH2, and MSH6 genes and LR testing of the EPCAM gene. LR testing is performed by quantitative multiplex PCR and multiplex ligation-dependent probe amplification (MLPA) for MLH1 and MSH2 and MLPA for MSH6 and the 3' region of EPCAM. MLPA reagents used for this test have not been approved or cleared by the FDA. However, Myriad Genetic Laboratories, Inc. has validated the performance characteristics of this test. Rare interfering variants may exist which could lead to false positive or negative results. Testing at Myriad found that LR mutations account for ~17% of MLH1 and ~37% of MSH2 mutations. The classification and interpretation of all variants identified in this assay reflect the current state of scientific understanding at the time this report was issued. The classification and interpretation of such variants may change as new information becomes available.

It is our understanding that this patient was identified for testing due to a personal or family history suggestive of Lynch syndrome (hereditary non-polyposis colorectal cancer, HNPCC). No deleterious mutation was found in MLH1, MSH2 or MSH6 by full sequence and rearrangement testing, and no deleterious mutation was found in the 3'UTR of the EPCAM gene by rearrangement testing. Sequence analysis identifies mutations in all 19 exons and ~560 non-coding base pairs of MLH1, all 16 exons and ~480 non-coding base pairs of MSH2, and all 10 exons and ~ 300 non-coding base pairs of MSH6. Quantitative multiplex PCR analysis and/or MLPA identify duplications and deletions involving one or more exons of MLH1, MSH2, MSH6 and EPCAM. There are rare genetic abnormalities in these genes that this test will not detect, and other genes, such as PMS2, may be responsible for Lynch syndrome. This result, however, rules out the majority of disease associated abnormalities. If this individual has never had a Lynch Syndrome related cancer, it is recommended that testing an affected relative be considered to help clarify the clinical significance of this negative test result.

Please contact Myriad Professional Support at 1-800-469-7423 to discuss any questions regarding this result.

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These test results should only be used in conjunction with the patient's clinical history and any previous analysis of appropriate family members. It is strongly recommended that these test results be communicated to the patient in a setting that includes appropriate counseling. The accompanying Technical Specifications summary describes the analysis, method, performance characteristics, nomenclature, and interpretive criteria of this test. This test may be considered investigational by some states. This test and its performance characteristics were determined by Myriad Genetic Laboratories. It has not been reviewed by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.