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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

GENETIC VARIANT OF UNCERTAIN SIGNIFICANCE

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	A604D (1811C>A)	Uncertain Significance
*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). The MSH2 variant A604D results in the substitution of aspartic acid for alanine at amino acid position 604 of the MSH2 protein. Because the effect of this variant on the function of the MSH2 protein is not yet known, its significance with regard to the relative risk of cancer cannot be determined from this analysis.

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.