Comprehensive COLARIS AP® APC Analysis and MYH Mutation Panel Result

PHYSICIAN	SPECIMEN			PATIENT	
John Smith, MD Comprehensive Medical Center 1100 Grand Ave Away, GA 12345	Specimen: Draw date: Accession date: Report Date:	Blood Aug 01, 2010 Aug 02, 2010 Aug 12, 2010	Name: Date of Birth: Patient ID: Gender: Accession #: Requisition #:	Doe, Jane April 1, 1492 000000 Female 00000000-BLD 0000000	

Test Results and Interpretation

NO MUTATION DETECTED

Test Performed: APC sequencing comprehensive rearrangement

G382D (1145G>A) MYH Y165C (494A>G) MYH

Result: No Mutation Detected No Mutation Detected

No Mutation Detected No Mutation Detected

Interpretation: No Mutation Detected No Mutation Detected

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Analysis consists of sequencing of all exons and immediately adjacent intronic regions of the APC gene and a comprehensive rearrangement test of APC by Southern blot, as well as analysis of the specific MYH mutations indicated above. The classification and interpretation of all variants identified in this assay reflects the current state of scientific understanding at the time this report was issued. In some instances, the classification and interpretation of such variants may change as new scientific information becomes available.

No deleterious mutation was found in the APC gene in this individual by full sequence and Southern blot analysis. Full sequence analysis identifies mutations in all 15 exons and approximately 440 adjacent non-coding base pairs of APC. Southern blot analysis identifies duplications and deletions involving one or more exons of APC. While there are unusual abnormalities in APC that this test will not detect, this result rules out the majority of mutations responsible for Familial Adenomatous Polyposis (FAP). This analysis did not detect either of two MYH mutations, Y165C and G382D. Current data suggest that these two mutations are the most common MYH mutations in individuals of European descent (N Engl J Med 2003;348:791-799; Lancet 2003;362:39-41). This analysis does not rule out the possibility that other deleterious MYH mutations, which this test is not designed to detect, may be present. If this individual has never had a diagnosis of colorectal polyposis and/or 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 necessarv.