

StageCheck

Previstage™ GCC Colorectal Cancer Staging Test Report

Patient Data			
Patient Name		Specimen ID #	
Patient Address		Submitting Diagnosis	
Patient DOB		Date Received	
Patient Sex		Date Reported	
Medical Record #		Date Collected	
Accession #		Specimen Source	

Medical Team Data			
Ordering Physician		Surgeon	
Pathologist		Additional Physician	

Assay Description
The Previstage™ GCC Colorectal Cancer Staging Test evaluates lymph nodes (LNs) for the presence of GCC mRNA, normally found in gastrointestinal epithelium. Quantitative RT-PCR is used to detect and measure the level of GCC mRNA. This test identifies GCC-expressing cells that would have been detected by histological examination if the entire node (or half node) could have been examined and therefore may more accurately stage these patients.

Previstage™ GCC Results					
	Submitted	Tested	Uninterpretable	GCC Negative	GCC Positive
# of Lymph Nodes					
Results Summary					

Results Interpretation
<p>Positive Result: A positive result indicates that the LNs tested contained levels of GCC mRNA exceeding the test's limit of detection (LOD). Analytical sensitivity of the assay was determined by analyzing LNs from Stage III colon cancer patients and comparing the Previstage™ GCC results to histopathology. The analytical sensitivity of Previstage™ GCC was determined to be 92%.</p> <p>Negative Result: A negative result indicates that the LNs tested contained levels of GCC mRNA less than the test's LOD. Analytical specificity of the assay was determined by analyzing LNs from patients with other diseases and comparing the Previstage™ GCC results to histopathology. The analytical specificity of Previstage™ GCC was determined to be 100% on a subset of patients which demonstrated 98% specificity in R&D.</p> <p>Cutoff Value: The Cutoff Value is defined as the test's LOD. A value exceeding the LOD is comparable to that found in histopathology positive LNs from Stage III colon cancer patients and a value less than the LOD is comparable to patients with other diseases. The Cutoff Value for the Previstage™ GCC Colorectal Staging Test discriminates between pN0 and pN1/pN2 patients and was tested using a cohort of 49 Stage III and 50 Stage I and II colon cancer patients and 286 patients with other diseases.</p>

The Previstage™ GCC Colorectal Cancer Staging Test was performed at DiagnoCure Oncology Laboratories, US.

Signature	Lab21 Lab Director Position	Date
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This test was developed and its performance characteristics determined by DiagnoCure Oncology Laboratories. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) in the US and is qualified to perform high-complexity clinical testing. This test has not been cleared or approved by the U.S. Food and Drug Administration. These test results are an adjunct to clinical and pathologic evaluation by the clinician. This technology is currently covered by U.S. Patents No. 5,601,990, 5,731,159, 5,928,873, 6,120,995, 7,135,333, 7,316,902 and 7,402,401 and validation of European patent EP0734264 in UK and Ireland which are used under license. More patents are pending in the U.S. and in other countries. Previstage™ GCC is a trademark of DiagnoCure Inc.

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