

Previstage™ GCC Colorectal Cancer Staging Test

Frequently Asked Questions:

What is the current standard of care in staging colorectal cancer?

Traditional staging tests for colorectal cancer (CRC) are not as sensitive and accurate as clinicians would like them to be. Current standard of care requires that pathologists examine under a microscope only thin slices of lymph node tissue to see if cancer has spread beyond the intestine. This methodology may only identify one cancer cell in every 200 normal cells. With this standard of care, as many as 30% of patients thought to have disease confined to the intestine return with recurrent disease, presumably through occult metastases that have escaped detection.

Why are occult mesastases important?

Occult metastases are important in the prediction of the risk of disease recurrence in stage I/II colon cancer. Significant recent research including an article published in the *Journal of Molecular Diagnostics* in November of '07 indicates that occult lymph node metastases detected by molecular methods were consistently found to be prognostically significant.

What is GCC and why is it important?

Guanylyl Cyclase C (GCC) is a biomarker that is normally found in the intestine and functions in modulating water transport. Scientific research has determined that when GCC is found outside of the intestine (such as in the lymph nodes surrounding the cancer) it is an early indication that CRC has spread. The technology employed in Previstage GCC test can detect as few as one cancer cell in up to 10 million cells, versus one in 200 normal cells via traditional methodology. GCC should provide clinicians a significantly more sensitive tool for staging a patient with CRC.

What is the significance of molecular diagnostics?

Molecular Diagnostics are becoming an increasingly important tool in the detection of occult metastases. Traditional methods of detection rely on manual microscopy to detect cancerous cells in a field of normal cells. The detection limit of this method is about one cancer cell in 200 normal cells. Molecular methods detect with great sensitivity the presence of GCC-expressing genes that should not normally be present outside the intestine. The technique employed in the Previstage GCC test, RT-PCR, is nearly 100,000-times more sensitive than microscopy, and can detect a single metastatic cell out of 10 million normal cells. This extremely powerful tool is a major adjunct to traditional methods of histopathology and could greatly assist the pathologist in detecting and identifying metastatic disease.

What does a Previstage GCC test result tell the clinician and the patient?

Early research has indicated that detecting the expression of GCC mRNA may provide a more definitive answer to the question “has my cancer spread?” This may be helpful in determining which patients should receive further “adjuvant” therapy such as administration of toxic and expensive chemotherapeutic agents.

Where and when is the Previstage test available?

DiagnoCure Oncology Laboratories will be the only laboratory offering the Previstage GCC Staging Test. DiagnoCure has secured ownership of a lab in West Chester, PA, just outside of Philadelphia and will begin exclusively offering this high-value diagnostic test for the staging of colorectal cancer in the second half of 2008.

Why is staging of a patient with colorectal cancer important?

Staging a patient with CRC is crucial because it may determine the patient’s course of treatment. Currently, about 30% of patients with no pathological evidence of metastatic spread to the lymph nodes (stage I and II cancers) may be under-staged, and therefore do not receive adjuvant therapies such as chemotherapy when they should.

What makes DiagnoCure so confident that Previstage is a significant addition to current staging methods?

Strong data from early studies supports the importance of GCC and a clinical trial of 1,000 patients conducted over five years has just been completed and final data is currently being analyzed. Findings from the study are expected to be presented and published in 2008.