

DiagnoCure Oncology Laboratories

Overview of the Laboratory

Location:

DiagnoCure Oncology Laboratories (DOL) is a CLIA-certified laboratory located in West Chester, Pennsylvania, approximately 2 miles from West Chester University and 25 miles west of Thomas Jefferson Hospital, the University of Pennsylvania Hospital and Hahnemann University Hospital, all located in Center City Philadelphia. The West Chester area is also home to some of the top pharmaceutical and biotech companies in the industry. The hub for UPS, FedEx and DHL shipping companies is about 20 miles from DOL at the Philadelphia International Airport, which allows for easy delivery of all samples coming to and from the lab.

Advanced Molecular Technologies & Testing Capabilities:

Real-time RT-PCR methods are one of the most advanced techniques by which RNA can be detected in tissues today. The laboratory staff of DOL are highly experienced in molecular biology testing, with significant expertise in quantitative RT-PCR, nucleic acid extraction, electrophoresis and design of primers and probes. With this sophisticated technology, DOL has been able to bring to the forefront of pathologic assessment, Previstage™ GCC, the first molecular test to improve staging of colorectal cancer patients. Traditional methods of staging generally interrogate only a single 5µm section of tissue. Previstage GCC examines approximately half of each lymph node, increasing the probability of finding occult metastases that would have remained unseen using current histological methods.

Quality Assurance:

A Quality System, in compliance with CLIA and other regulations, has been implemented at DiagnoCure Oncology Laboratories. This Quality System includes quarterly in-house and annual external quality assurance reviews of procedures and patient records, bi-annual proficiency testing and competency reviews, in-service training to keep the laboratory staff current with medical practice, quality control testing of all incoming reagents and materials to ensure they meet quality specifications, and regular monitoring of environmental conditions, equipment maintenance and laboratory cleanliness. Strict quality control procedures, including bar-coding of all specimens, ensures specimen identity, integrity and tracking at all times. Previstage™ GCC has been validated as a Laboratory Developed Test on over 1,000 lymph nodes from patients diagnosed with Stage I, II and III colorectal cancer and non-cancerous gastrointestinal diseases. Further validation and ongoing clinical studies are being conducted.

Service & Support:

DOL offers expert customer and technical support to all patients and clinicians. Our Customer Care group is available to answer your questions, and pathologic and oncologic clinical consultations are available upon request. Billing assistance is offered through our patient assistance program for those patients in need.

Data Management & Connectivity Solutions:

All patient samples shipped to and from DOL will be tracked through FedEx's bar-coding system. All samples will be received and recoded to ensure safe and successful transfer of all samples from the receiving area to the laboratory. Once received, patient information is recorded in a customized Laboratory Information Management System (LIMS; InterfaSys, Inc) and, pursuant to HIPAA regulations, is securely saved. Samples and associated paperwork are bar-coded at accessioning to ensure samples are processed smoothly. Quality control steps are embedded into the Previstage™ GCC test, as well as monitored by the LIMS. Quality checkpoints ensure that each section of the test has been successfully completed before proceeding with the next step of the test. Final results are generated using an ABI 7900HT Fast Real Time PCR System and connectivity with the LIMS allows the results to be interpreted by the LIMS and inserted into the patient report. Quality assurance checks of the reports are conducted to ensure patient reports are accurate before a board-certified pathologist signs off on the report. Final reports can be faxed, express mailed or mailed by USPS. Additional connectivity options, which will be available in the future, include on-line ordering and results reporting using secure access interfaces. Additional information about Previstage™ GCC can be found at www.diagnocurelabs.com.

Clinical Expertise:

Our medical and technical services team is dedicated to serving your needs. This group consists of pathologists, oncologists and laboratory professionals who can assist you with any questions that you may have regarding the Previstage™ GCC Colorectal Cancer Staging Test.

Key Features & Benefits

- High-complexity, CLIA-certified laboratory in West Chester, Pennsylvania
- State-of-the-art molecular technologies for optimal sensitivity, specificity and reproducibility
- QA/QC programs to ensure highest standards of quality and accuracy
- Service and support programs to ensure rapid, accurate reporting of results
- Access to pathologists and oncologists for clinical consultations
- Patience assistance program for billing
- New Previstage™ GCC Colorectal Cancer Staging Test to molecularly identify occult metastases and more accurately stage CRC patients

Previstage™ GCC Colorectal Cancer Staging Test Ordering Information

Specimen*	Collection Instructions*	Turnaround Time*	Shipping*
Formalin-fixed paraffin embedded whole or half-lymph nodes following colectomy in colorectal cancer patients. A minimum of 12 lymph nodes is requested.	Call DiagnoCure Customer Care group at 877-701-9007 to request a Previstage™ GCC collection kit.	Seven (7) days from date of receipt	Ship overnight in prepaid & addressed Previstage™ collection kit by FedEx to DiagnoCure Oncology Laboratories

*Subject to change

Note: The greater the portion of each lymph node examined, the more sensitive the Previstage™ GCC test will be for detecting occult metastases. For small nodes (<2mm diameter) it is preferred to utilize the entire lymph node for GCC testing.

References

1. Frick GS, Pitari GM, Weinberg DS, Hyslop T, Schulz S, Waldman SA. Guanylyl cyclase C: a molecular marker for staging and postoperative surveillance of patients with colorectal cancer. *Expert Rev Mol Diagn* 2005;5:701-13.
2. Schulz S, Hyslop T, Haaf J, et al. A validated quantitative assay to detect occult micrometastases by reverse transcriptase polymerase chain reaction of Guanylyl Cyclase C in patients with colorectal cancer. *Clin Canc Research* 2006;12:4545-52.
3. Lucas KA, Pitari GM, Kazerounian S, et al. Guanylyl cyclases and signaling by cyclic GMP. *Pharmacol Rev* 2000;52:375-413.
4. Birbe R, Palazzo JP, Walters R, et al. Guanylyl cyclase C is a marker of intestinal metaplasia, dysplasia, and adenocarcinoma of the gastrointestinal tract. *Hum Pathol* 2005;36(2):170-9.
5. Cagir B, Gelmann A, Parks J, et al. Guanylyl cyclase C messenger RNA is a biomarker for recurrent stage II colorectal cancer. *Ann Intern Med* 1999;131:805-12.

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) 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 which are used under license. More patents are pending in the U.S. and in other countries.