

OncoDefender™-CRC Fact Sheet

OncoDefender-CRC Predicts Risk of Recurrence: OncoDefender-CRC is the world's first molecular diagnostic test capable of accurately predicting the risk of recurrence of cancer in patients previously treated with surgical resection (i.e. removal) of a Stage I or Stage II colon cancer tumor or a Stage 1 rectal cancer tumor.

According to an independent statistical review, OncoDefender-CRC test results correlate well with accurately predicting colorectal cancer recurrence. No other currently available molecular diagnostic test approaches the performance capabilities of OncoDefender-CRC in this regard.

- The OncoDefender-CRC test is performed at the Ann Arbor, Michigan headquartered laboratory of Everist Genomics. The tumor analysis requires a small sample of the tumor tissue which is typically provided by a treating physician.
- **Results Reported Rapidly:** Results of the OncoDefender-CRC assay are available within 7 to 10 days from the date the tumor sample is received by Everist Genomics.

Clinical Benefits of OncoDefender-CRC: Patients identified by OncoDefender-CRC at high-risk of cancer recurrence are likely to benefit from adjuvant therapy or other more aggressive treatment options.

- Independent studies¹ have demonstrated a significant improvement in overall survival rates for high-risk Stage I and Stage II colo-rectal cancer patients receiving adjuvant therapy within 60 days following surgical resection of their tumor.
- The OncoDefender-CRC test will help patients and physicians make appropriate post-surgical decisions about the potential need for adjuvant therapy.

Eligible Patients: All patients that have undergone surgical resection of a Stage I/II colon cancer tumor or Stage I rectal cancer tumor are eligible for the Everist Genomics OncoDefender-CRC test and are likely to benefit from use of the test. The OncoDefender-CRC test can only be ordered by a physician.

¹ Gastrointestinal Cancers Symposium, Source reference: Biagi JJ et al. "Time to adjuvant chemotherapy in colorectal cancer: Systematic review and meta-analysis" *ASCO G/ 2011*; Abstract 364; Bayraktar UD, Chen E, Bayraktar S, Sands LR, Marchetti F, Montero AJ, Rocha-Lima CM. Does delay of adjuvant chemotherapy impact survival in patients with resected stage II and III colon adenocarcinoma? *Cancer*. 2010 Dec 17.; *J Clin Oncol*. 2010 Jan 20;28(3):460-5. Epub 2009 Dec 14. Association between disease-free survival and overall survival when survival is prolonged after recurrence in patients receiving cytotoxic adjuvant therapy for colon cancer: simulations based on the 20,800 patient ACCENT data set. [de Gramont A](#), [Hubbard J](#), [Shi Q](#), [O'Connell MJ](#), [Buyse M](#), [Benedetti J](#), [Bot B](#), [O'Callaghan C](#), [Yothers G](#), [Goldberg RM](#), [Blanke CD](#), [Benson A](#), [Deng Q](#), [Alberts SR](#), [Andre T](#), [Wolmark N](#), [Grothey A](#), [Sargent D](#). Hôpital Saint Antoine, Group Hospitalier Pitie-Salpetriere, Paris, France; et. Al.

Regulatory Clearance: The developers of OncoDefender-CRC, Everist Genomics, Inc., have secured registration to perform the OncoDefender-CRC test from the United States Clinical Laboratory Improvement Amendments, (CLIA); CLIA ID number 23 D 201 7844. CLIA is administered by the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid services (CMS) and the Centers for Disease Control (CDC).

- CLIA regulations are based on the complexity of the test method. The more complicated the test, the more stringent the requirements. By law, laboratories conducting High-Complexity testing are required to meet CLIA specified quality standards, proficiency measures and undergo proficiency testing.
- The OncoDefender–CRC test has been classified as a High-Complexity test according to CLIA guidelines and meets the most stringent requirements and quality standards established by CLIA required for High-Complexity testing.

Clinically and Economically Important Advance: OncoDefender-CRC test represents an important advance in the assessment of risk of recurrence of colo-rectal cancer and overcomes the limitations of currently available tests:

- OncoDefender-CRC exceeds the performance characteristics which are typically achieved by applying standard of care guidelines alone.
- OncoDefender-CRC also overcomes the limitations of currently available molecular diagnostics. These limitations include:
 - The competing test is confined to use in Stage II colon cancer patients alone. Whereas, OncoDefender-CRC can be used for assessing risk of recurrence in Stage I/II colon cancer and Stage I rectal cancer patients.
 - The competing test is significantly less effective in identifying patients at high-risk of recurrence relative to OncoDefender.
 - The competing test fails to provide a test result in about 25% of all patients tested. Competitors also refer to this as a 'no-call result'. This means 25 out of every 100 patients referred for the competing test will get no usable results, while each patient will have previously paid for testing.
 - By contrast the OncoDefender-CRC test produces zero no-call results and provides an accurate assessment of risk of recurrence for every patient tested.

Insurance Coverage and Financial Assistance: Regardless of a patient's insurance coverage or financial status, the Everist Genomics Customer Support team will assist in obtaining the testing the patient needs. Everist Genomics will help quickly verify whether or not insurance will cover the test and will bill the insurance company (or Medicare) directly on their behalf.

- In the event that the insurance company denies coverage, or if financial assistance is required, Everist Genomics also has a generous financial assistance program. Qualifying patients are eligible to have up to 80% of the cost of the OncoDefender-CRC test covered through one of the Everist Genomic Financial Assistance programs.
- Financial Benefits Confirmed Rapidly: Within 3 to 4 working days of receiving the completed application for OncoDefender-CRC testing, Everist Genomics will provide the patient and physician with written confirmation of their financial benefits as well as how to proceed with testing.