

Onko-Sure® Compared to Other Tests

Onko-Sure® Advantages Over CEA:

- Onko-Sure® DR-70 (FDP) antigen is freely diffusible in blood and therefore is easy to measure. However, CEA is normally firmly attached to cancer cells since it is an adhesion molecule and less abundant in blood, therefore more difficult to measure.
- Onko-Sure® has an advantage over CEA for lung cancer detection and monitoring, specially in patients with low CEA values.
- Unlike CEA, a commonly used tumor marker for lung cancer, Onko-Sure® measurements are not affected by smoking.

Onko-Sure® Compared to D-dimer:

- D-dimer is not approved for cancer detection or monitoring.
- Onko-Sure® detects all of the breakdown products of Fibrin and Fibrinogen, including a unique cancer-related breakdown product, Initial Plasmin Degredation Product (IPDP).

Onko-Sure® The Power of Knowing



For comprehensive product information
and clinical studies, please visit:

www.onko-sure.com

or email
info@radient-pharma.com



Important Facts You Should Know About ...



Onko-Sure® The Power of Knowing

Onko-Sure[®]

The Power of Knowing

Onko-Sure[®] is a cancer monitoring test to help determine the effectiveness of post-surgery therapy and treatments for colorectal cancer (CRC). Onko-Sure[®] is an ELISA-based assay and was evaluated as an informative test for monitoring disease progression in colorectal cancer patients. Onko-Sure[®] is US FDA cleared for colorectal cancer monitoring. It is used to check for cancer recurrence of disease status during cancer treatment.



Intended Use for Onko-Sure[®]

The intended use for Onko-Sure[®] is as a monitoring test for disease progression in patients previously diagnosed with colorectal cancer. The test should be used in conjunction with other clinical modalities considered to be the standard of care for CRC disease progression monitoring.

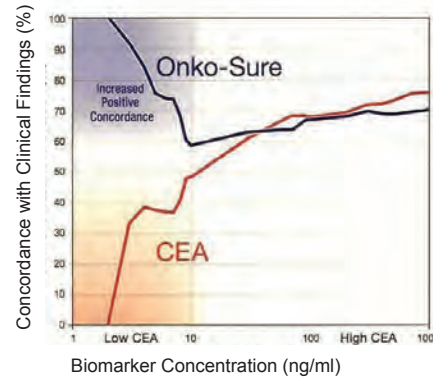


Figure 1. 50% or more CRC patients have low CEA values (<30). As demonstrated in the graph above, Onko-Sure[®] (blue line) showed increased positive concordance, i.e. ability to monitor patients with low CEA values.

Clinical Significance

Onko-Sure[®] is the first new cancer test to be cleared in the USA for the monitoring of CRC in over 25 years. In early CRC stages (Dukes stages A & B) between 68% and 97% of the biopsy positive patients have negative CEA values and are unable to be monitored with CEA.



Published Clinical Studies

1. Small-Howard, AL, and Harris, HH. "Advantages of the AMDL-ELISA DR-70 (FDP) Assay over Carcinoembryonic Antigen for Monitoring Colorectal Cancer Patients." *Journal of Immunoassay and Immunochemistry*, Volume 31, Issue 2 (March 2010)
2. Kerber, A, Trojan, J, Herrlinger, K, Zgouras, D, Caspary, WF, and Braden, B. "The new DR-70 immunoassay detects cancer of the gastrointestinal tract: a validation study." *Aliment Pharmacol Ther* 20, 983-987 (2004).
3. Rucker, P, Antonio, SM and Braden, B. "Elevated Fibrinogen-Fibrin Degradation Products (FDP) in Serum of Colorectal Cancer Patients." *Analytical Letters* 37, 2965-2976 (2004).