

## ELISA Kit for the detection of Carcinoembryonic Antigen (CEA) Immune Complexes (CEA-IgM) in Colon Rectal Cancer (CRC)

Colorectal Carcinoma (CRC) ranks as the third most commonly diagnosed cancer. It represents approximately 11% of all new cases of cancer. The lifetime risk of developing colorectal cancer has been estimated to be approximately 6%, while the estimated lifetime risk of colorectal cancer death is approximately 2.6%. Colorectal cancer affects men and women with nearly equal frequency and is the third most common cancer in both men (after lung and prostate cancer) and women (after lung and breast cancer) (1). Survival of patients with colorectal cancer depends to a large extent on the stage of disease at diagnosis. Thus, in patients with localized disease, 5-year survival is approximately 90%, whereas in patients with regional spread of disease, 5-year survival decreases to approximately 60%. In patients with distant metastases, 5-year survival is less than 10%. There is now substantial evidence that reductions in colorectal cancer mortality can be achieved through detection and treatment of early-stage cancers. Unfortunately, only a minority of colorectal cancers are discovered when they are still localized. An adequate screening strategy can not be followed due to the lack of effective, low cost and non-invasive diagnosis tests (2).

Carcinoembryonic antigen (CEA) is an extensively characterized tumor-associated molecule. At present there is no role for serum CEA assessment as screening tool or diagnostic marker for early cancer detection, due to the very low sensitivity of this test. In fact, free CEA (fCEA) levels are elevated in a wide number of cases only in the latest phases of cancer progression

(i.e. Duke's stage C and D) (3). In CRC patients CEA can be detected bound to IgM immunoglobulins, as CEA Immune Complexes (CEA-IgM), while is undetectable in healthy controls (4). Colon-IC is a highly specific and sensitive ELISA assay for CRC detection designed to measure CEA-IgM in patients sera. CEA-IgM levels are significantly elevated in particular in a high number of cases in early staging (Duke's stage A) colorectal cancer patient sera, resulting in a higher sensitivity than that provided by the analysis of serum free CEA (fCEA) levels (29% vs 8% respectively) (figure 2). Furthermore, combined determination of the two forms of circulating CEA significantly increases the efficiency for discriminating CRC from normal individuals (5).

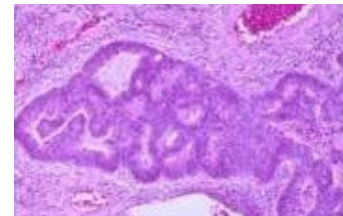


Figure 1: Histological appearance of Colorectal Carcinoma (CRC).

Table 1 shows a comparison of sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) between CEA-IgM, fCEA and combined biomarkers levels in patients with cancer and normal controls.

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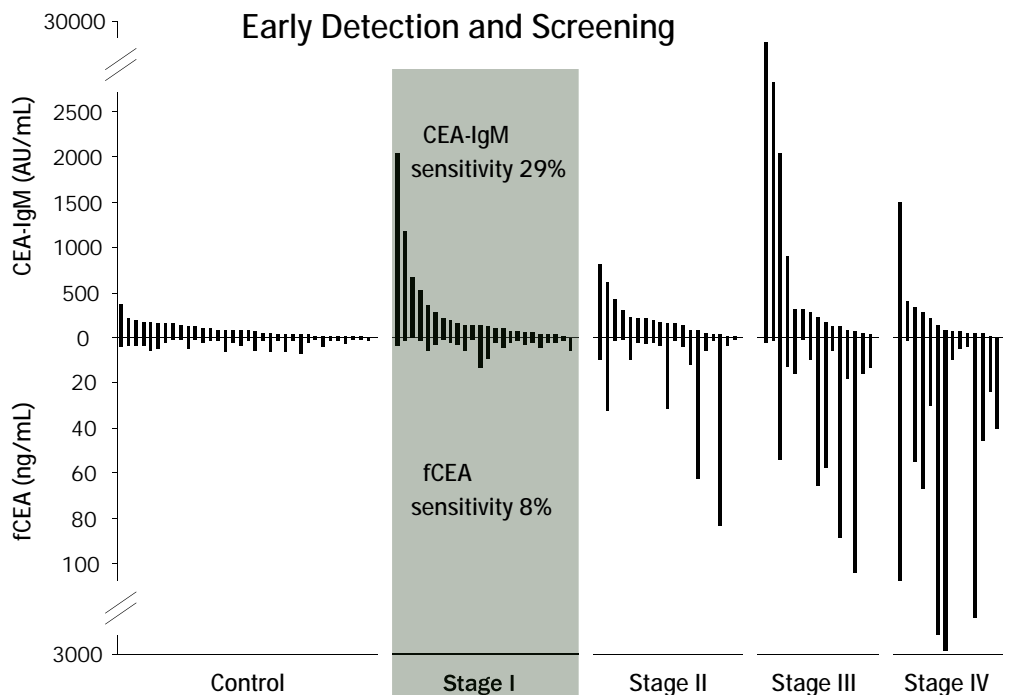


Figure 2: Comparison of serum levels of CEA-IgM and fCEA according to CRC staging.

