D6. Measurement G (In Vitro Assay, CEA)

Basic and Clinical Evaluation of CEA Radioimmunoassay

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Plasma CEA levels were measured by RIA in order to evaluate CEA Roche Kit based on the Hansen’s Z-gel method and clinical usefulness was investigated.

Method: Plasma sample (0.5 ml) was deproteinized using HClO₄, and then dialyzed for 12~16 hrs. in deionized water and ammonium acetate buffer. Dialized sample was incubated at 45°C for 30 minutes each following the addition of anti-CEA antibody and ¹²³I-CEA. Centrifugation after the addition of Z-gel separated B from F.

Materials: Materials included 24 healthy volunteers and 129 patients without carcinoma and 107 patients with various carcinoma. In addition samples from 125 pregnant women were measured.

Results: Our preliminary investigation of the technique revealed satisfactory results showing within assay error; 19~11\% (n=20) in C.V., between assay error; 16\% in C.V. (n=10 in 4 months), recovery rate; 100~118\% (m 111\%). Independent measurements of the same samples in 2 institutes resulted in good agreement (r=0.97).

CEA levels in 24 normal controls showed 2.34±1.21 ng/ml (m±1 S.D.). Therefore, normal range was determined as below 5.0 ng/ml taking m±2 S.D. In 129 patients without carcinoma, 92\% showed CEA levels of less than 5.0 ng/ml, none exceeded 7.5 ng/ml. Forty two percent of patients with carcinoma revealed CEA level greater than 5 ng/ml. Among 14 cases whose CEA level exceeded 25.0 ng/ml, 13 cases (93\%) had proven metastasis. Relatively high incidence of positivity was noted in colonic, gastric and pulmonary carcinoma, though high organ specificity of CEA was not observed. Serial measurement of plasma CEA levels were useful in the evaluation of effectiveness of treatment and follow up study of certain patients. In contrast with α-FP, plasma level of CEA remained unchanged during the course of pregnancy.

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