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EVALUATION OF CA15-3 RIA KIT. K.Kozakai, M.Takano,Y.Maruyama,M.Noguchi,K.Morishita and Y.Miyaji.Toho University,Tokyo. D. Tsujino.St.Marianna University School of Medicine,Kawasaki. Y.Sasaki.Gunma University,Maebashi.

As monoclonal antibodies specifically reacting to mammary cancer tissue,115 D8 and DF3 were prepared by Hilken et.al in 1981 and by Kufe et.al in 1984 respectively. This report concerns fundamental and clinical evaluation of CA15-3 RIA Kit (manufactured by Centocor,U.S.A. offered by Toray-Fuji Bionics) recognized by these two kinds. The principle of two site immunoradiometric assay is used in this kit. The results of the fundamental evaluation shows:Incubation time:one hour was enough as per their instructions for use. Reproducibility,Recovery and Dilution were good. No crossreactivity was observed with 6 kinds of tumor related materials. Clinical evaluation indicates:No significant difference in values was observed between normal male and female. Serum-plasma ratio was insignificant. As a whole,normal pregnant women's values were higher than non-pregnant women's and the highest value was obtained after 30 weeks of pregnancy. Among cancer diseases,highest values were obtained in the case of mammary cancer,then the values of pulmonary and pancreatic cancers were rather higher and the values beyond detectable ranges were observed in the cases of mammary,ovarian and rectal (distant metastasis) cancers. Also,the comparison data with other tumor markers (CEA,TPA and Ferritin) using mammary cancer sera are available for presentation.

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CLINICAL EVALUATION OF TUMOR ASSOCIATED ANTIGEN CA 15-3. M.Hamazu,T.Yamazaki, S.Hosoda,M.Imokawa,Y.Ochi,Y.Ura,Y.Kajita and T.Hachiya. Shiga Univ.of Med.Sci. and Kyoto Pref.Univ.of Med.

Clinical usefulness of CA 15-3 determination as tumor marker (especially breast cancer) were examined. Normal subject (50) showed 14.4 ± 3.1 U/ml (Mean ± SD). 30 U/ml were chosen as cut-off limit of normal according to Tobias' report. Elevated serum levels were found in patients with breast cancer (25.8%), lung cancer (23.8%), pancreas cancer (29.2%), gastric cancer (21.0%), and ovarian cancer (42.1%). CA 15-3 levels were positive in the 10% of clinical stage I-III in both breast cancer and lung cancer. Highly positive cases with high elevation levels were observed in metastatic breast cancer (75.0%, 95.7 U/ml (mean)) and also in metastatic lung cancer (52.8%, 63.8 U/ml (mean)). The increased value was also observed in pancreas cancer (45.5%), gastric cancer (64.3%), and kidney cancer (25.0%).

Elevated serum levels could be found in a few months before clinically detectable metastases. CA 15-3 determination is useful for monitoring patients with metastatic breast cancer. When the serum of patient with breast cancer was fractionated on Sepharose 6B, CA 15-3 activity was found in the MW of about 1,000,000 - 2,000,000 daltons. CA 15-3 activity was destroyed by neuraminidase treatment. From these experiments, CA 15-3 assay may recognize a glycoprotein with sialic acid residue.

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CLINICAL AVAILABILITY OF THE MEASUREMENT CA15-3 FOR BREAST CANCER. Y.Horino,A.Komori,H.Eguchi,Y.Miyamoto,H.Yamamoto(JMC& Co.Ltd.),S.Azumi(Kyoto Daiichi Red Cross hospital),H.Kodama(Kodama Clinic of the mammary gland).

CA15-3 is the antigen related with breast cancer, detected in 1984 by Hilkens,Kufe,etc. It is paid attention as a new tumor marker of breast cancer. This time, we examined clinical availability for breast cancer making use of ELSA CA15-3 kit (Midori Juji).

The value of serum CA15-3 at the sample of healthy body 227 was 11.2 ± 4.3U/ml, the value of Cut Off was 20U/ml. The positive rate at a case of breast cancer was 36.3%(28/77), according to stages, StageI 10.0%(1/10), StageII 15.7%(3/19), StageIII 66.7%(4/6), StageIV 100.0%(1/1), and at the sample of a relasped after an operation 60.7%(17/28), in this way, the positive rate rose with the advance in a decease stage. Moreover at the sample of a nonrelasped after an operation 15.3%(2/13). In metastasized breast cancer, the positive rate was raised by the combination of CA15-3 and CEA. Now we are examining the correlation of CA15-3 and metastasis parts.

Therefore, though CA15-3 seems to have a trouble in an early diagnosis of breast cancer, it is suggested to be available to the judgement of cure effect and the inspection of metastasis for progressing breast cancer including metastasis.

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FUNDAMENTAL AND CLINICAL STUDIES ON ELSA CA 125 RIA KIT. Y.Saiki,T.Hamazaki,K.Nasu, H.Yamaguchi,H.Ito,F.Handa,Y.Habuchi,S.Bito, M.Hino and K.Ikekubo. Kobe General Hospital, Kobe.

Fundamental and clinical studies on IRMA CA 125 kit for ovarian cancer(Ca.) were performed. Recovery test was satisfactory. However,Dilution test didn't show good linearity:the diluted sera had higher values than expected (prozone). Within and between assay C.V. were 8.2-18.2% and 14.2-22.8% respectively. Serum CA 125 levels in 36 normal subjects were less than 29 U/ml. The mean concentrations were 15.8±7.8(SD) U/ml and cutt-off value was determined as 31.4 U/ml (mean+2SD). Of 25 patients with ovarian Ca., 92% had elevated CA 125 levels. The mean value was 621.8±718.8 U/ml. The other patients with gynecologic disorders had serum CA 125 values less than 300 U/ml. CA 125 levels were elevated in 45.5% of 25 ovarian cyst, 25% of 36 cervical Ca.,27.3% of 11 corpus Ca., 62.5% of 24 myoma uteri and 50% of 4 endometriosis. Of 12 patients with lung Ca.,84.6 % had elevated CA 125 values with a range from 17 to 280 U/ml. Of 4 patients with liver diseases,a case with hepatoma had extremely high CA 125 levels(>500 U/ml). A marked reduction of serum CA 125 levels were observed in 2 patients who had treatment for ovarian Ca.

In conclusion. Serum CA 125 measurement is clinically very useful for the diagnosis and follow-up of the patients with ovarian Ca.

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