

Monobind Technical Support Memo

Subject; CEA & CA 19-9 Ranges and "0" Values Date; April 2011

QUESTION:

Our client uses Monobind's CEA and CA 19-9 kits for determination of concentration for all patients with no diagnosis but referral from oncologists for the tests. The lab receives satisfactory results in general but sometimes there is a result that the concentration = 0. Is it possible for CEA and CA 19-9 to provide a value of "0" for patients?

The instrument used for optical density measurement and concentrate calculation cannot count the concentration when optical density of the patient serum is lower than the optical density of Calibrator A.

The client is confused with "0" results and whether or not this is related to instrument limitations.

ANSWER:

In short, yes these results can be expected and therefore not related to the instrument. CEA is normally present in very low concentrations and in many patients a zero value is found. This is as expected since "0" is normally included in the reference range of CEA.

Regarding CA 19-9, patients must possess the ability to express the Lewis blood group antigen or they will be unable to produce the CA 19-9 antigen even in the presence of proven malignancy. A patient with a positive genotype for the Lewis antigen may produce varying levels of CA 19-9. Thus, zero levels of CA 19-9 would be encountered when the patients are negative for the ability to express CA 19-9 antigen (phenotyping).

Authorized by: April-08-2011

Quality Representative