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Method Change: CA 125

Effective September 2, 2003, CA 125 testing will be changed to the DPC Immulite 2000. As a result of the change, **the new reference interval for CA 125 will be changed to 0 - 21 U/mL (established by DPC and verified by CPAL Lab)**. Please notify your physicians of the method change and the time of the change.

Background:

The precise nature of CA 125 is not well defined. Elevations may be seen in the presence of ovarian malignancy as well as in the presence of a variety of non-malignant conditions (i.e. endometriosis, first trimester pregnancy, ovarian cysts, cirrhosis and inflammatory conditions of mesothelium). Assay of CA 125 has been shown to be useful in monitoring response to therapy and in detecting residual disease in patients with ovarian cancer. The assay is not recommended as a screening procedure to detect cancer in the general population.

Correlation Studies:

A total of 208 samples were tested by the current immunoassay on Abbott AxSYM (fluorescence signal) and the new immunoassay on DPC Immulite 2000 (chemiluminescence signal). Figure 1 shows the comparative results obtained by both methods.

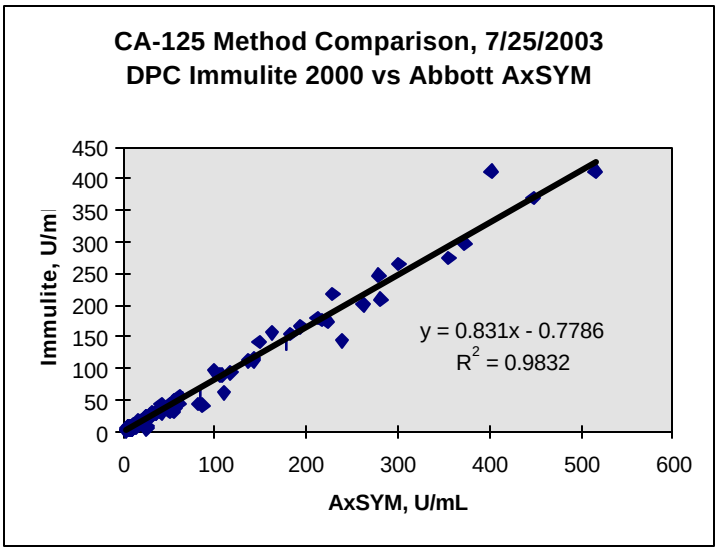

Figure 1

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For question about this, and other, information, call Central Pennsylvania Laboratory at 1-888-480-1422

The results of CA-125 by the two methods correlate very well in the range of 3 - 515 U/mL. A linear relationship exists between the two results: Immulite = 0.83 * AxSYM - 0.7786. In most cases, the new results are approximately 0.83 times the old results in the range of 3 - 515 U/mL. Using the new cutoff value of 21 U/mL, 151 normal results and 49 abnormal results were concordant (96%). There were 8 (3.8%) discordant results. All of the discordant results had values greater than the cutoff using the DPC Immulite 2000 and values less than the cutoff using the Abbott AxSYM.

All result will be reported with the following footnote until September 1, 2004: "Assay reported prior to September 2, 2003 were performed by a different method. The previous reference range was 0-34 U/mL. Serial assays must be interpreted in light of this change."

It should be noted that there has been shown to be a variation in results between different test methods. Direct comparison of CA 125 results by two different methods can not be reliably performed by the simple application of a mathematical conversion factor. CPAL will retain the frozen specimens for 30 days after testing. If the current CA 125 assay result is found to be significantly different from previous results on a given patient, you may request a repeat measurement by the previous method (via a reference lab send out).

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