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A spokesman for Clinical Assays comments:

To the Editor:

Fritz and Bunker urge users of the Clinical Assays GAMMADAB® PAP and β-HCG methods to be cautious when interpreting results for hyperlipidemic patients; we recommend that this caution be exercised for all laboratory results obtained for serum from such patients. The fact that abnormally high serum lipid concentrations often interfere with immunoassays as well as many other assays in the clinical laboratory is not surprising. It is their speculation that this phenomenon is peculiar to methods involving polyethylene glycol that is dangerous and warrants discussion. In particular, it is well known that lipemia interferes with antigen binding, even when antibodies are linked to a solid support. As a result, the only way validly to estimate the degree of lipid interference is to compare results with the same patient’s serum after the lipids have been cleared from the blood. Certainly a simple comparison of results from an RIA with those of an IRMA method offers no insight, because the same interfering phenomenon may simply result in false values in opposite directions.

Indeed, Fritz and Bunker have designed their evaluation and chosen their population so that low results are always desired; not a single sample was included in which an increased PAP or β-HCG concentration would correlate with the clinical condition of the patient. How could false negatives be ruled out?

In both the PAP and the HCG kits of Clinical Assays a second antibody separation is used, which is enhanced by polyethylene glycol. These methods have been extensively validated in clinical trials over the entire physiological range of measurements. For example, a multicenter study (1) conducted to determine the normal values for PAP included not only 343 normal men, but an additional 150 with prostatic cancer and 68 with nonprostatic cancer as well. Similarly, a clinical study (2) involving over 1100 measurements provides the base of data from which reference values are obtained for the β-HCG immunoassay kit.

As noted by Fritz and Bunker, there appears to be no consistent correlation between the degree of interference and the lipid concentrations, so we again urge users to follow our protocol directions as well as common laboratory practice to avoid the use of lipemic samples in these assays.

References


2. Private communication from Prof. K. Thomas, M.D., Dept. of Obstetrics and Gynecology, Université Catholique de Louvain, Brussels, Belgium. Information available from Clinical Assays.

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Improved Sample Extraction before Liquid Chromatography of Prednisone and Prednisolone in Human Serum

To the Editor:

Current liquid-chromatographic assays of prednisone and prednisolone in serum (1, 2) involve much glassware, multiple extraction and transfer steps, and much time. We improved the sample-extraction procedure for both drugs by using a commercially supplied column-type extraction tube as follows.

Place a 1.0-mL serum sample for prednisone and prednisolone assay in a disposable tube and add dexamethasone (internal standard, 40 μL of a 2 mg/mL solution in methanol). Then add 1 mL of 0.1 mol/L sodium hydroxide and vortex-mix. Pour the sample into a "ClinElut" tube (cat. no. 1003; Analytichem International, Harbor City, CA 90710) and allow it to absorb onto the column packing for 2–3 min. Then rinse the disposable tube with 5 mL of methylene chloride, and pour it into the extraction tube. Collect the eluate in a 15-mL centrifuge tube fitted with a Teflon screwcap. After 5 min, add a second 5-mL portion of methylene chloride to the extraction tube and collect the eluate. Evaporate these combined organic eluates at 35 °C with an analytical evaporator, under a gentle stream of nitrogen. Redissolve the residue in 100 μL