Test Precision and High-Density-Lipoprotein Cholesterol

To the Editor:
Recently there have appeared many methods and modifications of methods to improve the accuracy and precision of high-density-lipoprotein (HDL) cholesterol analysis. Indeed, it was emphasized to laboratories that would perform this test (1) that the laboratory must attain good precision to avoid an intolerably high misclassification rate. Laboratories that cannot achieve CVs of less than 5% at the 300-400 mg/liter HDL cholesterol concentration have no business offering this test procedure.

The recent paper by Cobb and Sanders (2) advocating the use of an electrophoretic technique to separate the lipoproteins seems to ignore this paramount objective. They describe an overall precision of 17% CV for HDL. Based on their own data, their pool with a mean HDL cholesterol of 389 mg/liter would have a 95% confidence range of 257 to 521 mg/liter.

Do these authors seriously suggest the use of their technique to assign medical (and economic) risk factors?

References

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A representative of Helena Laboratories responds:

To the Editor:
Dr. Goldberg's statement regarding the need for CVs of 5% or less at the 300-400 mg/liter range goes without saying. Our objectives were to develop a procedure that overcame some of the problems associated with precipitation methods, yet had the accuracy and reproducibility necessary to properly assign risk factors.

Our results for studies concluded last November (1) indicated that our procedure did overcome the disadvantages of precipitation methods. This, plus the fact that the cholesterol content of VLDL and LDL fractions could be quantitated at the same time, made us believe the technique worthy of presentation.

The overall CV of 17% for HDL was obtained with a cellulose acetate plate available at that time. We realized that 17% CV was too high and began development of a membrane especially suited for lipoprotein cholesterol determinations. Our quality control department found a CV of 5.4% on the first six lots of this new membrane. These results were presented at the recent national meeting in San Francisco (2). Subsequent lots of HDL plate have yielded CVs as low as 3%.

We appreciate Dr. Goldberg's concern and can assure him that we share his desire for precise and accurate methods for measuring HDL cholesterol.

References

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Results by the Phadebas Amylase Test for Human Sera in the Presence and Absence of Albumin

To the Editor:
The Phadebas method seems now to be one of the most suitable methods for routine laboratory determination of α-amylase (1,4-α-D-glucan glucohydrolase, EC 3.2.1.1). The influence of some factors on the Phadebas amylase test has been studied extensively, especially the effect of added bovine serum albumin (BSA) on this enzymic activity (1-6). For urine samples, an enhanced activity results, but no such comparison has been done for serum. Because all Phadebas amylase tablets now contain BSA, we investigated serum amylase activity with the Phadebas method in the presence and absence of BSA.

The Phadebas amylase test was performed exactly according to the instructions of the manufacturer. The amylase activity was calculated from the standard curve accompanying each batch of Phadebas amylase tablets.

Phadebas amylase tablets without BSA (batch CF 0310) and with BSA (batches CH 0312 and CE 0311) were obtained from Pharmacia Diagnostics. Figure 1 shows the amylase activity of 45 serum samples determined in the presence and in the absence of BSA. The enzymic activity in the absence is higher than in the presence of BSA for all specimens determined. When, however, not the activities but the absorbances at 620 nm are compared, there is a good agreement between values obtained without and with BSA in the tablet.

It is striking to observe a good agreement between enzymic activities determined without and with BSA, when BSA is added to the reaction medium separately in a concentration of 250 mg/liter and the determination is done with tablets lacking BSA (Figure 2).

![Fig. 1. Serum amylase activity and absorbance values at 620 nm determined in the absence and presence of bovine serum albumin](image1)

![Fig. 2. Serum amylase activity in the absence and presence of added BSA](image2)