Clinical Chemistry and Clinical Toxicology Devices Panel Meeting
12/6/06
Questions

Based on the current state of knowledge, please provide input on the following questions:

1. Is there sufficient information available to conclude that HDL and/or LDL subfractions can be used:
    a. to assess a patient's risk of developing CVD?
    b. to diagnose dyslipidemia?
    c. to monitor treatment of dyslipidemic patients?
    d. for any other use?
2. If sufficient information is available for clinical use, should HDL and/or LDL subfractions be used:
    a. as a stand-alone test?
    b. as an adjunctive test to be used with other traditional risk assessment tools (e.g., Total, HDL, and LDL cholesterol) and clinical judgment?
3. When used either as a stand-alone test or in conjunction with other lipid measurements (with values defined as non- cardiac risk by the NCEP ATPIII guidelines), will changes in treatment based upon the abnormal lipid subfractions pose an acceptable level of benefits compared to risk to the patient?
4. How would the accuracy of these subfractions be established? What is an appropriate reference method? What are appropriate acceptance criteria when comparing to the reference method?
5. How should expected values be determined for lipid subfraction assays? Is it possible to make meaningful test interpretations in cases where reference ranges for normal and "diseased" patients overlap?
6. If used (either as an adjunctive test to traditional lipid measurements or as a stand alone diagnostic) to diagnose or predict risk for dyslipidemia or atherosclerosis, does the lack of standardized nomenclature or differences in assay performance (e.g., reference ranges, precision, fractions analyzed, etc.) pose an unreasonable risk to the patient?
7. Is there a difference in the assessment of lipid subfractions based upon particle size versus particle number? If so, what are the strengths and weaknesses of each method? Please discuss.