

The National Academy of Clinical Biochemistry

Presents

LABORATORY MEDICINE PRACTICE GUIDELINES

**GUIDELINES AND RECOMMENDATIONS
FOR LABORATORY ANALYSIS IN THE
DIAGNOSIS AND MANAGEMENT
OF DIABETES MELLITUS**



Guidelines and Recommendations For Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus

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An Approved Guideline of the National Academy of Clinical Biochemistry "Laboratory Medicine Practice Guidelines". These guidelines were reviewed by the Professional Practice Committee of the American Diabetes Association in June 2001 and were found to be consistent in those areas where the ADA has also published Clinical Practice Recommendations. The Clinical Practice Recommendations of the ADA are updated annually and the most recent version should be consulted.

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OVERVIEW

Background: Multiple laboratory tests are used in the diagnosis and management of patients with diabetes mellitus. The quality of the scientific evidence supporting the use of these assays varies substantially.

Approach: An expert committee drafted evidence-based recommendations for the use of laboratory analysis in patients with diabetes. An external panel of experts reviewed a draft of the guidelines, which were modified in response to the reviewers' suggestions. A revised draft was posted on the Internet and was presented at the AACC Annual Meeting in July, 2000. The recommendations were modified again in response to oral and written comments. The guidelines were reviewed by the Professional Practice Committee of the American Diabetes Association.

Content: Measurement of plasma glucose remains the sole diagnostic criterion for diabetes. Monitoring of glycemic control is performed by the patients measuring their own plasma or blood glucose with meters and by laboratory analysis of glycosylated hemoglobin. The potential roles of non-invasive glucose monitoring, genetic testing, autoantibodies, microalbumin, proinsulin, C-peptide and other analytes are addressed.

Summary: The guidelines provide specific recommendations based on published data or derived from expert consensus. Several analytes are of minimal clinical value at the present time, and measurement of them is not recommended.

Nonstandard abbreviations: OGTT, oral glucose tolerance test; FPG, fasting plasma glucose; IMD, immune-mediated diabetes; SMBG, self-monitoring of blood glucose; GHb, glycosylated hemoglobin; DCCT, Diabetes Control and Complications Trial; UKPDS, United Kingdom Prospective Diabetes Study; ADA, American Diabetes Association; NGSP, National Glycohemoglobin Standardization Program; CI, confidence intervals; GDM, gestational diabetes mellitus; WHO, World Health Organization; IGT, impaired glucose tolerance; IFG, impaired fasting glucose; DKA, diabetic ketoacidosis; AcAc, acetoacetate; β HBA, β hydroxybutyrate; CAP, College of American Pathologists; MODY, maturity onset diabetes of youth; ICA, islet-cell cytoplasm antibodies; GAD₆₅, 65-kDa isoform of glutamic acid decarboxylase; IAA, insulin autoantibodies; JDF, Juvenile Diabetes Foundation; FDA, Food and Drug Administration; HDL, high density lipoprotein; LDL, low density lipoprotein; CAD, coronary artery disease; CDC, Centers for Disease Control.