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Special Report

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

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

APPROACH: An expert committee compiled evidence-based recommendations for laboratory analysis in screening, diagnosis, or monitoring of diabetes. The overall quality of the evidence and the strength of the recommendations were evaluated. The draft consensus recommendations were evaluated by invited reviewers and presented for public comment. Suggestions were incorporated as deemed appropriate by the authors (see Acknowledgments). The guidelines were reviewed by the Evidence Based Laboratory Medicine Committee and the Board of Directors of the American Association of Clinical Chemistry and by the Professional Practice Committee of the American Diabetes Association.

CONTENT: Diabetes can be diagnosed by demonstrating increased concentrations of glucose in venous plasma or increased hemoglobin A_{1c} (Hb A_{1c}) in the blood. Glycemic control is monitored by the people with diabetes measuring their own blood glucose with meters and/or with continuous interstitial glucose monitoring (CGM) devices and also by laboratory analysis of Hb A_{1c}. The potential roles of noninvasive glucose monitoring, genetic testing, and measurement of ketones, autoantibodies, urine albumin, insulin, proinsulin, and C-peptide are addressed.

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

Introduction

Diabetes mellitus is a group of metabolic disorders of carbohydrate metabolism in which glucose is both underutilized and over-produced, resulting in hyperglycemia. The disease is classified conventionally into several clinical categories, although these are being reconsidered based on genetic, metabolomic, and other characteristics and underlying pathophysiology. The revised classification published in 2014 (1) is indicated in Table 1. Type 1 diabetes mellitus is usually caused by autoimmune destruction of the pancreatic islet β-cells, rendering the pancreas unable to synthesize and secrete insulin (3). Type 2 diabetes mellitus results from a combination of insulin resistance and inadequate insulin secretion (4, 5). Gestational diabetes mellitus (GDM), which resembles type 2 diabetes more than type 1, develops during approximately 17% (ranging from 5% to 30%, depending on the screening method, diagnostic criteria used, and maternal age) of pregnancies, usually remits after delivery, and is a major risk factor for the development of type 2 diabetes later in life. Type 2 diabetes is the most common form, accounting for

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