THE ROLE OF MEDICAL LABORATORY IN THE DIAGNOSIS AND MANAGEMENT OF DIABETES

Diabetes mellitus is a group of metabolic disorders of carbohydrate metabolism in which glucose is underutilized and overproduced, causing hyperglycemia. The disease is classified into several categories.

Type 1 diabetes mellitus, formerly known as insulin-dependent diabetes mellitus (IDDM) or juvenile-onset diabetes mellitus, is usually caused by autoimmune destruction of the pancreatic islet β-cells, rendering the pancreas unable to synthesize and secrete insulin.

Type 2 diabetes mellitus, formerly known as non-IDDM or adult-onset diabetes, is caused by a combination of insulin resistance and inadequate insulin secretion.

Gestational diabetes mellitus (GDM), which resembles type 2 diabetes more than type 1, develops during approximately 7% of pregnancies, usually remits after delivery, and constitutes a major risk factor for the development of type 2 diabetes later in life. Other types of diabetes are rare. Type 2 is the most common form, accounting for 85%–95% of diabetes in developed countries. Some patients cannot be clearly classified as type 1 or type 2 diabetes.

ROLE OF LABORATORY

Multiple laboratory tests are used to diagnose and manage patients with diabetes mellitus. The quality of the scientific evidence supporting the use of these tests varies substantially.

In addition to long-standing criteria based on measurement of plasma glucose, diabetes can be diagnosed by demonstrating increased blood hemoglobin A1c (HbA1c) concentrations. Monitoring of glycemic control is performed by self-monitoring of plasma or blood glucose with meters and by laboratory analysis of HbA1c. The potential roles of noninvasive glucose monitoring, genetic testing, and measurement of autoantibodies, urine albumin, insulin, proinsulin, C-peptide, and other analytes are addressed.

The diagnosis of diabetes is established by identifying the presence of hyperglycemia. For many years the only method recommended for diagnosis was a direct demonstration of hyperglycemia by measuring increased glucose concentrations in the plasma.

In 1979, a set of criteria based on the distribution of glucose concentrations in high-risk populations was established to standardize the diagnosis. These recommendations were endorsed by the WHO. In 1997, the diagnostic criteria were modified to better identify individuals at risk of retinopathy and nephropathy.

Criteria for the diagnosis of diabetes

Any one of the following is diagnostic:

1. HbA1c ≥6.5% OR
2. FPG ≥126 mg/dL OR
3. 2-h Plasma glucose ≥200 mg/dL during an OGTT OR
4. Symptoms of hyperglycemia and casual plasma glucose ≥200 mg/dL

Diagnostic Significance of Glucose and Hemoglobin A1c Concentrations

Individuals Suitable for Testing	**Marker**	**Clinically Significant Level**	**Interpretation**
Non-pregnant individuals with diabetes risk factors or age ≥45 years and pregnant women with risk factors (first prenatal visit)	FPG 2-h OGTT (75 g) HbA1c level	≥126 mg/dL ≥200 mg/dL ≥6.5%	Diabetes
	FPG 2-h OGTT (75 g) HbA1c level	100-125 mg/dL 140-199 mg/dL 5.7%-6.4%	Increased risk for Diabetes
All pregnant women (24-28 weeks of gestation)	2-h OGTT (75 g) • Fasting • 1 h • 2 h	≥92 mg/Dl ≥180 mg/dL ≥153 mg/dL	Gestational diabetes

Tests Used in Diabetes Diagnosis and Management

Test Name	Primary Clinical Use and Differentiating Factors
Glucose, Plasma	Diagnosis based on FPG
Glucose Tolerance Test, 2 Specimens (75g)	Diagnosis based on fasting and 2-hour (post 75g glucose loading) specimens (2-h OGTT)
Glucose Tolerance Test, Gestational, 4 Specimens (100g)	Diagnosis of gestational diabetes
GlycoMark®	Measures PPG excursions; may help differentiate contributions of FPG and PPG to hyperglycemia in patients with moderately- or well-controlled HbA1c levels.
Hemoglobin A1c	Determines long-term average blood glucose, expressed as a percentage.
Hemoglobin A1c with eAG	Determines long-term average blood glucose; expressed in percent HbA1c and conventional blood glucose units for more convenient comparison to SMBG values.
Hemoglobin A1c with eAG with Reflex to GlycoMark®	Determines long-term average blood glucose levels, expressed in percent HbA1c and conventional blood glucose units. Measures PPG excursions; may help differentiate contributions of FPG and PPG to hyperglycemia in patients with moderately- or well-controlled HbA1c levels.
Hemoglobin A1c with Reflex to GlycoMark®	Determines long-term average blood glucose levels, expressed as a percentage. Measures PPG excursions; may help differentiate contributions of FPG and PPG to hyperglycemia in patients with moderately- or well-controlled HbA1c levels.
Self-Monitoring of Blood Glucose (SMBG)	Determines response to insulin therapy on a daily basis.

Monitoring Diabetic Complications

Laboratory Tests

Creatinine Includes estimated glomerular filtration rate (eGFR)	Monitor onset and progression of kidney disease
Lipid Panel Includes total cholesterol, HDL cholesterol, LDL cholesterol (calculated), VLDL cholesterol (calculated), and triglycerides	Monitor dyslipidemia and thus risk of heart disease
Microalbumin, Random Urine with Creatinine	Monitor onset and progression of kidney disease

Clinical Tests

Blood pressure	Monitor hypertension and thus risk of heart disease
Eye exam	Monitor onset and progression of eye disease
Foot exam	Monitor onset and progression of nerve disease and peripheral arterial disease

Testing to detect type 2 diabetes in asymptomatic people, previously controversial is now recommended for those at risk of developing the disease.

An HbA1c, FPG, or 2-h OGTT evaluation is appropriate for screening . The IDF recommends that the health service in each country decide whether to implement screening for diabetes. FPG is the suggested test. In contrast, the International Expert Committee and the ADA have recommended that HbA1c can be used for screening for diabetes. If an FPG result is <5.6 mmol/L (100 mg/dL) and/or a 2-h plasma glucose concentration is <7.8 mmol/L (140 mg/dL), testing should be repeated at 3-year intervals. Screening should be considered at a younger age or be carried out more frequently in individuals who are overweight (BMI ≥25 kg/m2) or obese and who have a least one additional risk factor for diabetes.

Individuals with diabetes are at increased risk of heart and kidney disease, retinopathy, and neuropathy. Routine eye and foot exams, along with blood pressure, lipids, microalbumin, and creatinine/eGFR testing are recommended to detect the onset and monitor progression of these complications

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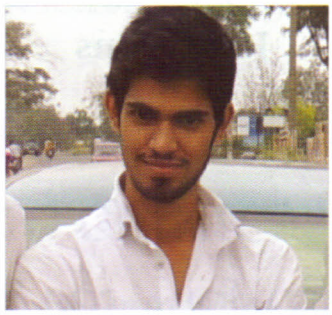

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