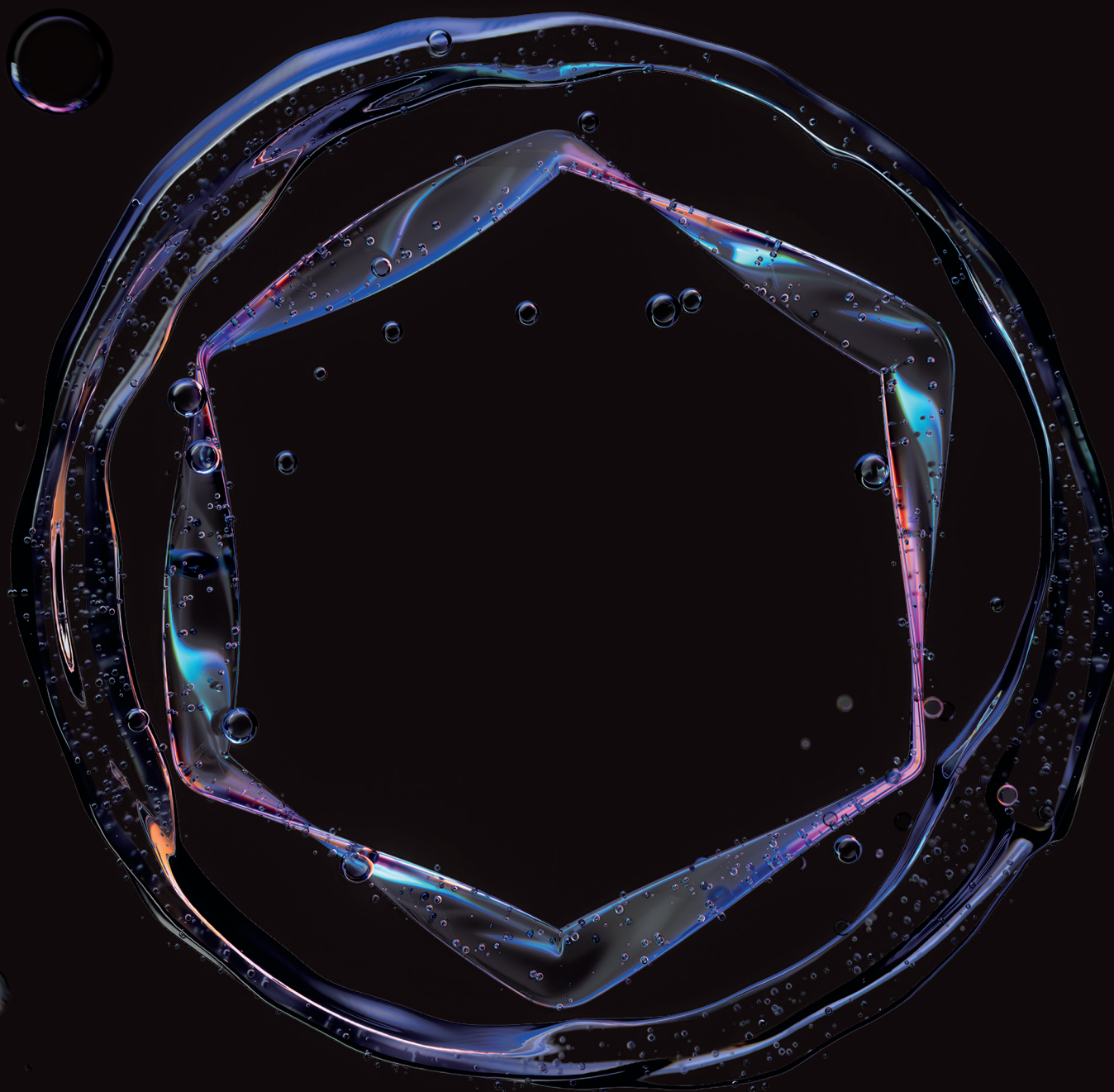




BBISOLUTIONS.COM

Diabetes

Reagents for manufacturers



Advancing health, together.

For over 70 years, we've specialized in the development and manufacturing of world-class reagents, both native and recombinant, helping IVD and life science teams transform scientific innovation into trusted, life-saving diagnostics.

Across our portfolio, from antibodies, enzymes, and antigens to complex conjugates and custom solutions, every product is developed with precision to support performance, regulatory compliance, and diagnostic accuracy.

But it's not just about the products. We know what's at stake. That's why our scientists work shoulder-to-shoulder with yours, solving challenges, refining performance, and accelerating progress from concept to commercialization. Our continued investment in next-generation recombinant technologies reflects that commitment: enabling you to bring diagnostics and life science solutions to market faster, with greater confidence, resilience, and sustainability.

As you explore this brochure, we hope you'll see what sets BBI apart – not just in what we make, but in how we show up as your partner.

Welcome to BBI. Let's advance health, together.

Alex Socarrás
Group CEO

Contents

04 Introduction

05 Tools for assay manufacturers for diagnosing and monitoring diabetes

06 Diabetes types & diagnostics

06 Type 1 Diabetes

06 Type 2 Diabetes

06 WHO testing algorithm

07 Diabetes diagnostics tools

07 Reagents from BBI for diabetes diagnostics

08 Methods used in diabetes diagnosis & care

08 Fasting Blood Glucose test (FBG)

08 Oral Glucose Tolerance test (OGTT)

09 Hemoglobin A1c Test

09 Random Blood Glucose Test

10 Continuous Glucose Monitoring (CGM)

10 Self-Monitoring of Blood Glucose (SMBG)

11 Urine Glucose Testing

12 Diagnostic Immunoassays for Type 1 Diabetes

12 Diagnosis of Diabetic Ketoacidosis (DKA)

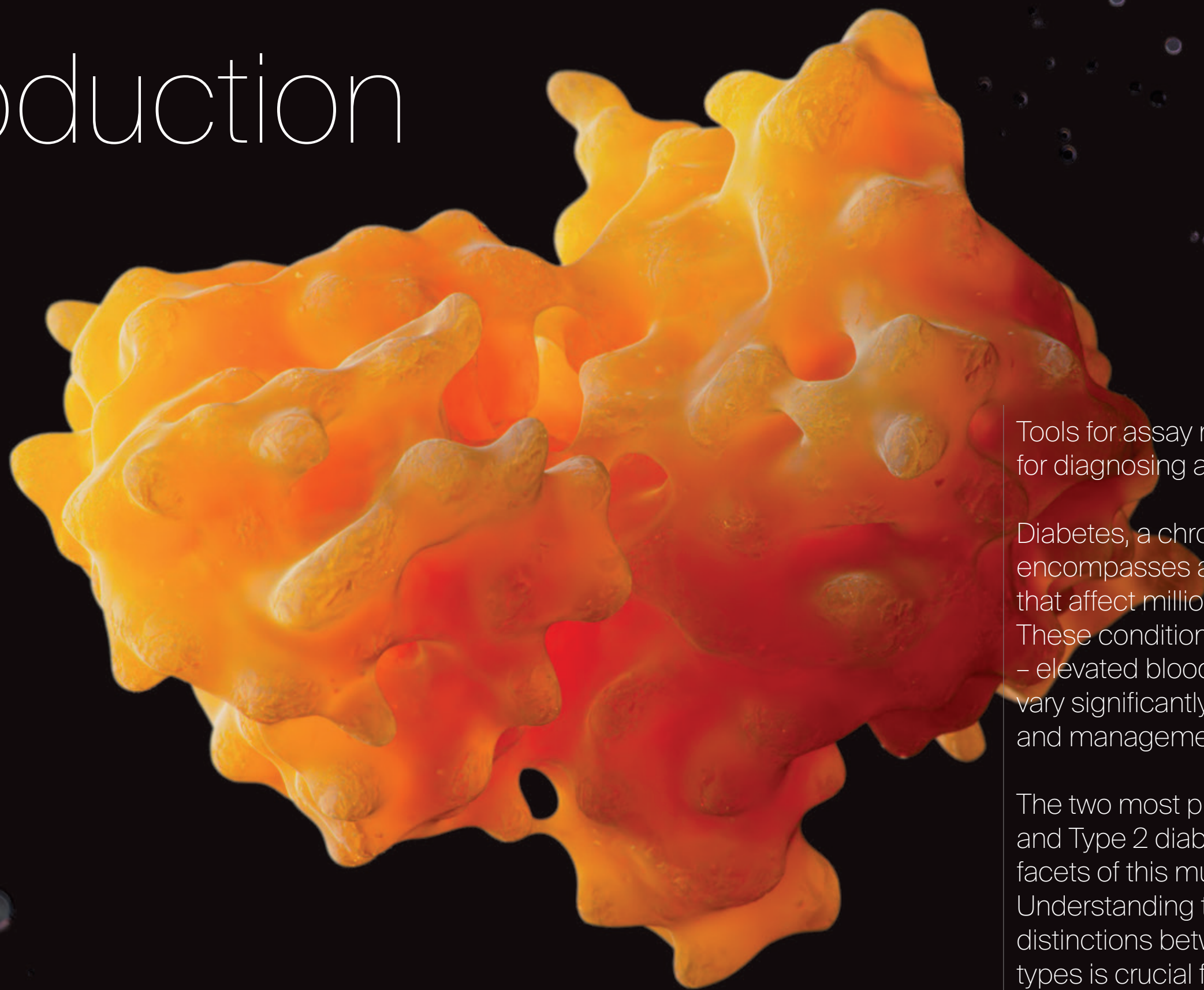
13 C-Peptide Test

14 Insulin Test

14 Glycated Albumin Testing: Short-term glycemic control

15 Solutions available from BBI

Introduction



Tools for assay manufacturers for diagnosing and monitoring diabetes.

Diabetes, a chronic metabolic disorder, encompasses a spectrum of conditions that affect millions of individuals worldwide. These conditions share a common feature – elevated blood sugar levels – but they vary significantly in their underlying causes and management approaches.

The two most prevalent types, Type 1 and Type 2 diabetes, represent distinctive facets of this multifaceted disease. Understanding the root causes and distinctions between these primary types is crucial for both diabetes test manufacturers and healthcare professionals in providing effective diagnostics.

Diabetes types & diagnosis

Type 1 Diabetes

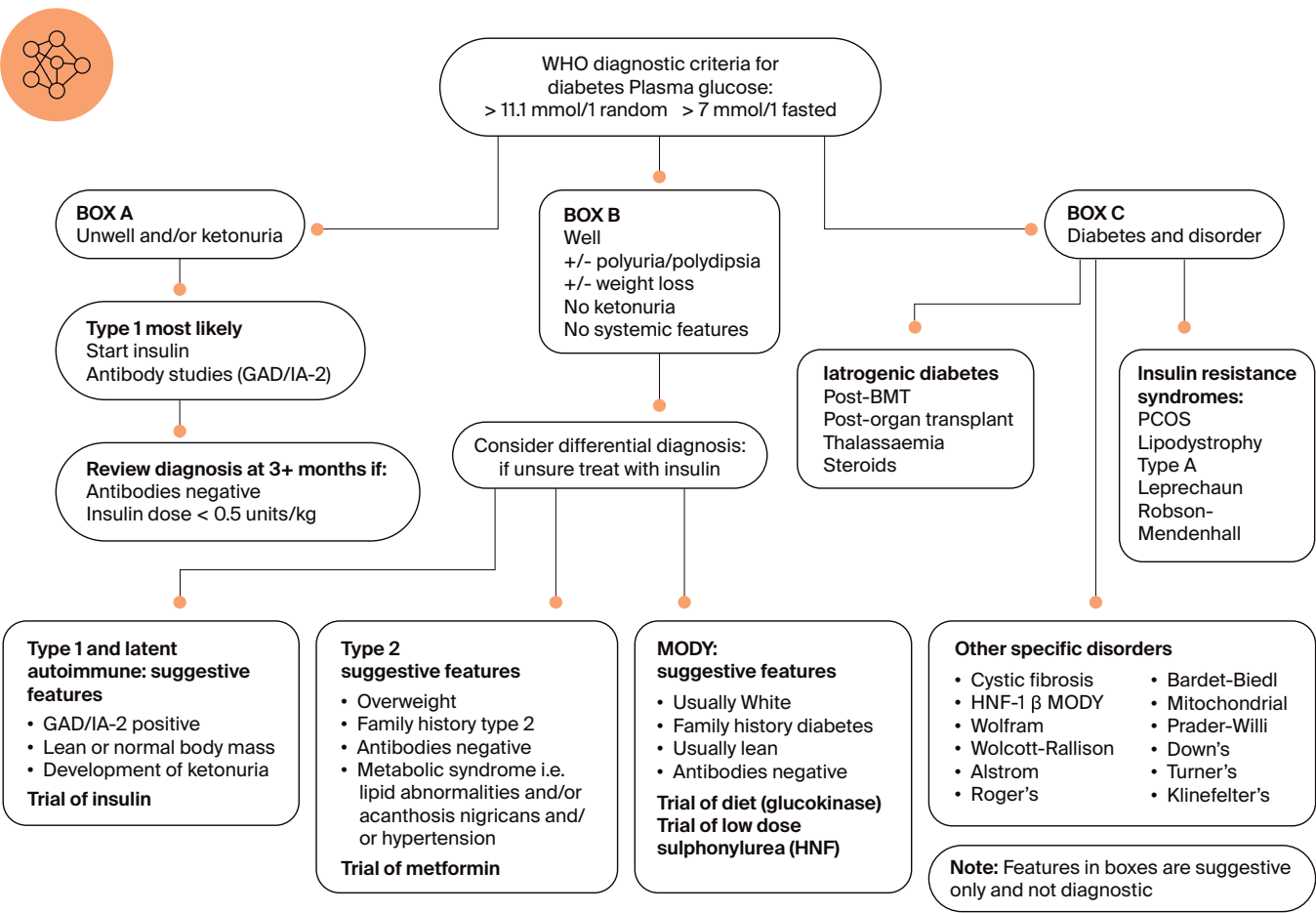
Type 1 diabetes, often diagnosed in childhood or adolescence, is primarily an autoimmune disorder. It arises when the immune system mistakenly attacks and destroys insulin-producing beta cells in the pancreas. This autoimmunity leaves individuals with a severe insulin deficiency, necessitating lifelong insulin therapy. The root cause lies in genetic predisposition, with environmental triggers like viral infections potentially contributing. Type 1 diabetes comprises a relatively small percentage of all diabetes cases, estimated at around 5-10%.

Beyond these types, other forms, such as gestational diabetes, monogenic diabetes, and secondary diabetes, exist, each with its unique etiology and clinical features. Recognizing the diversity of diabetes types and their respective root causes is pivotal for advancing diagnostics and treatments tailored to each individual's specific condition.

Type 2 Diabetes

Conversely, Type 2 diabetes, the more prevalent form, is characterized by insulin resistance and relative insulin deficiency. It typically occurs in adulthood, although it is increasingly diagnosed in younger individuals due to lifestyle factors. The primary root causes of Type 2 diabetes are obesity, sedentary lifestyles, and genetic predisposition. Lifestyle modifications, such as diet and exercise, alongside oral medications and, in some cases, insulin, are often the primary treatments. Type 2 diabetes accounts for the majority of diabetes cases worldwide.

WHO diabetes testing algorithm



From Porter and Barrett, ArchDisChild 2004;89:1138-1144.
This graphic is meant for informational purpose only and is not intended to be used for medical advice.

Diabetes diagnostic tools

Reagents from BBI Solutions for diabetes diagnostics

Glucose Oxidase	High purity GO (360 U/mg protein) giving higher specificity and better stability	GO2BS
	Multiple grades available – optimize your assay	GO3A
	High volume and high capacity for large scale requirements	GO3B3
	Used in over 5 billion test strips every year	GOL7
FAD-dependent Glucose Dehydrogenase		GO3B2
	Optimized purification method resulting in fewer contaminants giving reduced backgrounds	GLD1
	Improved performance on test strips	GLD3
	Great stability: Minimum 12 months from date of manufacture	GLD4
HbA1c Reagents	No additives or animal derived materials	
	Not affected by variations in oxygen levels	
	For calibrator and control manufacturing	PS186-0 (<3%)
	Multiple formations available	PS186-9 (>25%)
HbA1c Antibodies	Customizable for specific applications	P186-0B (~96%)
	Matched antibody pair	BM300-H2E2
	HbA1c specific and haemoglobin	BM302-S6B9
	For immunoassay and lateral flow	
GAD65 Antigen	Recombinant baculovirus production	31900
	QC by line immunoassay using patient samples	31901
	QCed in immunoassays using patient and blood donor samples	
	High purity >80%	
IA-2 (ICA 512)	Recombinant production - secure supply and very high lot-to-lot consistency	30500
	QCed in immunoassays using patient and blood donor samples	30501
HBDH	Recombinant production - secure supply and very high lot-to-lot consistency	rHBDH
	Activity: >400 U/mg (Unit definition: amount of enzyme causing the reduction of one micromole of NAD per minute at 37°C and pH 8.5	
	Purity: >90% by SDS-PAGE	

Methods used in diabetes diagnosis and care

01

Fasting Blood Glucose Test (FBG)

The Fasting Blood Glucose Test is a fundamental tool for diagnosing diabetes. It requires patients to fast overnight, typically for at least 8 hours, before a blood sample is taken. This test measures the concentration of glucose in the blood using enzymes such as glucose oxidase.

A fasting blood glucose level of 126 milligrams per deciliter (mg/dL) or higher on two separate tests is indicative of diabetes. FBG is a simple and cost-effective method. FBG is often used for initial screenings and monitoring glucose levels in individuals at risk for diabetes. However, it doesn't provide a comprehensive picture of daily glucose fluctuations, which is essential for effective diabetes management.

Associated products

Product name	Code
Glucose Oxidase	GO2BS
	GO3A
	GO3B3
	GO3B2
	GOL7
FAD-dependent Glucose Dehydrogenase	GLD1
	GLD3
	GLD4

02

Oral Glucose Tolerance Test (OGTT)

The Oral Glucose Tolerance Test (OGTT) is a more comprehensive evaluation of glucose metabolism.

OGTT involves fasting overnight and then consuming a high-glucose solution. Blood sugar levels are measured at specific intervals over a few hours to assess the body's ability to process glucose. Elevated levels (≥ 200 mg/dL) at the 2-hour mark can indicate diabetes. OGTT is particularly useful for diagnosing gestational diabetes and identifying individuals with impaired glucose tolerance. OGTT offers insights into how the body responds to glucose challenges and is an essential tool for diagnosing prediabetes and diabetes.

Associated products

Product name	Code
Glucose Oxidase	GO2BS
	GO3A
	GO3B3
	GO3B2
	GOL7
FAD-dependent Glucose Dehydrogenase	GLD1
	GLD3
	GLD4

03

Hemoglobin A1c Test

The Hemoglobin A1c (HbA1c) test is a critical tool for monitoring long-term glucose control. It measures the percentage of hemoglobin that is glycated, reflecting average blood sugar levels over the past ~90 days.

HbA1c provides a valuable perspective on overall glucose management. The results are not affected by daily fluctuations, making it an excellent choice for assessing the effectiveness of long-term treatment plans. HbA1c values below 5.7% are considered normal, while levels of 6.5% or higher typically indicate diabetes. This test is widely used for diabetes management, helping patients and healthcare providers make informed decisions about treatment adjustments. It's important to note that the HbA1c test may not be suitable for individuals with certain medical conditions, such as anemia, as it can yield inaccurate results. However, it remains a cornerstone of diabetes care.

Associated products

Product name	Code
HbA1c Reagent	PS186-9
	PS186-0
	P186-0B
HbA1c Antibody	BM300-H2E2

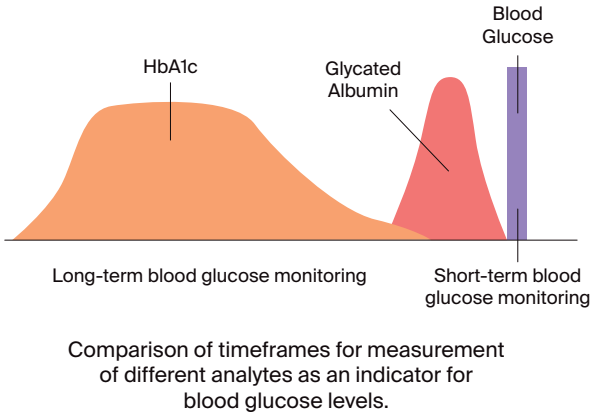
04

Random Blood Glucose Test

The Random Blood Glucose Test is a convenient but less precise method of assessing blood sugar levels. It can be performed at any time of the day and does not require fasting. Elevated levels may suggest diabetes if symptoms like frequent urination, increased thirst, and unexplained weight loss are present. However, this method is less accurate than fasting blood glucose or OGTT for diagnosing diabetes. It is more commonly used as a preliminary screening tool, with further diagnostic tests recommended if results are above the normal range. Despite its limitations, the random blood glucose test is valuable for quick assessments and can help identify potential diabetes cases, especially in emergency healthcare settings.

Associated products

Product name	Code
Glucose Oxidase	GO2BS
	GO3A
	GO3B3
	GO3B2
	GOL7
FAD-dependent Glucose Dehydrogenase	GLD1
	GLD3
	GLD4



Methods used in diabetes diagnosis and care

05

Continuous Glucose Monitoring (CGM)

Continuous Glucose Monitoring (CGM) is a revolutionary method for real-time glucose tracking. It provides individuals with diabetes and healthcare providers with continuous data on blood sugar levels, allowing for the monitoring of fluctuations throughout the day.

CGM systems utilize a small sensor inserted under the skin to measure glucose levels in interstitial fluid. This data is then transmitted to a monitor or smartphone, offering a comprehensive view of glucose patterns.

CGM is particularly advantageous for individuals with Type 1 diabetes, those with Type 2 diabetes on intensive insulin therapy, and pregnant women with gestational diabetes. CGM aids in identifying trends, patterns, and nocturnal hypoglycemia, enabling timely adjustments to insulin dosages and dietary choices. The use of CGM is also associated with an improvement in the hemoglobin A1c (HbA1c) level and a reduced risk for hypoglycemia. Real-time monitoring empowers individuals to make immediate decisions regarding their diabetes management, improving overall glycemic control and quality of life.

Associated products

Product name	Code
Glucose Oxidase	GO2BS
	GO3A
	GO3B3
	GO3B2
	GOL7
FAD-dependent Glucose Dehydrogenase	GLD1
	GLD3
	GLD4

06

Self-Monitoring of Blood Glucose (SMBG)

Self-Monitoring of Blood Glucose (SMBG) involves individuals with diabetes testing their blood sugar levels at home. It is a crucial component of daily diabetes management.

SMBG typically entails pricking a finger to obtain a small blood sample, which is then analyzed using a glucose meter. SMBG helps patients track their daily blood sugar levels, allowing them to make informed decisions about insulin dosage, dietary choices, and physical activity. SMBG is essential for understanding the impact of different factors on blood glucose levels, such as meals, exercise, and stress. It also aids in identifying hypoglycemia and hyperglycemia episodes, enabling timely interventions.

SMBG data can be shared with healthcare providers, enabling them to tailor treatment plans to individual needs. Advanced glucose meters offer features like memory storage, data analysis, and connectivity to smartphone apps, enhancing the convenience and effectiveness of SMBG for diabetes management.

Associated products

Product name	Code
Glucose Oxidase	GO2BS
	GO3A
	GO3B3
	GO3B2
	GOL7
FAD-dependent Glucose Dehydrogenase	GLD1
	GLD3
	GLD4

07

Urine Glucose Testing

Urine Glucose Testing, while less common today, can provide a rough estimate of blood sugar levels. This method involves collecting a urine sample and using reagent strips to detect the presence of glucose. If glucose is detected in the urine, it may indicate high blood sugar levels.

However, Urine Glucose Testing has several limitations. It does not provide real-time data and does not measure blood glucose levels directly. Furthermore, it may not detect mild or intermittent hyperglycemia as the body usually does not get rid of sugar through the urine. For these reasons, urine glucose testing is generally not recommended for precise diagnosis or routine monitoring of diabetes. Instead, it has been largely replaced by more accurate and convenient blood-based tests like fasting blood glucose, OGTT, HbA1c, and continuous glucose monitoring.

Nevertheless, Urine Glucose Testing can still be useful in specific situations, such as when blood glucose monitoring is not feasible or for initial screenings in resource-limited settings.

Associated products

Product name	Code
Glucose Oxidase	GO2BS
	GO3A
	GO3B3
	GO3B2
	GOL7
FAD-dependent Glucose Dehydrogenase	GLD1
	GLD3
	GLD4



Methods used in diabetes diagnosis and care

08

Diagnostic Immunoassays for Type 1 Diabetes

Diagnostic immunoassays play a crucial role in the diagnosis of Type 1 diabetes, primarily focusing on autoantibodies that indicate the autoimmune destruction of insulin-producing beta cells in the pancreas. Commonly tested autoantibodies include glutamic acid decarboxylase (GAD), islet antigen-2 (IA-2), and insulin autoantibodies (IAA).

These tests are pivotal in distinguishing Type 1 diabetes from Type 2 diabetes or other forms of diabetes. Elevated levels of these autoantibodies in the blood are strong indicators of an autoimmune attack on pancreatic beta cells, leading to insulin deficiency. These immunoassays are often performed alongside traditional blood glucose tests to establish a definitive diagnosis. Early detection of Type 1 diabetes through immunoassays enables healthcare providers to initiate appropriate treatments, such as insulin therapy and close monitoring, to prevent severe complications and improve long-term outcomes for patients.

Associated products

Product name	Code
GAD65	31900/31901
IA-2 (ICA 512)	30500/30501

09

Diagnosis of Diabetic Ketoacidosis (DKA)

Diabetic Ketoacidosis (DKA) is a life-threatening complication of diabetes characterized by dangerously high blood sugar levels and the presence of ketones in the blood. It can lead to severe acidosis and must be diagnosed and treated promptly.

One of the diagnostic tools used in the assessment of DKA is the measurement of β -Hydroxybutyrate with the help of the enzyme β -hydroxybutyrate dehydrogenase (HBDH) in the blood. Elevated serum levels of β -Hydroxybutyrate are indicative of tissue damage. However, it's important to note that β -Hydroxybutyrate is just one component of DKA diagnosis, and healthcare providers use a combination of clinical symptoms, blood glucose levels, electrolyte imbalances, and other blood tests to confirm the presence of DKA. Rapid diagnosis of DKA and immediate intervention with intravenous fluids and insulin therapy are essential for preventing life-threatening complications associated with this condition.

Associated products

Product name	Code
HBDH	rHBDH

10

C-Peptide Test

The C-Peptide Test is a valuable diagnostic tool used to evaluate endogenous insulin production in individuals with diabetes. It measures the concentration of C-Peptide in the blood, which is a byproduct of insulin synthesis and is released when the pancreas produces insulin. This test provides critical insights into the functioning of the pancreas and helps differentiate between Type 1 and Type 2 diabetes.

In Type 1 diabetes, an autoimmune response leads to the destruction of insulin-producing beta cells in the pancreas. As a result, C-Peptide levels in individuals with Type 1 diabetes are typically low or undetectable. The absence of C-Peptide confirms the autoimmune destruction of beta cells and the need for lifelong exogenous insulin therapy.

In Type 2 diabetes on the other hand insulin resistance and relative insulin deficiency are common. The C-Peptide Test is particularly useful in Type 2 diabetes. In this case, C-Peptide levels may be normal or elevated as the pancreas may compensate by producing more insulin to overcome insulin resistance. Elevated C-Peptide levels may indicate that the pancreas is still capable of producing insulin, and lifestyle interventions, along with oral medications, may be effective in managing blood sugar levels.



Methods used in diabetes diagnosis and care

11

Insulin Test

Insulin tests are a crucial component of diabetes care, aiding in the assessment and fine-tuning of treatment plans. These tests measure the concentration of insulin in the blood, providing valuable insights into the status of insulin production and utilization in the body.

In Type 1 diabetes, the autoimmune destruction of insulin-producing beta cells in the pancreas leads to a severe deficiency of endogenous insulin. Consequently, insulin tests in individuals with Type 1 diabetes typically reveal very low or undetectable levels of insulin. These results confirm the necessity for exogenous insulin therapy, enabling healthcare providers to determine appropriate insulin dosages.

Type 2 diabetes often involves insulin resistance, where the body's cells do not respond effectively to the available insulin. Insulin tests in Type 2 diabetes can yield variable results. Initially, there may be higher insulin levels as the pancreas attempts to compensate for insulin resistance by producing more insulin. However, over time, insulin production may decline, leading to reduced insulin levels. These tests guide the management of Type 2 diabetes by indicating the need for insulin therapy if endogenous production becomes insufficient to maintain optimal blood sugar control.

Testing for Insulin levels also assist in evaluating the effectiveness of insulin therapy and adjusting insulin regimens to achieve target glycemic control. Regular monitoring of insulin levels aids in preventing complications and tailoring treatment plans to meet individual patient needs, ultimately enhancing the quality of life for those living with diabetes.

12

Glycated Albumin Testing: Short-Term Glycemic Control

Glycated Albumin Testing is an emerging and valuable tool in the realm of diabetes management. Unlike traditional markers like HbA1c, which reflect long-term glycemic control over several months, Glycated Albumin provides insights into short-term changes in blood glucose levels.

It measures the percentage of albumin, a protein in the blood, that has bound to glucose.

This test is particularly useful in situations where HbA1c results may not accurately represent recent glycemic fluctuations, such as in individuals with conditions affecting red blood cells or those with frequent changes in glucose levels. Glycated Albumin testing enables healthcare providers to make real-time adjustments to diabetes treatment plans, optimizing therapy and improving overall glycemic control. It has proven valuable in fine-tuning insulin regimens and dietary recommendations, ultimately enhancing the precision and effectiveness of diabetes management.



Solutions available from BBI Solutions

Application/ Test Method

	Glucose Oxidase	FAD-dependent Glucose Dehydrogenase	HbA1c Antigen	HbA1c Antibody	GAD65	IA-2 (ICA 512)	Lateral Flow Development & Manufacturing Service	Recombinant HBDH
01. Fasting Blood Glucose Test (FBG)	●	●						
02. Oral Glucose Tolerance Test (OGTT)	●	●						
03. Hemoglobin A1c Test			●	●				
04. Random Blood Glucose Test	●	●						
05. Continuous Glucose Monitoring (CGM)	●	●						
06. Self-Monitoring of Blood Glucose (SMBG)	●	●						
07. Urine Glucose Testing	●	●						
08. Autoimmunity tests for diabetes risk assessment					●	●		
09. Diagnosis of Diabetic Ketoacidosis (DKA)								●



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