



Review

# Comparing Glucometer-Based and Laboratory-Based OGTT for Diabetes Diagnosis: A Narrative Review

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#### **Abstract**

Background: The oral glucose tolerance test (OGTT) is the gold standard for diagnosing diabetes; however, its use is often limited by the need for laboratory infrastructure, trained personnel, and extended turnaround times. In contrast, glucometer-based OGTT offers a convenient and affordable alternative, especially in resource-limited settings. Objective: This narrative review aims to assess the diagnostic accuracy of glucometer-based OGTT compared to standard laboratory-based OGTT, while also evaluating its feasibility and potential application in diabetes screening programs. Evidence Summary: Studies consistently demonstrate a strong correlation between capillary glucose levels measured by glucometers and venous plasma glucose concentrations obtained through standard laboratory methods. Many studies reported high sensitivity and specificity, often exceeding 90%, particularly when using well-calibrated, newer-generation devices. These findings support the diagnostic utility of glucometer-based OGTT in various populations, although performance may vary by device model and clinical context. Standardization of testing protocols remains essential for consistent results. Conclusions: Glucometer-based OGTT shows promise as a reliable, rapid and cost-effective diagnostic approach, particularly in low-resource and community-based settings. While it is not a complete substitute for laboratory-based OGTT, it offers substantial advantages in accessibility, affordability, and scalability. Continued research with newer-generation glucometers and standardized testing protocols is essential to support broader clinical implementation and public health integration.

**Keywords:** oral glucose tolerance test (OGTT); glucometer-based OGTT; laboratory-based OGTT; diabetes diagnosis; point-of-care testing; diagnostic accuracy of diabetes



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## 1. Introduction

The prevalence of diabetes is continuously increasing worldwide and remains one of the leading causes of both morbidity and mortality [1]. Uncontrolled diabetes or a delayed or missed diagnosis could lead to several complications, including cardiovascular, renal, and metabolic dysfunction [2]. A timely diagnosis of diabetes is crucial to prevent complications and allow healthy physiological functioning [3]. Unfortunately, there continues to

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be a substantial prevalence of undiagnosed diabetes, especially in low- and middle-income countries [4].

The oral glucose tolerance test (OGTT) is considered the gold standard for diagnosing diabetes and prediabetes [5]. In standard clinical practice, the patient fasts overnight followed by collection of a fasting venous sample [5]. During the second phase of the OGTT, the patient consumes 75 g of anhydrous glucose dissolved in water, and after 120 min, a second venous blood sample is collected [6]. In standard laboratory procedures, enzymatic methods like hexokinase or glucose oxidase assays measure the blood glucose concentrations. The standard OGTT requires trained phlebotomists, laboratory facilities, and logistic support [6], making OGTT unfeasible for community screening or diagnosing diabetes in low-resource areas in many parts of the world [7].

HbA1c testing, which reflects the mean glycemia status over approximately three months, has gained popularity for diagnosing type 2 diabetes as it does not require fasting, is less affected by short-term biological variability, and remains relatively stable during sample transport [5]. However, HbA1c can be influenced by factors such as hemoglobinopathies, anemia, and altered red blood cell turnover [5,8], and may miss cases of impaired glucose tolerance detected by OGTT [6]. By contrast, OGTT—whether performed using venous plasma in the laboratory or capillary whole blood via glucometer—assesses acute glucose handling and post-challenge hyperglycemia, which may better reflect early pathophysiological changes [6,8]. Several studies have demonstrated limited concordance between HbA1c and OGTT, underscoring that these tests may identify overlapping but distinct subsets of individuals with dysglycemia [9]. Despite these differences, OGTT remains the reference (gold standard) method for detecting glucose intolerance because of its direct measurement of the body's glycemic response to a standardized glucose load [6].

Although continuous blood glucose monitoring is an effective way of managing diabetes, it is neither practical nor feasible to monitor glucose in routine venous blood measurement [10]. Lab-based glucose monitoring requires regular venipuncture and is not a practical or feasible option for many people [10], with the use of point-of-care (POC) devices being the best solution for monitoring blood glucose [11]. Several POC devices are available for this purpose, such as standard glucometers, hospital-grade glucose analyzers, and portable electrochemical glucose meters [11]. Unlike standard lab practices, POC devices do not need venipuncture or lab facilities [10]. They are easy to use, portable, provide rapid results, and require minimal training [11].

Glucometers are the most commonly used POC devices for blood glucose monitoring [12] and are compact, portable, and require only a small drop of capillary blood for analysis [11]. Most modern glucometers operate on electrochemical principles, whereby enzymes such as glucose oxidase (GOx) or glucose dehydrogenase (GDH) react with glucose in the sample to generate an electric current [13]. This current, directly proportional to the glucose concentration, is digitally displayed within seconds [13]. Studies have reported that the results from the glucometer could vary by 10-15% from the lab results [14], with values obtained from the glucometer typically higher than the lab values [14]. A 10-15% deviation from laboratory reference values may lead to misclassification of diabetic status, especially in borderline cases [15]. For example, a patient who's actual 2 h plasma glucose is 198 mg/dL that is just below the diabetes threshold of 200 mg/dL which might receive a falsely elevated reading from a glucometer (e.g., >200 mg/dL), as glucometers often report slightly higher glucose values than laboratory methods, potentially leading to a false-positive diagnosis of diabetes.

Glucometer-based OGTT could be an affordable option for the diagnosis of diabetes and could be used as a community screening tool if satisfactory evidence emerges. Since

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standard laboratory-based OGTT is much more expensive than the glucometer-based OGTT anywhere in the world, the expense of the test is another critical consideration [16].

Several studies have been conducted to identify the accuracy of glucometer-based OGTT. In a community-based study conducted in India, capillary blood glucose measurements using calibrated glucometers, particularly the Glucose Dehydrogenase—Flavin Adenine Dinucleotide (GDH-FAD method), demonstrated strong agreement with venous plasma glucose values measured via the hexokinase method, meeting ISO 15197:2013 accuracy standards and showing minimal bias, thereby supporting its potential as a reliable alternative for diabetes screening in field settings [17]. Similarly, a study conducted in Portugal demonstrated that glucometer-based OGTT correctly classified 94% of individuals when compared to the standard laboratory OGTT, highlighting its potential as a reliable alternative in low-resource settings [18]. These findings align with global health initiatives aimed at expanding point-of-care diagnostics, where portable glucometers are increasingly integrated into primary care frameworks to improve diabetes detection and monitoring [19]. The primary objective of this review is to evaluate whether glucometer-based oral glucose tolerance testing (OGTT) can serve as a reliable and cost-effective alternative to laboratorybased OGTT for the diagnosis of diabetes. To achieve this, we examine the sensitivity, specificity, and overall diagnostic accuracy of glucometer-based OGTT across various population-based and clinical studies.

# 2. Laboratory-Based OGTT: Method and Standards

In standard lab practice, two enzymatic methods are used to measure blood glucose levels, including the hexokinase method and the glucose oxidase method [13]. In the early 1950s, the glucose oxidase method (GOx) was the first enzymatic technique that was applied for blood glucose measurement [20]. This process involves catalyzing the oxidation of glucose to gluconic acid and hydrogen peroxide using the enzyme glucose oxidase [21]. Hydrogen peroxide is produced which reacts with a chromogenic substance in the presence of peroxidase, producing a colored compound that is measured spectrophotometrically [21]. This method is less expensive compared to the hexokinase method, but there are possibilities of deviation from the result due to the influence of ascorbic acid, uric acid, and bilirubin [22]. These substances can distort the final color of the compound, which may give falsely elevated or reduced readings [21]. These limitations make the GOx method less reliable in a clinical context that requires high specificity and accuracy [22].

Despite its shortcomings, the GOx method is still being used in many laboratories due to its low cost and acceptable performance for general glucose screening in clinical populations, particularly in low- and middle-income countries [16].

The hexokinase method which was developed in 1957 but gained widespread use in clinical laboratories during the 1960s and 1970s [22], involves the phosphorylation of glucose by the hexokinase enzyme in the presence of ATP and glucose-6-phosphate is produced [22]. The glucose-6-phosphate is then oxidized by glucose-6-phosphate dehydrogenase (G6PDH) to form NADH, which is measured at 340 nm using spectrophotometry. The concentration of NADH is directly proportional to the glucose concentration [22].

The hexokinase method shows superior analytical performance compared to the Gox method, is highly specific, has minimal interference from endogenous substances, and can reproduce results [23]. Because of its reliability, the hexokinase method is considered the reference (gold standard) method for laboratory glucose measurement in both diagnostic and research settings [22].

When comparing both methods side by side, the hexokinase method consistently provides more accurate and precise glucose measurements than the GOx [8]. The GOx method tends to either underestimate or overestimate glucose concentrations in samples,

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particularly in the presence of compounds such as bilirubin, ascorbic acid, and uric acid [21]. In contrast, the hexokinase method remains stable and accurate across various clinical conditions, including hemolysis, hyperbilirubinemia, and oxidative stress [8].

Studies have findings demonstrate that glucose values obtained using the hexokinase method are typically 1–3% higher than those from the GOx method in matched samples, not because of overestimation, but due to better analytical specificity and reduced susceptibility to interference [23]. For this reason, laboratories performing critical diagnostics, such as those for diabetes, neonatal care, or hyperglycemic emergencies, prefer the hexokinase method for its unmatched accuracy and reliability [8]. However, in many validation studies of blood glucose monitoring systems (BGMS), the YSI 2300 STAT Plus (YSI Life Sciences, Yellow Springs, OH, USA) which uses a glucose oxidase method, has historically been used as the reference analyzer [24]. The YSI 2300 was widely adopted because it provides rapid, precise measurements on fresh whole blood or plasma, minimizing pre-analytical glycolysis, and has demonstrated strong agreement with the hexokinase method (typically within 2–3%) [25]. For this reason, despite not being the chemical gold standard, the YSI 2300 was considered the practical reference standard for BGMS accuracy testing until it was recently discontinued in 2021, creating a gap now filled by newer devices such as the Nova Primary (Nova Biomedical, Waltham, MA, USA) analyzer [25].

Despite being the reference standard, laboratory-based OGTT is prone to developing pre-analytical errors that can significantly influence glucose levels [26]. Even when blood is collected in tubes containing appropriate anti-glycolytic agents such as sodium fluoride–potassium oxalate, glycolysis-related glucose degradation can still occur, which could lead to losses of up to 10–15% of glucose within the first hour before stabilization [20]. Other factors, which include centrifugation delays [26], extended uncentrifuged sample transfer times [26], and the type of sample (plasma vs. serum) [8], can all lead to an underestimation of glucose concentrations. Rapid processing, including immediate centrifugation, is essential to minimize glucose loss and maintain the accuracy of results [23].

### 3. Glucometer-Based Glucose Measurement: Method and Mechanism

Glucometers have gained worldwide popularity as a handy tool for self-monitoring of blood glucose, particularly among individuals living with diabetes. They are compact, portable POC devices designed for rapid and convenient blood glucose testing [11]. They use capillary blood for measuring blood glucose, whereas standard lab practice uses venous blood [11]. A glucometer requires only a small drop of capillary blood [the size of the drop of blood needed by different models varies from 0.3 to 1  $\mu$ L) obtained from slightly piercing a fingertip with a lancet, then placing it on a disposable test strip, calculating the blood glucose level [27]. The meter then displays the level in units of mg/dL or mmol/L within seconds [27].

The core mechanism of a glucometer relies on an electrochemical method and an enzymatic reaction. The electrode on test strip of the glucometer contains enzymes, primarily GOx or glucose dehydrogenase [GDH) [13]. These enzymes catalyze the oxidation of glucose in the blood sample, during which they are reoxidized by an electron mediator—commonly ferricyanide or an osmium bipyridyl complex [21]. The mediator then transfers electrons to the electrode, generating an electrical current [13]. The magnitude of this current is directly proportional to the glucose concentration in the sample, which the glucometer quantifies and displays as the blood glucose level [13].

GOx catalyzes the oxidation of glucose to gluconic acid and hydrogen peroxide [22]. Many glucose meters employ the oxidation of glucose to gluconolactone catalyzed by GOx, producing hydrogen peroxide [21]. The generated hydrogen peroxide is then detected amperometrically [21]. GOx-based glucometers are more sensitive to oxygen concentration,

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and their accuracy may be affected in hypoxic conditions [22]. Additionally, certain interfering substances such as ascorbic acid, uric acid, and acetaminophen may alter readings [22].

GDH catalyzes the oxidation of glucose using cofactors such as NAD<sup>+</sup>, PQQ, or FAD, and these systems are less oxygen-dependent and generally more resistant to electrochemical interference [24]. However, some GDH-PQQ-based devices have been shown to react with other sugars (e.g., maltose, galactose), which can lead to falsely elevated glucose readings, especially in patients receiving certain peritoneal dialysis solutions or immunoglobulin therapies [21]. Therefore, not all GDH-based devices are equally suitable in all clinical contexts [21].

In terms of preference, GDH-based glucometers are generally favored in clinical settings that require higher accuracy and reduced interference from oxygen variability [21]. Their stability under diverse environmental conditions and less susceptibility to common interfering substances make them more reliable than GOx-based systems for diagnostic use [24]. However, GOx-based glucometers remain a cost-effective and widely accessible option for routine home monitoring and general field use [22].

Glucometers do not use the hexokinase method, as it is a multi-step enzymatic reaction that requires precise spectrophotometric detection, which is not feasible in handheld formats [12]. Instead, their electrochemical detection systems prioritize speed and simplicity over analytical complexity [13].

Studies have reported that glucometer readings can deviate from laboratory hexokinase measurements by  $\pm 10$ –15%, depending on the device model, environmental conditions, user technique, and calibration quality [28]. While such variation is clinically acceptable for glucose self-monitoring, it poses challenges in diagnostic settings such as OGTT, where borderline values can result in misclassification of glycemic status [17].

Regulatory guidelines such as the ISO 15197:2013 standard require that 95% of glucometer readings fall within  $\pm 15$  mg/dL of the reference value for glucose concentrations [24]. Although most FDA-approved glucometers meet these thresholds, their performance still lags behind that of laboratory-based hexokinase assays, particularly at critical decision points in the diagnosis of diabetes [24].

Multiple factors apart from the intrinsic performance of the device can affect the glucose level measured by the glucometer [20]. The variations in hematocrit concentration may alter electrochemical readings [28], while regular biological variation in the body's glucose responses can influence the result in repeated measurements [29]. Environmental conditions like temperature as well as humidity, and test strip quality and storage, may further affect accuracy [30,31]. Lack of user expertise in use, such as inadequate blood volume [27], improper strip insertion, or failure to calibrate, could introduce errors that could be avoided by training on proper technique of use [20,27,30].

## 4. Accuracy of Glucometer-Based OGTT: Evidence and Performance

Although the term "glucometer-based OGTT" is not formally recognized in clinical guidelines, several studies have investigated the feasibility and diagnostic accuracy of glucometers during OGTT procedures. Findings from these studies suggest that using glucometers during OGTT may offer a promising and practical alternative for diabetes screening, particularly in resource-limited settings.

One of the most compelling examples comes from India, where Suresh Babu et al. conducted a hospital-based study evaluating the accuracy of a glucometer in diagnosing gestational diabetes mellitus (GDM) among 182 pregnant women [32]. The results revealed a sensitivity of 100% and a specificity of 98.8%, with an area under the ROC curve (AUC) of 0.994, indicating near-perfect diagnostic accuracy [32]. The authors endorsed the use of

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a single finger-prick capillary sample for immediate diagnosis, arguing that it provides a viable alternative to venous sampling in busy clinical settings [32].

In an earlier prominent population-based study in Chennai, India, Priya et al compared capillary and venous glucose measurements during OGTT among over 400 adults [33]. The study reported a strong correlation (r = 0.897) between 2 h capillary blood glucose and venous plasma glucose, with a diagnostic sensitivity of 91.1% using WHO criteria [33]. These findings confirm that calibrated glucometers can serve as reliable tools for community-based diabetes screening, especially in settings lacking access to laboratory facilities [33].

A more recent investigation by Al-Hasani et al. [34] in the United Kingdom assessed the performance of the StatStrip® point-of-care glucometer (Nova Biomedical, Waltham, MA, USA) in diagnosing GDM among 230 pregnant women [34]. The results were noteworthy: at 2 h, the sensitivity reached 97% and specificity was 79%, while predictive values at extreme glucose concentrations (e.g., fasting glucose  $\leq 5.0$  mmol/L or 2-h glucose > 9.5 mmol/L) achieved 100% accuracy [34]. The authors concluded that while POC testing may not entirely replace laboratory OGTT, it is a valuable tool for ruling in or ruling out GDM in clinical practice, especially when timely diagnosis is critical [34].

Further supporting the feasibility and reliability of glucometer-based OGTT, Tan et al. [35] conducted a feasibility study in Singapore involving high-risk individuals who self-administered the OGTT using capillary blood measurements [35]. This approach yielded a sensitivity of 94.1% and a negative predictive value of 91.7% in identifying prediabetes or type 2 diabetes [35]. The study also reported an excellent correlation (r = 0.95) between capillary and venous glucose measurements at both fasting and 2 h time points [35]. Participants expressed high levels of confidence in self-testing, and the convenience of home-based testing offers significant potential for expanding screening coverage, particularly in populations with limited access to healthcare facilities [35].

Another noteworthy contribution comes from Vučić Lovrenčić et al. [9] in Croatia, where researchers also evaluated the diagnostic accuracy of a StatStrip<sup>®</sup> glucometer in a sample of 237 adults undergoing standard OGTT [9]. Capillary and venous samples were analyzed concurrently, and the correlation between the methods was strong (r = 0.9768) at the 2 h post-load measurement [9]. The diagnostic concordance, measured using weighted Kappa statistics, was 0.858, indicating a good agreement between the POC device and the reference laboratory method [9]. Only a small fraction of patients were misclassified when using the glucometer, suggesting its reliability for use in primary care settings where central laboratory services may not be immediately available [9].

Laboratory-based OGTT results may be inaccurate when there are delays in sample processing which could potentially lead to underdiagnosis of glucose intolerance [26]. This aspect has been well documented in gestational diabetes research, such as the ORCHID study conducted in rural and remote Western Australia, where median delays of 5 h (range 2.3–124 h) before laboratory analysis resulted in an estimated 62% of GDM cases being missed compared with optimally handled samples kept on ice [36]. Even a 4 h delay at room temperature can lower the glucose concentration by more than 0.4 mmol/L [36]. Under such conditions, glucometer-based OGTT, which gives immediate results without delay, may provide a more accurate diagnosis than delayed laboratory testing, particularly in low-resource or remote settings [36].

However, a few studies have raised concerns regarding the diagnostic reliability of glucometer-based OGTT, particularly in specific clinical contexts or with certain device models. For example, Adam et al. [37], in a prospective cohort study involving 529 pregnant women in South Africa, found that the Roche Accu-Chek Active glucometer demonstrated a sensitivity of only 27% for detecting gestational diabetes, despite a specificity of 89.4% [38]. The study identified systematic biases at different OGTT time points and concluded that

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the device was not appropriate for diagnostic use in GDM [38]. Similarly, Lippi et al. [29] evaluated glucometer-based fasting glucose measurements against the laboratory-based hexokinase method and reported a sensitivity of 50%, despite a specificity of 100% [29]. Although overall diagnostic accuracy was high, the study emphasized the risk of missed diagnoses in cases near the diagnostic threshold [29].

These findings underscore the need for caution when interpreting glucometer results in clinical diagnostics, particularly in critical populations such as pregnant women. Device variability, environmental factors, and physiological conditions may all contribute to reduced accuracy in certain scenarios.

The majority of studies reviewed show favorable diagnostic performance for glucometer-based OGTT, with many reporting high correlation with venous plasma glucose, strong sensitivity and specificity values, and practical advantages in resource-limited settings. Taken together, the evidence supports the potential utility of glucometer-based OGTT as a cost-effective and scalable alternative for diabetes screening and early detection, particularly where laboratory infrastructure is limited. With appropriate device selection and validation, glucometer-based OGTT holds promise for broader integration into community health initiatives.

The tables below show a brief overview of the characteristics of multiple studies that have compared the results obtained from the two methods of evaluating glucose levels. Table 1 depicts the general characteristics and brief methodology employed in the studies and Table 2 briefly illustrates the results obtained and their implications.

<b>Table 1.</b> Characteristi	cs of Included S	tudies on Glucose	e Testing and Dia	betes Diagnosis.

Author, Year	Country	Sample Characteristics	Study Setting	Brief Study Protocol	Standard Criteria Used
Priya et al., 2011 [39]	India.	The sample size was 407. Participants were aged 20 years or older 54.1% were male With no known diabetes.	tertiary diabetes center.	CBG and VPG were assessed concurrently both in the fasting state and 2 h after a 75 g glucose load.	Diabetes, impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) were defined using American Diabetes Association (ADA) and World Health Organization (WHO) criteria.
Suresh Babu, G. et al., 2015 [40]	India	n = 182 pregnant women	Cross-sectional prospective study conducted at the Biochemistry laboratory of a hospital	Objective: To compare the blood glucose levels by glucometer and laboratory method in the diagnosis of GDM Both Venous and capillary blood were tested for glucose levels 2 h after 75 g Glucose load.	All testing was conducted by the same qualified and experienced lab technicians and under ambient conditions.

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 Table 1. Cont.

Author, Year	Country	Sample Characteristics	Study Setting	Brief Study Protocol	Standard Criteria Used
Gallardo et al., 2020 [41]	Mexico	<ul><li>n = 328 pregnant</li><li>women without</li><li>diabetes</li></ul>	multicenter longitudinal cohort study in primary healthcare clinics.	The Objective was to compares the accuracy of two glucometers for GDM detection.	All participants were tested with OGTT for the diagnosis of GDM based on the ADA 2019 guidelines.
Adam et al., 2018 [37]	South Africa	The sample size included 529 pregnant women without diabetes	Prospective cohort observational study at a primary healthcare clinic.	Objective: To evaluate the performance of the glucometer in the diagnosis of GDM. A 75 g 2 h OGTT was scheduled at 24–28 gestational weeks. Glucose was measured in venous and capillary blood	GDM was diagnosed via FIGO criteria.
Lippi et al., 2025 [29]	Italy	n = 241 pregnant women	local phlebotomy center	Fasting glucose was measured in capillary blood using glucometer and in plasma with laboratory method using the hexokinase reference assay	NA
Eskandarifar et al., 2019 [42]	Iran	The sample size included 130 critically ill infants less than 1 year of age	Besat hospital, Sanandaj at IRAN	Objective: To determine the accuracy of glucometer for early diagnosis of hypoglycemia in acutely ill infants. Blood sugar was measured by glucose oxidase method and glucometer reagent strip.	NA
Wolde et al., 2018 [30]	Ethiopia	n = 200 100 with diabetes 100 healthy controls	Prospective cross-sectional study at Addis Ababa University	Four randomly selected POCG devices were evaluated against hexokinase method	ISO 15197:2003 and ISO 15197:2013 standards

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 Table 1. Cont.

Author, Year	Country	Sample Characteristics	Study Setting	Brief Study Protocol	Standard Criteria Used
Ogunbosi et al., 2022 [31]	Nigeria	A total of 295 children between the ages of 0 and 15 years were included.	A cross-sectional study conducted in pediatric emergency and outpatient departments of two major hospitals.	Blood glucose levels were measured with One Touch® (LifeScan Inc., Milpitas, CA, USA) and Accu-Check® (Roche Diagnostics, Mannheim, Germany) glucometers and the glucose oxidase method at the same time and determined the effect of hematocrit on glucose readings. Study period: over a 6-month period.	NA
Daly et al., 2017 [43]	Ireland	A total of 108 pregnant women between 24 and 28 weeks of gestation were enrolled	The study followed a prospective observational design at a perinatal facility	Women screened selectively with a one-step 75 g OGTT recruited. At each OGTT time point two venous samples and one capillary sample taken A capillary sample was used for glucometer testing.	NA
O'Malley et al., 2020 [44]	Ireland	The study included 202 female participants.	Prospective observational study	The objective was to evaluate the use of POC measurements of maternal glucose to diagnose GDM with a 1-step 75 g OGTT.  Maternal plasma and capillary glucose measured at fasting and at 1 and 2 h post glucose load.	Using updated laboratory standards as the reference

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 Table 1. Cont.

Author, Year	Country	Sample Characteristics	Study Setting	Brief Study Protocol	Standard Criteria Used
Khambule et al., 2025 [45]	South Africa	n = 1076 pregnant women	Cross-sectional study in a prenatal clinic in Johannesburg.	Both venous and capillary blood evaluated for laboratory-based and POC glucose measurements	The up-to-date International Association of Diabetes and Pregnancy Study Groups diagnostic criteria were used.
Pastakia et al., 2017 [46]	Sub-Saharan Africa (SSA)	n = 616 Pregnant women between 24 and 32 weeks of a singleton pregnancy	Prospective study at antenatal clinic	Objective: To assess utility of various GDM POC screening strategies in a resource-constrained setting Testing over two days.  Day 1: a POC 1 h 50 g glucose challenge test (GCT) and a POC glycated hemoglobin (HbA1c) assessed.  Day 2: fasting blood glucose, 1 h and 2 h 75 g oral glucose tolerance test (OGTT) determined using both venous and POC tests, along with a venous HbA1c.	OGTTs conducted as per International Association of Diabetes and Pregnancy Study Groups (IADPSG) guidelines.
Vučić Lovrenčić et al., 2013 [9]	Croatia	n = 237 participants with a previous history of dysglycemia	Prospective observational study at Vuk Vrhovac University Clinic	Objective: to investigate the diagnostic accuracy of an innovative, interference-resistant POC glucose meter Venous and capillary blood sampling for the reference laboratory procedure and POC-glucose measurement was carried out at fasting and 2 h OGTT.	The International Association of Diabetes in Pregnancy Study Group (IADPSG) criteria was used to diagnose GDM.

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Table 1. Cont.

Author, Year	Country	Sample Characteristics	Study Setting	Brief Study Protocol	Standard Criteria Used
Al-Hasani et al., 2024 [34]	UK	n = 230 pregnant women	Prospective cohort study at antenatal clinics	Objective: To assess the clinical utility of POC CBG testing in the assessment of GDM during OGTT CBG was measured using the POC. VPG was measured by Roche analyzer The two methods were compared statistically	Categories of glucose tolerance were classified according to 2006 WHO diagnostic criteria.
Fabre- Estremera et al., 2024 [18]	Spain	n = 98 pediatric patients	Prospective observational study at La Paz University Hospital.	Objective: To evaluate the accuracy POCT glucometers during an OGTT for prediabetes and diabetes diagnosis in a comparison study. Glycaemia measured in venous blood using two glucometers with lab analysis as a reference	GDM was diagnosed based on the 2015 National Institute for Health and Clinical Excellence (NICE) Clinical Guideline criteria.
Tan et al., 2021 [35]	Singapore	<ul><li>n = 30 patients</li><li>with history of</li><li>gestational</li><li>diabetes or</li><li>prediabetes</li></ul>	Prospective observational study at polyclinic	Objective: to assess the feasibility and precision of a self-administered capillary OGTT for type-2 diabetes mellitus in high-risk individuals.  Self-administered the capillary OGTT and concurrently their venous glucose samples were obtained.	NA
					NA

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**Table 2.** Sensitivity, Specificity, Agreement, and Clinical Implications of Glucose Measurement Techniques.

Author, Year	Sensitivity and Specificity	Agreement Between Capillary and Venous Blood	Conclusion	Implications
	-ry	Glucose Measurement		
Priya et al., 2011 [38]	NA	r = 0.681 (p < 0.001) (fasting state) $r = 0.897 (p < 0.001)$ for the 2 h PG load Diabetes diagnosis $rate: (capillary vs.$ $venous)$ $= 31.9% versus 21.1%$ (ADA) $= 43.2% versus 38.6%$ (WHO) Accuracy of identifying diabetes $= 83.3% (ADA)$ $= 90.9% (WHO)$	CBG measurement by Glucometer is a feasible alternative in developing countries.	CBG measurement by Glucometer can be used for screening of diabetes and IGT in epidemiological studies It can be used where obtaining venous samples may be difficult.
Suresh Babu, G. et al., 2015 [39]	sensitivity = 100% specificity = 98.8%	AUC = 0.994 Good agreement between glucometry and laboratory analysis, r = 0.9681 Bland—Altman (difference) Plot: a constant bias 1.7% with SD 4.3 (95% CI: -6.7 to 10)	Estimation of glucose using single step approach with a single finger prick capillary blood drop and instant results is a promising test.	Clinical judgment is a must for final decision. Safe to diagnose diabetes using a glucometer, i.e., CBG Usage requires high precision Continuous quality assurance procedures needed.
Gallardo et al., 2020 [40]	First model POC venous OGTT sensitivity = 100% specificity = 62.8%. The second model, POC capillary OGTT; Sensitivity = 78.57% specificity = 74.1%	For the first model, POC venous OGTT; GDM incidence = 41.66% compared to 7.05% of the plasmatic test, The second model, POC capillary OGTT; GDM incidence = 30.23% compared to 8.13% of the plasmatic test ROC area under the curve for GDM prediction was 0.81 95% CI = 0.77–0.85 compared to the first model, ROC area under the curve = 0.76 95% CI = 0.65–0.88	Capillary OGTT is a valid alternative to the gold standard OGTT Especially important in low resource setting. The positive bias could be beneficial. As early treatment and control related to better perinatal health outcomes	POC OGTT can reduce diagnosis time. Reduce cost of diagnosis. Helpful in low resource setting. Further analysis needed to improve GDM, POC screening interventions.

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Table 2. Cont.

Author, Year	Sensitivity and Specificity	Agreement Between Capillary and Venous Blood Glucose Measurement	Conclusion	Implications
Adam et al., 2018 [37]	Sensitivity = 27.0% specificity = 89.4%	Diagnosed with GDM by laboratory = 26.7% and glucometer measurements = 14.9%, CV = 15% to 17%. Bland–Altman plots: a positive bias of the glucometer results at 0 h, a negative bias at 1 and 2 h of the OGTT.	They had not recommended use of the Roche Accuchek Active glucometer for the diagnosis of GDM	The use of POC glucometers is not recommended.
Lippi et al., 2025 [29]	Sensitivity = 50.0% Specificity = 100.0% (For diagnosing fasting glucose values ≥ 7.0 mmol/L compared to the laboratory assay).	The diagnostic accuracy = 99.2% The mean turnaround time (TAT) laboratory-based strategy vs. Glucometer = 32 min 8 vs. 8 s Imprecision of the glucometer vs. laboratory assay = 3.4% vs. 0.8%	Screening fasting glucose in capillary blood with a POC glucometer allows faster patient management but is associated with higher imprecision, inaccuracy, costs and avoidable finger pricks	POC capillary blood protocol is associated with higher imprecision
Eskandarifar et al., 2019 [42]	sensitivity = 72%, specificity = 53%,	Positive predictive value = $62\%$ Negative predictive value = $7\%$ correlation was significant ( $p < 0.001$ ). Kappa statistics = $42\%$ .	Glucometer based test cannot be regarded as a very suitable and reliable tool for diagnosis of hypoglycemia in critically ill infants.	Glucometer cannot be used in diagnosing hypoglycemia in critically ill infants It may be appropriate for rapid screening in emergency situations
Wolde et al., 2018 [30]	NA	All four PoCG devices had strong positive relationship (>80%) with the reference method concentrations. None of the devices fulfilled the minimum accuracy measurement set by ISO standards.	Four PoCG measurements were poorly correlated with standard reference method.	The study highlighted the need for a standardized evaluation process before new glucometers are introduced to the Ethiopian market.

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Table 2. Cont.

Author, Year	Sensitivity and Specificity	Agreement Between Capillary and Venous Blood Glucose Measurement	Conclusion	Implications
Ogunbosi et al., 2022 [31]	NA	Bland–Altman: acceptable level of bias (3.9 mg/dL) between the two glucometers. Correlation analysis: significant correlation between each of the glucometer methods and laboratory blood sugar	Though it can aid rapid decision-making, there is a need to periodically cross-check with the glucose oxidase method in the laboratory to optimize outcome	Use of a tested glucometer in clinical settings can aid in rapid decision-making
Daly et al., 2017 [43]	Sensitivity = 92.5%, specificity = 76.5%, (based on adjustment of the POC fasting diagnostic threshold from ≥5.1 to ≥4.8 mol/L (aPOC))	GDM was detected in using the reference standard, $47.2\%$ ( $n = 51$ ), customary practices, $17.6\%$ ( $n = 19$ ) and POC, $24.1\%$ ( $n = 26$ ) ( $p < 0.001$ ). based on adjustment of the POC fasting diagnostic threshold from $\geq 5.1$ to $\geq 4.8$ mol/L (aPOC), PPV = $69.8\%$ , NPV = $94.5\%$ Accuracy = $94.5\%$	POC capillary maternal glucose tests were superior to customary laboratory practices for diagnosing GDM, particularly in low resource healthcare settings.	In low resource setting POC capillary maternal glucose test is useful in diagnosing GDM
O'Malley et al., 2020 [44]	NA	Based on the plasma measurements, 53.5% had GDM. As a predictor of GDM, diagnostic accuracy of POC measurement 83.0% Diagnostic accuracy of POC measurement = 83.0%	POC device can be used in low resource setting though not recommended in high resource setting.	If measures to inhibit glycolysis are available to implement, then use of POC device use may not be recommended.
Khambule et al., 2025 [45]	POC glucometers sensitivity = 17.6% to 87.18%, Specificity = 62.7% and 99.8%. (Laboratory-based fasting plasma glucose (FPG) sensitivity = 94%, specificity = 100%)	Bland–Altman plots: All POC glucometers showed moderate to poor reliability. The AUC = 0.59 to 0.79. (AUC = 0.98 for laboratory-based test)	They recommended laboratory-based FPG over POC glucometer as a diagnostic test for GDM.	Laboratory methods are recommended for the diagnosis of GDM

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 Table 2. Cont.

Author, Year	Sensitivity and Specificity	Agreement Between Capillary and Venous Blood Glucose Measurement	Conclusion	Implications
Pastakia et al., 2017 [46]	Compared to IADPSG testing, POC IADPSG had a sensitivity = 55.6% and specificity = 90.6%, respectively, while that of POC 1 h 50 g GCT was sensitivity = 55.6% and specificity = 63.9%.	GDM was diagnosed in 18 women, a prevalence of 2.9%	Though POC screening strategies feasible, it showed poor sensitivity for GDM detection in resource-constrained population of low GDM prevalence.	Studies required to identify sensitive and specific POC GDM screening strategies using adverse pregnancy outcomes as end points.
Vučić Lovrenčić et al., 2013 [9]	NA	Weighted Kappa = 0.858. Bland-Altman analysis: slight bias between the RLP- and POC-FPG	StatStrip POC glucose meter could serve as a reliable tool for the diabetes diagnosis, particularly in primary healthcare facilities with dispersed blood sampling services.	POC glucose could be used as an alternative to laboratory methods in low resource settings.
Al-Hasani et al., 2024 [34]	For the POC StatStrip® test, at 95% CI, Fasting Sensitivity = 88% (52–99%) Specificity = 97% (93–98%) at 2 h, Sensitivity = 97% (91–99%) Specificity = 79% (71–84%)	POC StatStrip® test versus laboratory VPG measurement 15 (6.5%) versus eight (3.4%) at fasting and 105 (45.6%) versus 72 (31.1%) at 2 h Specificity and the NPV for the POC StatStrip® test for concentrations of ≤5.0 mmol/L at fasting or <7.5 mmol/L at 2 h were 100%, and Sensitivity and the PPV for concentrations of >9.5 mmol/L at 2 h were 100%.	Though POC measurement of CBG cannot entirely replace the laboratory method for the OGTT; it can be used to rule out/rule in GDM for glucose concentrations of ≤5.0 mmol/L at fasting or <7.5/>9.5 mmol/L at 2 h.	POC CBG can be used to aid in diagnosing GDM

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Table 2. Cont.

Author, Year	Sensitivity and Specificity	Agreement Between Capillary and Venous Blood Glucose Measurement	Conclusion	Implications
Fabre-Estremera et al., 2024 [18]	NA	The diagnostic concordance between connected glucometer and the central laboratory was 71.1% Same clinical decision in the 92.8% of the cases, but treatment would have not been indicated in 4 patients (4.1%).	POCT glucometers show high correlation and accuracy compared with standard procedures but may not be used for diagnosis yet as severe clinical impact could happen.	POCT glucometers can reduce time Reduce cost Highly correlated to central laboratory testing
Tan et al., 2021 [35]	capillary OGTT sensitivity = 94.1%	NPV = 91.7% r = 0.95; $p < 0.001$ (for fasting) and 2 h post-OGTT, r = 0.95; $p < 0.001The Fleiss' KappaScore (0.79,p < 0.0001$ )	Self-administered capillary OGTT is feasible and acceptable, especially among younger adults, with excellent sensitivity and NPV compared with plasma-based OGTT	Capillary OGTT can be useful in identifying prediabetes and T2DM (comparing to venous sample)

 $POC = point-of-care \ p < 0.001 = significant correlation, The Pearson's correlation coefficient = r, Confidence Interval = CI, Area Under Curve = AUC, coefficient of variance = CV, Negative predictive value = NPV, note: Laboratory values are venous plasma glucose; glucometer values are capillary whole blood reported as plasma-equivalent glucose unless otherwise stated.$ 

Across the included studies, most comparisons between glucometer and laboratory-based OGTT results were made using paired samples collected from the same participant at the same time point during the OGTT. Glucometer readings were obtained immediately from fresh capillary whole blood, whereas laboratory analyses were typically performed on venous samples. However, there was variation in the sample type reported for the laboratory method (plasma vs. whole blood) and in whether glucometer values were expressed as blood glucose or plasma-equivalent glucose. Additionally, in several studies, laboratory samples were subject to processing delays ranging from minutes to several hours, which could lead to glycolysis and lower measured glucose concentrations if samples were not immediately centrifuged or kept on ice. These methodological differences should be considered when interpreting the agreement between glucometer- and laboratory-based OGTT results.

Many of the included studies did not provide detailed information on venous sample handling, such as the type of glycolytic inhibitor used, timing of centrifugation, or delays before analysis. Therefore, differences in sample handling may have contributed to variability in the agreement between glucometer and laboratory OGTT results.

Among the studies included in Tables 1 and 2, the details provided about laboratory analyzers and enzymatic methods significantly differ. Four studies specified the enzymatic method they used. Vučić Lovrenčić et al. [9] used the hexokinase method. Jamieson et al. [26] used the hexokinase method on a Roche Cobas 8000 analyzer. Priya et al. [39] and Adam and Rheeder [37] employed the glucose oxidase method. Only Dickson et al.

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and Jamieson et al. reported that both the enzymatic method as well as the specific analyzer model. The absence of such methodological details in many other studies limits comparability across research, as differences in enzymatic method (hexokinase versus glucose oxidase) and analyzer type can influence measured glucose concentrations and the agreement observed between glucometer- and laboratory-based OGTT results.

#### 5. Potential Benefits of Glucometer-Based OGTT

Studies have revealed that glucometers used during OGTT can be cost-effective compared to centralized laboratory testing [16]. Glucometer testing can be 48.8% cheaper than lab-based testing [32] with the cost per case identified ranging from USD 176 to USD 236 in the laboratory-based OGTT [47]. In contrast, a glucometer-based strategy may incur an incremental cost of only a few cents or euros per patient; for example, the glucometer-based OGTT had a cost of EUR 0.17 per patient [48]. It has been reported from another study that the total direct cost of a single laboratory OGTT was estimated at USD 3.27  $\pm$  0.49, which included 57 cents for disposable supplies, 19 cents for the cotton ball, bandage, alcohol swab, and lancet, and 38 cents per blood glucose test strip [49]. This estimate represents only the direct laboratory expense per test, in contrast to the higher programmatic costs (USD 176–236) reported per case identified in screening initiatives. Moreover, the cost of laboratory OGTT testing included personnel training and logistics supplies. The percentage of costs attributed directly to patient lab testing does not include expenses incurred while measuring OGTT with a glucometer [26].

The cost of glucometer-based OGTT is not solely determined by the brand of the glucometer but encompasses a range of related factors such as test strips, features, and regional prices [50]. It is important to consider these factors when selecting a glucometer for OGTT testing [50]. A glucometer can be used for several years, typically 3–5, depending on the manufacturer's warranty and the device's condition [51]. It can be used as many times as the user needs, and the glucometer itself is reusable, but the test strips and lancets are single-use items [51].

Using glucometers for OGTT requires less infrastructure than traditional venous blood sampling [16]. Capillary blood glucose monitoring with glucometers can be conducted in various locations, including homes and clinics, whereas venous blood sampling typically requires a well-equipped laboratory [52]. This advantage makes glucometer-based OGTT more accessible and convenient for individuals and healthcare providers, particularly in resource-limited settings [52]. Glucometer-based OGTT can be a suitable alternative to the traditional OGTT, especially in rural and low-resource areas [16]. This is because capillary blood glucose testing using a glucometer is more simple, less expensive, and more feasible to perform in settings where access to traditional laboratory testing is limited [53]. OGTT measurement using a glucometer can be performed quickly and efficiently, enabling larger-scale screening efforts [33]. This is particularly important for national programs. For instance, national diabetes programs can use glucometer-based OGTTs as a tool for mass screening and monitoring [33]. This can help identify individuals at risk and develop targeted interventions to improve public health [33].

Overall, glucometer-based OGTT has several potential benefits. It is significantly cheaper than lab-based OGTT, requiring less expertise and personnel, less infrastructure, and simplified logistics. It is suitable and accessible to rural communities and low-resource areas. Additionally, it is highly feasible for mass screening and national diabetic programs.

## 6. Advances in Glucometer Technology and Implications for OGTT Accuracy

Improvements in technology can significantly enhance the accuracy of glucometers during OGTT, leading to more reliable diagnoses of diabetes. For example, many immobi-

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lization methods have been proposed to increase enzyme loading and stability, including covalent attachment, cross-linking, physical entrapment, and adsorption [21]. In enzymatic glucose biosensors, glucose oxidase and glucose dehydrogenase are the common enzymes employed to develop glucose biosensors [54]. Appropriate GOx enzyme immobilization onto the nanomaterial-modified electrode surface is essential to ensure a stable and efficient enzymatic glucose biosensor [54]. Recently, a graphite rod modified with dendritic Au nanostructure, GOx enzyme, and phenazine methosulfate as the soluble redox mediator was developed for use as an electrochemical glucose biosensor [54].

Additionally, the way to attach enzymes is through electro polymerization, which means placing an enzyme into 3D structures like a special film, a mixed material, a light-sensitive material, a gel made of silica, a sugar-based material, or a carbon paste [55]. Using this method, enzymes, mediators, and additives can be immobilized simultaneously on the same sensing layer, so any modification to the biological molecules is not required [54]. This method is simple and guarantees that the enzyme is well preserved during the immobilization process. 3 Another intriguing approach in GOx enzyme immobilization is the enzyme precipitation coating (EPC) [56]. The EPC approach involves three basic steps of covalent binding of the GOx enzyme: GOx enzyme precipitation via the addition of salts, organic solvents of polymeric materials, and cross-linking of the GOx enzyme with bifunctional reagents [56].

However, the calibration of the commercially available Continuous Glucose Monitoring (CGM) sensor is critical to ascertain the accuracy of the measurement. Some of the commercially available CGM devices are Medtronic Guardian 3, Abbott Freestyle Libre, Dexcom G4 Platinum, Dexcom G5, and Dexcom G6 [14]. All these devices measure interstitial glucose levels based on a glucose oxidase-based chemical reaction, which is converted into an electrical signal directly proportional to the glucose concentrations [57]. A calibration function mediates this conversion. This function must be updated occasionally due to variations that might occur as a result of instrumental drift and biocompatibility issues [57].

Whereas earlier-generation glucometers showed deviations of approximately  $\pm 15\%$  from laboratory standards, updated glucometer models now demonstrate errors as low as  $\pm 10\%$ , marking a substantial improvement in diagnostic precision [58]. Recent research findings suggest that newer FDA-approved glucometers, such as OneTouch Verio Reflect, are far more accurate than older models [59]. A 2023 study found that this device met international ISO 15197:2013 standards, with nearly 98% of glucose readings under 100 mg/dL falling within  $\pm 10$  mg/dL of lab results, and 100% of higher readings falling within  $\pm 10\%$ . That is a significant improvement compared to earlier devices, which were up to  $\pm 15\%$  accurate [59].

Newer glucometers offer advancements in accuracy and reliability, making them a promising tool for OGTT application in the future. These devices can be used for a more accurate and reliable way of monitoring blood glucose levels throughout the test, which can help to identify undiagnosed or pre-diabetic conditions.

Recently, dedicated strip-based OGTT platforms have been developed to address known limitations of traditional laboratory-based testing, such as pre-analytical delays in venous sample processing and inconsistencies in timing of post-load sampling. Systems such as the GTT@home (Digostics Ltd., Abingdon, UK) integrate a pre-measured glucose load, lancets, and a connected glucometer with a built-in timer, enabling immediate analysis of capillary blood at fasting and 2 h intervals [34,35]. By eliminating transport and processing delays, these technologies reduce the risk of glucose degradation [26] and help ensure accurate timing, which is critical for OGTT validity [36]. Feasibility studies have

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also demonstrated their potential for out-of-clinic use, particularly in rural or low-resource settings where laboratory access is limited [16].

#### 7. Future Research Directions and Recommendations

Glucometer-based OGTT has reported considerable promise as a practical and affordable alternative to traditional laboratory-based methods for diagnosing diabetes, particularly in low-resource and community settings. With the advancement of glucometer technology, newer models are offering improved accuracy and reduced variability in glucose measurement. This makes them more suitable for diagnostic applications.

Glucometers are increasingly recognized as practical tools for diabetes diagnosis, particularly in settings where laboratory resources are limited. They are valuable for community screening, self-monitoring, and in remote areas where laboratories are not available. In some contexts, such as screening for GDM in rural clinics, glucometer-based OGTT is a feasible alternative when laboratory testing is unavailable. However, confirmatory laboratory OGTT remains necessary in cases with borderline values, high clinical risk, or where strict laboratory protocols are followed, to avoid misclassification.

In low- and middle-income countries, WHO supports the use of ISO 15197:2013–compliant glucometers for diagnosis, provided that quality assurance programs, validated cut-offs, and integration into routine workflows are in place [16,17]. Professional-use devices generally show better accuracy than home-use models, and variability between brands highlights the need for careful validation and ongoing monitoring. For scale-up, strategies should include training healthcare workers, ensure a reliable supply of devices and strips, and embed glucometer-based testing within primary care and community programs. Under these conditions, glucometers can deliver accurate, affordable, and scalable diabetes diagnosis in real-world healthcare contexts.

However, further research is essential to validate the diagnostic accuracy of glucometer-based OGTT across diverse populations and clinical scenarios, especially in borderline cases where small deviations can lead to misclassification. Additionally, its potential as a large-scale screening tool for early detection of diabetes should be explored through well-designed studies that assess its sensitivity, specificity, and cost-effectiveness in real-world settings. Standardized testing protocols, integration with digital health platforms, and long-term outcome studies will be crucial to determine its feasibility and reliability. If validated, glucometer-based OGTT could become a valuable component of national diabetes screening programs, offering a scalable and accessible solution for early diagnosis and intervention.

# 8. Conclusions

Glucometer-based OGTT presents a promising alternative to traditional laboratory-based methods for monitoring and diagnosing diabetes, particularly in low-resource and community settings. While laboratory-based OGTT remains the gold standard due to its high accuracy and reliability, glucometer-based approaches offer significant advantages in terms of cost, accessibility, and ease of use. Numerous studies have demonstrated strong correlations between capillary and venous glucose measurements, with acceptable sensitivity and specificity in many clinical and field settings. Technological advancements in glucometer design have further improved their accuracy, making them increasingly viable for diagnostic purposes. However, variability among devices and potential for misclassification in borderline cases highlight the need for continued research and standardization. With further validation and integration into public health strategies, glucometer-based OGTT could play a critical role in expanding diabetes screening and early detection, especially in underserved populations.

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