FIND
Diagnosis for all

LANDSCAPE OF

HbA1c POINT-OF-CARE TESTING DEVICES

CONTENTS

ABBREVIATIONS AND KEY DEFINITIONS

ACR	Albumin-to-creatinine ration
ADA	American Diabetes Association
ADVANCE	Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation
CE	Certification Europe (conformité européenne)
CLIA	Clinical laboratory improvement amendments
DCCT	Diabetes Control and Complications Trial
EDL	Essential Diagnostics List
FDA	US Food & Drug Administration
Hb	Haemoglobin
HbA1c	Glycated haemoglobin
HbF	Foetal haemoglobin
IDF	International Diabetes Federation
IFCC	International Federation for Clinical Chemistry and Laboratory Medicine
iFOBT	Immunochemical fecal occult blood test
IVD	In vitro diagnostics
LMIC	Low- and middle-income countries
NGSP	National Glycohemoglobin Standardization Program
PEN	Package of Essential Noncommunicable Disease Interventions
POC	Point of care
PT/INR	Prothrombin ratio/international normalized ratio
RBC	Red blood cell
SRA	Stringent regulatory authority
UKPDS	United Kingdom Prospective Diabetes Study
VADT	Veterans Association Diabetes Trial
WHO	World Health Organization

In vitro diagnostic tests – Tests used for in vitro evaluation of specimens derived from the human body to provide information for screening, diagnosis, or treatment monitoring purposes.

Parameter – Marker, analyte, molecule, or substance.

Primary care – The part of a health services system that assures person-focused care over time for a defined population, accessibility to facilitate receipt of care when it is first needed, comprehensiveness of care in the sense that only rare or unusual manifestations of ill health are referred elsewhere, and coordination of care such that all facets of care (wherever received) are integrated [1].

Point-of-care testing - Testing that is performed in close proximity to where the patient is receiving care. Testing is performed by health professionals, and results are typically available relatively quickly.

DISCLAIMER

Although all efforts have been made to ensure that the present landscape provides an accurate and comprehensive overview of HbA1c testing devices for use at the point of care in primary care facilities, some devices may not have been identified. The mention of specific companies or certain manufacturers' products does not imply that they are endorsed or recommended by FIND.

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EXECUTIVE SUMMARY

Globally, over 530 million people are living with diabetes and the prevalence is rapidly rising, particularly in low- and middle-income countries (LMICs) [2]. Over 50% of people with diabetes are undiagnosed and less than a third achieve good control of their condition [3]. Individuals with undiagnosed or uncontrolled diabetes are at greater risk of long-term complications and premature mortality, not only from diabetes but also infectious disease, such as tuberculosis and COVID-19 [4, 5].

Diabetes is diagnosed and managed through frequent measurement of blood glucose to assess the effectiveness of therapies and interventions [6]. Glycated haemoglobin A1c (HbA1c) is a surrogate measure for the average circulating glucose level over the lifespan of a red blood cell (RBC) [7], and has a strong predictive value for diabetes complications [6]. The World Health Organization (WHO) Package of Essential Noncommunicable Disease Interventions (PEN) for Primary Health Care in Low Resource Settings describes HbA1c as the most accurate measurement of long-term glycaemic control [8].

However, access to HbA1c testing in LMICs is limited, particularly in rural communities [9, 10]. Point of care (POC) HbA1c tests, which may be used in community settings and health facilities without laboratories for the diagnosis and monitoring of diabetes using capillary blood, can increase access to HbA1c testing for people with diabetes. As such, POC HbA1c tests are included in the WHO Essential Diagnostics List (EDL) [11]. POC HbA1c testing can facilitate appropriate treatment decisions and ultimately lead to improved glycaemic control [12-14].

The performance, intended use, and operational characteristics of POC HbA1c devices can vary. As a result, it can be challenging for providers to select the optimal HbA1c testing solutions for their needs. This technology landscape was compiled to support healthcare providers in selecting fit-for-purpose technologies for diagnosing and managing diabetes in primary care settings in LMICs. Although another landscape has previously been published [15], this field is rapidly evolving and devices are frequently entering and leaving the market. An updated landscape was therefore warranted, with a focus on devices available in LMICs.

Devices eligible for inclusion in the landscape were those with recent peer-reviewed clinical performance data, approval from at least one stringent regulatory authority, and which are actively marketed in LMICs. Included devices had to be self-contained, intended to be used without laboratory infrastructure or clinical laboratory personnel, and could detect HbA1c in whole blood from capillary sampling.

In total, 19 devices were included in the landscape. Of those, nine are based on boronate affinity methods, seven are immunoassay-based, and three use an enzymatic or other method. Seventeen are certified as both traceable to the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC) Reference Measurement procedure and are National Glycohemoglobin Standardization Program (NGSP)-certified methods, while one is IFCC-traceable alone, and one is NGSP-certified alone. Sixteen are benchtop analysers and three are handheld devices. Test sample sizes ranged from 1 µL to 10 µL and test times range from 1.5 minutes to 12 minutes.

The landscape also includes background information on HbA1c testing methodology limitations and confounding factors, as well as a summary of the biology and clinical utility of HbA1c testing. All the devices and reagents with available information in the landscape are approved by a stringent regulatory authority (SRA) and all manufacturers have a presence or distribution capabilities in LMICs. None of the reagents require freezing for shipping or storage and many are shipped and stored at room temperature; however, most of the reagents do require refrigeration for long-term storage. Most devices do not require very tight environmental storage or operating conditions.

The more recently developed tools have sophisticated software features such as bidirectional connectivity for communication with laboratory information systems and electronic medical records. Tests involve a minimal number of steps to be operated and many only require minimal training, meaning a non-laboratory-trained user can follow the instructions and operate them correctly.

Pricing information was not included in the landscape as devices and reagents are often sold through distributors; as sales channels around the world and prices vary significantly, a meaningful comparison of prices would not be feasible.

The landscape also includes a summary of the biological basis for the use of each of the minimal parameters for diagnosis and management, a description of their potential utility in LMICs, a comparison with laboratory-based tests, and information on relevant international guidelines.

INTRODUCTION

BIOLOGY AND CLINICAL UTILITY OF HbA1c TESTING

Diabetes mellitus is a group of chronic metabolic disorders characterized by a lack of insulin production or impaired insulin action (or both), resulting in elevated blood glucose (hyperglycaemia). Hyperglycaemia is associated with long-term macrovascular and microvascular complications such as cardiovascular disease, retinopathy, nephropathy, and neuropathy [16]. Individuals with undiagnosed or uncontrolled diabetes are at greater risk of long-term complications and premature mortality, not only from diabetes but also infectious disease, such as tuberculosis and COVID-19 [4, 5].

The most common types of diabetes are type 1 and type 2. Type 1 diabetes is a chronic autoimmune disease characterized by hyperglycaemia resulting from insulin deficiency [17]. Type 2 diabetes is characterized by insulin deficiency caused by pancreatic β-cell dysfunction and insulin resistance [18]. Diabetes diagnosis is determined based on clinical signs and symptoms combined with measuring the circulating levels of blood glucose and/or surrogate markers [19]. Following diagnosis, frequent blood glucose measurements are required to monitor the degree of glycaemic control and signal the need to adjust diabetes therapies.

Glycated haemoglobin (HbA1c) is a glycosylated haemoglobin variant found in red blood cells (RBCs). It is formed by the covalent binding of glucose to the amino-terminal valine residue of the beta chain of haemoglobin [7]. In a healthy adult, ~6% of haemoglobin is glycated [7]. Increased concentrations of circulating glucose result in higher levels of HbA1c. The concentration of HbA1c is a surrogate measure for the average circulating glucose level over the lifespan of an RBC (up to 120 days) [7]. Consequently, HbA1c is an essential parameter in monitoring long-term glycaemic control in diabetic patients. The World Health Organization (WHO) Package of Essential Noncommunicable Disease Interventions (PEN) for Primary Health Care in Low Resource Settings describes HbA1c as the most accurate measurement of long-term glycaemic control [8].

HbA1c is also a marker of complications associated with diabetes [6]. Intensive glucose management to improve glycaemic control has been demonstrated to reduce microvascular complications associated with diabetes in several large randomized controlled trials, including the United Kingdom Prospective Diabetes Study (UKPDS) [20], Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation (ADVANCE) [21] and Veterans Association Diabetes Trial (VADT) [22]. Evidence that intensive glucose reduction reduces macrovascular outcomes has not been replicated in all studies [23]. However, it is generally accepted that management of HbA1c levels prevents the progression of diabetes and may delay the onset of both microvascular and macrovascular complications.

The American Diabetes Association (ADA) and WHO recommend HbA1c testing at least twice a year in people with diabetes who are meeting treatment goals with stable glycaemic control [6, 24]. In those undergoing therapy change or who are not meeting glycaemic control goals, quarterly testing is recommended [6, 24]. The International Diabetes Federation (IDF) specifically recommends that HbA1c testing should be performed using a method that is National Glycohemoglobin Standardization Program (NGSP)-certified and standardized to the Diabetes Control and Complications Trial (DCCT) [25] and the UKPDS [26]. The ADA and WHO state that an HbA1c <7% is generally considered to be adequate glycaemic control, but in people with frequent severe hypoglycaemia, severe complications and low life-expectancy, this HbA1c goal may be relaxed, e.g. to <8% [6, 24].

In recent years, the ADA and WHO have increased advocacy for the use of HbA1c in the diagnosis of diabetes, due to the global standardization of the HbA1c assay and associated improvement of analytical performance. The IFCC reference measurement procedure for HbA1c is the analytical anchor for the worldwide standardization of all routine HbA1c assays. The ADA Clinical Practice Recommendations now recommend using HbA1c to diagnose diabetes using an NGSP-certified method that is standardized or traceable to the DCCT reference assay [27].

DIABETES AND HbA1c TESTING IN LMICs

The prevalence of diabetes in low- and middle-income countries (LMICs) is rising rapidly, with increasing premature mortality [16]. The increased prevalence of type 2 diabetes is attributed to changing lifestyles and risk factors. There is an additional burden from endemic type 1 diabetes affecting up to 0.1% of school-aged children in LMICs and atypical forms of diabetes affecting more than 1% of normal-to-underweight adults in the world's most impoverished populations [28].

The WHO Global Action Plan for non-communicable diseases conveys the need for diabetes monitoring in LMICs [8, 29]. However, access to blood glucose testing in LMICs is limited [9, 10]. Many people with diabetes in rural communities in LMICs do not own a blood glucose monitoring device for self-monitoring, making them reliant on services in public health centres, in which provision of blood glucose testing is variable [9, 10]. Often, blood glucose testing is only offered by facilities with laboratories or that require samples to be sent to laboratories for testing. While a fasting blood glucose test performed during health centre visits may provide some insights to physicians, this does not provide the long-term average data on glycaemic control required for effective diabetes management [9]. Studies suggest that limited access to HbA1c testing is associated with poor glycaemic control in resource-limited settings and should be addressed to improve patient outcomes of diabetes care [30, 31]. Point-of-care (POC) HbA1c tests, which can be used in community settings and health facilities without laboratories, can increase access to HbA1c testing, facilitating appropriate treatment decisions and ultimately leading to improved glycaemic control [12-14]. As such, POC HbA1c tests are included in the WHO essential diagnostics list (EDL) for the diagnosis and monitoring of diabetes using capillary blood [11].

HbA1c TESTING METHODOLOGIES

HbA1c testing is based on two methods that discriminate between glycated and non-glycated haemoglobin by detecting differences in either structure or charge [7]. Historically, charge-based separation of haemoglobin molecules has been conducted using ion-exchange chromatography or electrophoresis [7]. However, electrophoresis is no longer in common use [7]. Ion-exchange chromatography is where haemoglobin variants are separated by exploiting differences in ionic interactions between haemoglobin and cation exchange groups on a column resin surface [32].

Structural differences between haemoglobin molecules can be detected by immunoassay or boronate affinity chromatography [7]. Immunoassays use antibodies that bind specifically to N-terminal glycated HbA1c residues, forming immunocomplexes that can be optically detected [32]. Boronate affinity chromatography separates haemoglobin molecules based on structural differences imposed by glycation; this method exploits specific interactions between matrices of m-aminophenyl boronic acid and glycated haemoglobin residues [32]. Most POC HbA1c tests detect structural changes using either immunoassay or affinity chromatography techniques [7, 33, 34].

AIM OF THE LANDSCAPE

Many in vitro diagnostic (IVD) manufacturers have developed devices and tests for HbA1c for use in diabetes diagnosis and management. Healthcare providers in LMICs are increasingly interested in implementing these solutions at the point of care. However, as the performance, intended use, and operational characteristics of these devices vary, it can be challenging for providers to select the optimal HbA1c testing solutions for their needs.

FIND, the global alliance for diagnostics, compiled this technology landscape of IVD POC devices for HbA1c testing to support healthcare providers in selecting fit-for-purpose technologies for diagnosing and managing diabetes in primary care settings in LMICs.

SCOPE AND METHODOLOGY

This technology landscape focuses on POC IVD devices for testing HbA1c levels, to be used for the diagnosis and management of diabetes in primary care settings in LMICs. The methodology followed a structured approach to identify devices that met the scope described above.

An initial list of POC devices offering HbA1c tests was compiled using a combination of structured searches of scientific literature and search engines, together with an investigation of market reports, company websites, industry publications, and online diagnostic marketplaces. Online searches were keyword-based (employing a combination of a wide range of applicable keywords, e.g. “HbA1c test”, “near patient”, “point-of-care”, “bench-top test/instrument/device”, and others). Additional information sources were the list of certificate manufacturers published by the IFCC [35] and the list of certified methods published by the NGSP [36].

To be classified as a POC IVD device likely to be suitable for primary care settings in LMICs, all devices had to meet the technical criteria described in **Table 1**.

Table 1. Technical criteria required for inclusion in the landscape

Criterion	Description
Reagents	Self-contained reagent cartridges or strips containing all reagents to be used without additional reagent preparation steps (devices using cuvettes with bulk-reagents were not included)
Sample type	Ability to detect HbA1c in whole blood from capillary sampling (whole blood specimens sampled from venous blood are also compatible with many tests)
Device size and complexity	Intended to be used without laboratory infrastructure or clinical laboratory personnel (i.e. small benchtop or handheld devices intended for use by healthcare professionals)

HbA1c: glycated haemoglobin

A total of 76 devices meeting these technical criteria were identified (see **Appendix**).

To identify a smaller number of devices for detailed profiling in this technology landscape, additional quality assurance and distribution criteria were applied. These are described in **Table 2**.

Table 2. Quality assurance and distribution criteria for inclusion in the landscape

Criterion	Description
Regulatory status	Approval by any one or more SRAs [37]
Clinical performance data	Minimum of one clinical performance study documented as a peer-reviewed publication in the last ten years (2010–2020)
Distributed in LMICs	Product is actively marketed in at least one LMIC

LMIC: low- or middle-income country; SRAs: stringent regulatory authorities

For 28 devices of the original 76, no proof of SRA approval was found. A further 26 devices did not meet the second criterion, as neither they nor an earlier model of the same instrument had been the subject of a peer-reviewed clinical performance study. In practice, it was difficult to determine some manufacturers' distribution capabilities in LMICs. Consequently, no devices were excluded based on publicly available information about their distribution. However, one otherwise-eligible device was excluded when the manufacturer confirmed directly that it was not available in any LMIC.

The remaining 21 devices met all three criteria in Table 2. Closer examination revealed that two eligible devices shared many characteristics with related devices (also eligible) from the same manufacturer. To avoid repetition, it was decided to include only the A1cNow+ (and not the A1cNow+ SELF CHECK) for PTS Diagnostics and only the Clover A1c Plus (and not the Clover A1c) for OSANG Healthcare.

This resulted in 19 instruments being included in the technology landscape. These devices were profiled, and their technical characteristics summarized. The features presented here include appearance, assay type, regulatory approval, IFCC [35] and NGSP [36] certification status, test storage requirements, test procedure, and output units, among others. The data were extracted from the manufacturers' instructions for use or user manuals, from company websites and from peer-reviewed literature. Following this, manufacturers were contacted and requested to check the information. Most manufacturers responded. Where no response was received, best efforts were made by the authors to ensure accuracy and completeness.

TECHNOLOGY LANDSCAPE

The 19 POC HbA1c devices included in the technology landscape are listed in **Table 3**.

Table 3. Overview of the 19 POC HbA1c devices included in the technology landscape

Manufacturer name	Device name	SRA approval	Peer-reviewed publications
Abbott (USA)	Afinion 2	CE-IVD	[33, 44, 46, 51, 64-69]
	Nycocard Reader II	CE-IVD	[39-41]
Aidian (Finland)	QuikRead go	CE-IVD	[42]
Arkray Inc. (Japan)	The Lab 001	Japan	[42]
Boditech Med (Republic of Korea)	ichroma II	CE-IVD	[43]
Green Cross MEDIS Corp. (Republic of Korea)	CERA STAT 2000	CE-IVD	[40]
DiaSys (Germany)	InnovaStar	CE-IVD	[33, 39, 42, 44]
EKF Diagnostics (United Kingdom)	Quo-Lab	CE-IVD	[33, 38, 44]
	Quo-Test	CE-IVD, FDA	[33, 39, 44, 45]
HemoCue (Sweden)	HbA1c 501	CE-IVD	[33, 38]
HUMAN Gesellschaft für Biochemica und Diagnostica GmbH (Germany)	HumaMeter A1c	CE-IVD	[46]
i-SENS Inc. (Republic of Korea)	A1Care	CE-IVD	[42]
iXensor (Taiwan)	PixoTest	CE-IVD, FDA	[47]
Nova Biomedical (USA)	Allegro	CE-IVD	[42]
OSANG Healthcare (Republic of Korea)	Clover A1c Plus	CE-IVD, FDA	[33, 39]
PTS Diagnostics (USA)	A1cNow+	CE-IVD, FDA (CLIA waived)	[48]
Roche Diagnostics (Switzerland)	Cobas b 101	CE-IVD, FDA	[33, 42, 44, 49, 50]
Siemens Healthineers (Germany)	DCA Vantage	CE-IVD, FDA (CLIA waived)	[33, 39, 43, 44, 50-58, 64-66, 68, 70-71]
Wuxi BioHermes Biomedical Technology Co. (China)	A1C EZ 2.0	CE-IVD	[59, 60]

CE: Certification Europe (conformité européenne); CLIA: clinical laboratory improvement amendments; FDA: US Food and Drug Administration; HbA1c: glycated haemoglobin; SRA: stringent regulatory authority

The devices Afinion 2 (Abbott), InnovaStar (DiaSys), Cobas b 101 (Roche Diagnostics), DCA Vantage (Siemens Healthineers) and Allegro (Nova Biomedical) were included in a previous landscape conducted by FIND on cardiometabolic testing platforms for POC [61].

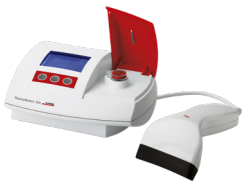
Detailed specifications for each of the 19 devices are summarized below.

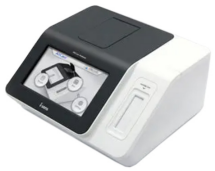


ANALYZER NAME	Afinion 2	NycoCard Reader II	QuikRead go
Manufacturer	Abbott	Abbott	Aidian
SRA approvals	CE-IVD, FDA (CLIA waived), Japan	CE-IVD	CE-IVD
Traceable/certified	IFCC, NGSP	IFCC, NGSP	IFCC, NGSP
Method	Boronate affinity	Boronate affinity	Immunoassay
Test design	Cartridge	Reader pen	Cartridge
Device design	Benchtop	Benchtop	Benchtop
Dimensions in mm	200 x 186 x 328	200 x 170 x 70	145 x 155 x 270
Device weight in kg	3.4	0.54	1.7
Additional tests available on analyzer	Lipid panel, ACR, CRP	CRP	CRP, CRP+Hb, wrCRP, wrCRP+Hb, Strep A, iFOBT
TECHNICAL			
Intended use	Afinion HbA1c is an in vitro diagnostic test for quantitative determination of glycated hemoglobin (hemoglobin A1c, HbA1c) in human whole blood. This test can be used as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes.	NycoCard HbA1c is an in vitro diagnostic medical device for quantitative determination of glycated hemoglobin (HbA1c) in human whole blood. For monitoring of long-term metabolic control in persons with diabetes mellitus	QuikRead go HbA1c is an in-vitro diagnostic test for quantitative measurement of glycated haemoglobin (HbA1c). The test can be used in monitoring the long-term blood glucose control in individuals with diabetes mellitus, as an aid in diagnosis of diabetes and in identifying patients at risk of developing diabetes mellitus.
Intended user	For professional near-patient testing and laboratory use	For professional near-patient testing and laboratory use	Trained healthcare professionals in clinical laboratories and near-patient testing settings
Sample type	Capillary whole blood, anticoagulated venous whole blood	Capillary whole blood, anticoagulated venous whole blood	Capillary whole blood, anticoagulated venous whole blood
Sample volume	1.5 µL	5 µL	1 µL
Testing time	3 min	3 min	5 min 50 sec
Reporting units	IFCC (mmol/mol) / NGSP/DCCT (%) values	IFCC (mmol/mol) / NGSP/DCCT (%) values	IFCC (mmol/mol) / NGSP/DCCT (%) values
PROCEDURE			
Cartridge and sample preparation	Collect the sample with the integrated sampling device. Place the sampling device back in the test cartridge.	Equilibrate reagents to room temperature. Add sample to reagent tube, mix well and leave the tube for 2–3 minutes. Then add sample to test device and apply washing solution.	The prefilled cuvette must reach room temperature before use. Collect the sample with the sample collector. Insert the sample collector into the cuvette.
Handling	Place the test cartridge in the analyser and close the lid	Measurement is not automated, it is performed with a pen device	Place the cuvette in the measurement well of the instrument
Equipment provided	Analyzer: Afinion 2 analyzer, power cable, power supply, 24 VDC, user manual. Test: test cartridges packaged separately in foil pouches with a desiccant bag, package insert	Analyzer: Nyocard Reader II, battery charger, batteries (rechargeable), calibration devices 10 units, pen tips, pen rings, pad. Test: test device, reagent, washing solution	Analyzer: QuikRead go, instructions for use, power supply, mains cable, certificate of analysis. Test: reagents caps, prefilled cuvettes, sample collector, instructions for use
Extra equipment needed and not provided	Standard blood collection equipment	Capillary tube or pipette (5 µL) for sample collection, Capillary tube holder, Pipette (25 µL) and pipette tips	Fingertip lancets
Control	Afinion HbA1c Control is a two point control kit with data	NycoCard HbA1c Control consists of two liquids, each 1,5 ml, Level I+II (normal/abnormal)	QuikRead go HbA1c Control Set contains two ready-to-use liquid controls.
Calibration	Each lot of an Afinion Test includes calibration data stored in the barcode label. The lot calibration data is read by the integrated camera and used for calculating results.	Black and white calibration of reader pen. Lot-specific calibration not required	Factory calibration with self-checks. Test-specific calubration
Cartridge storage temperature and shelf life	At 2–8°C, 24 months At 15–25°C, 3 months	2–8°C	At 2–8°C, 15 months At 18–25°C, 2 months
PERFORMANCE PER IFU			
Reportable range	4.0–15.0% / 20–140 mmol/mol	4.0–15.0% / 20–140 mmol/mol	4.0–15% / 20–151 mmol/mol
Limitations	Any cause of shortened erythrocyte life span results in a decrease in HbA1c values. Caution should be used when interpreting results from patients with hemolytic anemia or other hemolytic diseases, homozygous sickle cell trait, pregnancy, blood loss, polycythemia, iron deficiency etc. This test should not be used to diagnose: diabetes during pregnancy, patients with an elevated fetal hemoglobin (HbF >10 %), patients with a hemoglobinopathy (e.g. sickle cell trait), patients that have received a blood transfusion within the past 3 weeks, patients that have received cancer chemotherapy within the past 3 weeks	Hemolysed samples with plasma Hb >3 g/100 mL will interfere with the test system	Results may be affected by conditions causing changes in blood cell life span (haemolytic anaemia), pregnancy, sickle cell disease, blood loss and polycythaemia. Should not be used to diagnose patients during pregnancy, cancer chemotherapy treatment and recent blood transfusion patients, patients with elevated or persistent fetal haemoglobin
Precision	<3%	<5%	<3%
Interference	No significant interference (< 7%) was observed up to the following concentrations: Bilirubin conjugated 600 mg/L, Bilirubin unconjugated 600 mg/L, Glucose 10 g/L, Lipids (as Intralipid) 10 g/L, Rheumatoid factor 780 000 IU/L, Total protein 150 g/L, Glycated albumin 7.7 g/L	The following hemoglobin (Hb) variants have been analysed and found not to affect the NycoCard HbA1c Test result: HbAC, HbAE, HbAF, HbAJ, HbAS and Hb Yamagata. Carbamylated and pre-glycated hemoglobin does not affect the test. Elevated amounts of glucose, bilirubin, lipids and fructosamine were added to blood samples with normal and elevated HbA1c values. No interference was obtained.	Fetal haemoglobin >7%
ANALYZER			
Data export	Ethernet cable connection to LIMS systems using POCT1-A, HL7, ASTM 1381-85 (low level) or ASTM 1394-97 (high level) protocols		3 USB ports LIS/HIS connectivity
Printer	External	No	External
Barcode reader	External	No	External
Operating temperature	18–30°C	15–35°C (The recommended range is 18°C–25°C)	15–35C
Relative humidity	10–80% (non-condensing)	0–90% (non-condensing)	<80% up to 31°C / <67% at 35°C.
Power	Separate AC to DC power supply. Double insulated.	Rechargeable NiMH batteries only. Size AA 1.2 V. Recharge 8–18 hours	100–240 V AC 50–60 Hz power supply or accumulator unit
Display	Standard LCD colour display with back light and integrated touch panel.	LCD screen 2×16 Characters	Touch screen 116.16 x 87.12 mm
Results memory capacity	500 patient tests / 500 controls	2 KB	100 patient tests / 100 quality check results
PEER-REVIEWED DATA			
Publications	[33, 44, 46, 51, 64-69]	[39-41]	[42]

ANALYZER NAME	The Lab 001	ichroma II	CERA STAT 2000
Manufacturer	Arkray Inc.	Boditech Med	Green Cross MEDIS Corp.
SRA approvals	Japan	CE-IVD	CE-IVD
Traceable/certified	IFCC, NGSP	NGSP	IFCC, NGSP
Method	Capillary electrophoresis	Immunoassay	Boronate affinity
Test design	Cartridge	Cartridge	Cartridge
Device design	Benchtop	Benchtop	Benchtop
Dimensions in mm	220 x 362 x 298	276 x 220 x 91	178 x 195 x 75
Device weight in kg	10	1.3	0.73
Additional tests available on analyzer	No	More than 50 different assays available	No
TECHNICAL			
Intended use	The Lab 001 is an in vitro diagnostic medical device for quantitative determination of glycated hemoglobin (HbA1c) in human whole blood.	ichroma HbA1c is a fluorescence Immunoassay (FIA) for the quantitative determination of HbA1c(Hemoglobin A1c) in human whole blood. It is useful as an aid in management and monitoring of the long- term glycemic status in patients with diabetes mellitus. For in vitro diagnostic use only.	CERA-STAT 2000 analyzer is designed to measure the CERA-STAT HbA1c Test Kit . The colored responses of the tests are measured by spectral reflectance in three parts of the visible spectrum. For In Vitro Diagnostic Use.
Intended user	For professional near-patient testing and laboratory use	Hospital laboratories, physicians' clinics	Professional use
Sample type	Capillary whole blood, anticoagulated venous whole blood	Capillary whole blood, anticoagulated venous whole blood	Capillary whole blood, anticoagulated venous whole blood
Sample volume	1.5 µL	5 µL	5 µL
Testing time	1.5 min	12 min	<3min
Reporting units	IFCC (mmol/mol) / NGSP/DCCT (%) values	IFCC (mmol/mol) / NGSP/DCCT (%) / eAG (mg/dL)	IFCC (mmol/mol) / NGSP/DCCT (%) / eAG (mg/dL)
PROCEDURE			
Cartridge and sample preparation	Transfer the sample directly from the finger to the cartridge	Equilibrate reagents to room temperature. Transfer 100 µL of hemolysis buffer into detection buffer tube. Draw 5 µL of fingertip blood or tube blood using capillary tube. Put capillary tube into the detection buffer tube. Mix the sample thoroughly. Take out the cartridge from the i-Chamber (incubator) slot. Pipette out 75 µL of the sample mixture and load it into a sample well in the test cartridge. Insert the cartridge into i-Chamber slot. Leave for 12 minutes.	Equilibrate reagents to room temperature. Collect the sample using the capillary tube. Put the capillary tube into the R1/ Reagent tube and mix throughly. Stand the tube for 2 minutes for the incubation. Apply 25 µL of the reaction mixture to the membrane of the cartridge. After 10 seconds, apply 25 µL of the R2/Reagent to the membrane of the cartridge.
Handling	Insert the cartridge into the analyzer	Insert the cartridge into the analyzer	Open the tray and put the cartridge in the tray
Equipment provided		Analyzer: ichroma II, AC adaptor and power cable, operation manual, system check cartridge set. Test: cartridge, detection buffer tubes, haemolysis buffer vial, ID chip	Analyzer: Cera Stat 2000, battery, power adaptor, printer paper roll, calibration plate, user manual. Test: tubes of Reagent 1, cartridges and bottle of Reagent 2
Extra equipment needed and not provided		Standard blood collection equipment. 5 µL Capillary tube. i-Chamber (incubator)	Standard blood collection equipment, pipette, pipette tips
Control	Available	Boditech HbA1c Control consists of two liquids (level 1 and level 2). Carefully reconstitute each vial of lyophilized liquid with exactly 0.5 mL of sterilized distilled water.	CERA STAT 2000 Control kit contains two ready-to-use liquid controls
Calibration	Factory-calibrated Lot-specific calibration	Factory-calibrated Lot-specific calibration	Auto calibration
Cartridge storage temperature and shelf life	At 2–30°C, 12 months	Cartridge and Hemolysis buffer: at 4–30°C, 20 months Detection buffer: at 2–8°C, 20 months	At 2–8°C, 12 months
PERFORMANCE PER IFU			
Reportable range	4.0–16.0% / 20–151 mmol/mol	4.0–15% / 20–140 mmol/mol	3.0–15.0% / 9–140 mmol/mol
Limitations	4.0%. Below this level, an error is given off	The test may yield false positive result(s) due to the cross reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies. The test may yield false negative result. Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.	
Precision	Total Error ≤ 6.0%.	<5%	<3.1 %
Interference	Peak information of HbF, L-A1c, HbA0, HbE, HbD, HbS and HbC can be output as a reference information. As the detection is by electrophoresis, no interference is expected	No interference from significant variants and interfering substances	An Hb-concentration lower than 10g/dL or higher than 20g/Dl can cause inaccurate test results. The test results are not affected by albumin, ascorbic acid, biliorubin, flucose, lipid.
ANALYZER			
Data export	USB	USB 4 ports, LAN port, USB OTG port	USB, RS-232 interface
Printer	External	Built in thermal printer	Integrated thermal printer
Barcode reader	No	External	Yes
Operating temperature	10–30°C	15–35°C	15–35°C
Relative humidity	20–80%	10–70%	15–75%
Power	AC mains power No battery	DC 12V/5A, AC/DC Adaptor, (AA battery) DC 1.5V X 4ea. Input 100-240V ~ 50/60Hz, 1.8A. Output DC 12V/5A	AC mains power no battery
Display	LCD touch screen	LCD colour touch screen 153mm x 91mm	3.5 inch colour touch screen
Results memory capacity	1000 tests	1000 patient tests 500 system check results 1000 controls	300 tests
PEER-REVIEWED DATA			
Publications	[42]	[43]	[40]

ANALYZER NAME	InnovaStar	Quo-Lab	Quo-Test
Manufacturer	DiaSys	EKF Diagnostics	EKF Diagnostics
SRA approvals	CE-IVD	CE-IVD	CE-IVD, FDA
Traceable/certified	IFCC, NGSP	IFCC, NGSP	IFCC, NGSP
Method	Enzymatic	Boronate affinity	Boronate affinity
Test design	Cartridge	Cartridge	Cartridge
Device design	Benchtop	Benchtop	Benchtop
Dimensions in mm	200 x 170 x 150	205 x 135 x 95	205 x 135 x 205
Device weight in kg	4	0.7	1.3
Additional tests available on analyzer	CRP, glucose/haemoglobin	No	No
TECHNICAL			
Intended use	The InnovaStar is an analyzer for biochemical in-vitro diagnostics. oneHbA1c IS is the diagnostic reagent for quantitative in vitro determination of hemoglobin A1c in whole blood on InnovaStar.	The Quo-Lab A1C System is intended for the in vitro quantitative determination of glycated hemoglobin (HbA1c) in whole blood. The Quo-Lab A1C System is indicated in the management and treatment of diabetes mellitus and for monitoring long term glycemic control in patients diagnosed with diabetes.	The Quo-Test A1C System is intended for the in vitro quantitative determination of glycated hemoglobin (HbA1c) in whole blood. The Quo-Test A1C System is indicated in the management and treatment of diabetes mellitus and for monitoring long term glycemic control in patients diagnosed with diabetes.
Intended user	For professional use only	Clinics and laboratories in settings that demand low cost of operation and ease of use	For professional use only
Sample type	Capillary whole blood, anticoagulated venous whole blood	Capillary whole blood, anticoagulated venous whole blood	Capillary whole blood, anticoagulated venous whole blood
Sample volume	10 µL	4 µL	4 µL
Testing time	<5 min	4 min	4 min
Reporting units	IFCC (mmol/mol) / NGSP/DCCT (%) values	IFCC (mmol/mol) / NGSP/DCCT (%) values	IFCC (mmol/mol) / NGSP/DCCT (%) values
PROCEDURE			
Cartridge and sample preparation	Bring reagent to room temperature. Make sure that the reagent is at the bottom of the cartridge. Take the patient sample with open-end capillary as described in the user manual. Put the filled capillary in the sample cup. Mix the sample.	Insert cartridge into analyzer. Press reagent bead into cartridge. Insert sample tool into cartridge and snap off handle.	Collect blood sample. Insert sample collector into the cartridge.
Handling	Place sample cup into the analyzer and start the measurement directly.	Close analyzer lid	Insert cartridge into analyzer
Equipment provided		Analyzer: Quo-Lab Analyzer, barcode scanner, mains power cable, power supply, user manual. Test: test cartridges, blood collectors, calibration barcode, instructions for use	Analyzer: Quo-Test Analyzer, barcode scanner, mains power cable, power supply, user manual. Test: test cartridges, blood collectors, calibration barcode, instructions for use
Extra equipment needed and not provided	Standard blood collection equipmemt. Sample cups InnovaStar 10/500 (magenta cups) and open-end capillaries (10 µL/ heparinized)	Fingertip lancets	Fingertip lancets
Control	Two level control solutions: TruLab HbA1c liquid L1 TruLab HbA1c liquid L2	Quo-Lab A1c Control Kit contains two level control solutions	Quo-Test A1c Control Kit contains two level control solutions
Calibration	Factory-calibrated Pre-calibrated tests	Factory-calibrated Lot-specific calibration	Factory-calibrated Lot-specific calibration
Cartridge storage temperature and shelf life	2–8°C until expiry date	At 2–8°C, 12 months At 15–25°C, 30 days	At 2–8°C, 12 months At 15–25°C, 30 days
PERFORMANCE PER IFU			
Reportable range	3.0–14.0% / 9–130 mmol/mol	4.0–15% / 20–140 mmol/mol	4.0–15% / 20–140 mmol/mol
Limitations	The limit of detection is 30 mmol/mol HbA1c (4.9% hbA1c DCCT/NGSP). In very rare cases, samples of patients with gammopathy might give falsified results. Heterophile antibodies in patient samples may cause falsified results.	For haemoglobin concentrations outside the range of 6.5 g/dL to 20.4 g/dL (4.0 mmol/l to 12.7 mmol/l) or for HbA1c values outside the range of 4.0 % to 15.0 % DCCT (20 mmol/mol to 140 mmol/mol IFCC), a result will not be reported and an error message will be displayed.	For haemoglobin concentrations outside the range of 6.5 g/dL to 20.4 g/dL (4.0 mmol/l to 12.7 mmol/l) or for HbA1c values outside the range of 4.0 % to 15.0 % DCCT (20 mmol/mol to 140 mmol/mol IFCC), a result will not be reported and an error message will be displayed. Consult the Quo-Test Analyzer System User Manual for further details.
Precision	<2% at 6.24% DCCT	<3% @ 7% A1c	<3% @ 7% A1c
Interference	The variants AS, AC, AD, AG, DD and elevated A2 showed no significant interferences. The variants AE, AJ, SS, CC, SC, SE, EE, elevated F and elevated A2/F can lead to deviant HbA1c results (> 10% IFCC; > 7% DCCT/NGSP).	Unaffected by Hb variants which do not result in reduced erythrocyte life span	Unaffected by labile glycated haemoglobin and the following haemoglobin variants: Hb AS, Hb AC, Hb AD, Hb AE, Hb AJ, Hb SS, Hb CC, Hb SC, and elevated foetal haemoglobin (up to 6 %).
ANALYZER			
Data export		via USB to PC	via USB to PC
Printer		Optional label printer	Optional label printer
Barcode reader		Yes	Yes
Operating temperature		18–30°C	18–30°C
Relative humidity		10–80%	10–80%
Power		Separate AC to DC mains adapter Input: 100–240 V AC, 50-60 Hz, 30 W Output: 24 V DC, 1.25A	Separate AC to DC mains adapter Input: 100–240 V AC, 50–60 Hz, 30 W Output: 24 V DC, 1.25A
Display	2.8 inch colour touchscreen	Integrated screen	Blue LCD backlit monochrome display 128x64 pixels. Visible area 70x39mm
Results memory capacity		7000 tests	7000 tests
PEER-REVIEWED DATA			
Publications	[33, 39, 42, 44]	[33, 38, 44]	[33, 39, 44, 45]

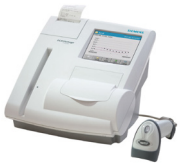




ANALYZER NAME	HemoCue HbA1c 501	HumaMeter A1c	A1Care
Manufacturer	HemoCue	HUMAN Diagnostics	i-SENS
SRA approvals	CE-IVD	CE-IVD	CE-IVD
Traceable/certified	IFCC, NGSP	IFCC, NGSP	IFCC, NGSP
Method	Boronate affinity	Boronate affinity	Enzymatic
Test design	Cartridge	Cartridge	Cartridge
Device design	Benchtop	Benchtop	Benchtop
Dimensions in mm	198 × 217 × 136	205 x 95 x 135	290 x 250 x 130
Device weight in kg	1.3	0.7	3.8
Additional tests available on analyzer	No	No	ACR
TECHNICAL			
Intended use	The HemoCue® HbA1c 501 System provides a convenient method for measuring the percentage of hemoglobin A1c (HbA1c %) in both capillary and anticoagulated venous whole blood samples. The test is for point of care use to monitor glycemic control in patients with diabetes mellitus.	For the in vitro quantitative determination of glycated hemoglobin (HbA1c) in whole blood obtained from finger prick or from venous blood samples collected into EDTA tubes. The HumaMeter A1c REAGENT KIT is indicated in the management and treatment of diabetes mellitus and for monitoring long term glycemic control in patients diagnosed with diabetes.	The A1Care Analyzer is a bench top, point-of-care (POC) in vitrodiagnostic (IVD) device for the measurement of HbA1c (%, mmol/mol) in whole blood samples
Intended user	Professionals in laboratories, clinics and hospitals.	Professional use	Professional use
Sample type	Capillary whole blood, anticoagulated venous whole blood	Capillary whole blood, anticoagulated venous whole blood	Capillary whole blood, anticoagulated venous whole blood
Sample volume	4 µL	4 µL	2.5 µl
Testing time	5 min	4 min	4 min 20 sec
Reporting units	IFCC (mmol/mol) / NGSP/DCCT (%) values	IFCC (mmol/mol) / NGSP/DCCT (%), JDA (%) / eAG (mg/dL)	IFCC (mmol/mol) / NGSP/DCCT (%) / eAG (mg/dL)
PROCEDURE			
Cartridge and sample preparation	If refrigerated, equilibrate to room temperature before use. The reagent pack is in the cartridge. Remove it and shake gently. Apply the reagent pack to the fingertip to collect blood from finger.	Equilibrate to room temperature. Scan lot calibration. Remove cartridge foil. IInsert cartridge into analyzer. Press reagent bead into cartridge. Insert sample stick into cartridge.	20 min warm up for cartridges if stored in the fridge. The sample collection device is in the cartridge. Remove it. Collect blood from finger.
Handling	Insert the test cartridge into the analyzer. Press the reagent pack into the cartridge.	Innovative blood collector inserts into cartridge. Non-pipetting capillary technology	Insert the test cartridge into the analyzer. Press the sample collector into the cartridge
Equipment provided	Analyzer: Hemocue® HbA1c 501 analyzer, operating manual, exclusive power adapter, fan filters, daily check cartridge, monthly check cartridge. Tests; cartridge with reagent pack	Analyzer: HumaMeter, user manual, barcode scanner, power supply. Tests: test cartridges, sample sticks, instructions for use, calibration barcode	Analyzer: A1Care analyzer, optical check cartridge, quick guide, user manual, power cord. Tests: cartridge with sample collector
Extra equipment needed and not provided			Lancet, wipes
Control	Built-in "self test". Check Cartridge. System can be verified using liquid controls	HumaMeter A1c Control Kit contains level 1 & level 2 liquids	A1Care HbA1c Control Kit consists of tqo liquids: level 1 (normal) and level 2 (abnormal)
Calibration	Factory calibrated. Lot-specific calibration	Factory calibrated. Lot-specific calibration	Factory-calibrated Lot-specific calibration
Cartridge storage temperature and shelf life	At 2–32°C, 18 months	At 2–8°C, 12 months At RT, 90 days	At 1–30°C, 24 months
PERFORMANCE PER IFU			
Reportable range	20–130 mmol/mol	4.0–15.0% / 20–140 mmol/mol	4.0–15.0% / 20–140 mmol/mol IFCC
Limitations	The HemoCue HbA1c 501 assay gives accurate and precise haemoglobin results in the range 7 to 20 g/dL. Patients with severe anaemia may have haemoglobin concentrations below 7 g/dL, and patients with polycythaemia may have haemoglobin concentrations above 20 g/dL. Patients known to have these conditions should be tested with another method for determination of HbA1c %		Total haemoglobin must be within 7–24 g/dL, very high levels of haemoglobin F (>10%), haemolytic anaemia, polycythaemia, homozygous HbS and HbS will cause lower than expected HbA1c
Precision	< 3%	<3% at 7%A1c	<3%
Interference	Studies confirm that no interference for the variants C, D, E, F and S were obtained, but HbF values above 20% may cause unreliable results.	No interference from Hb variants other than those affecting erythrocyte lifespan	A range of substances tested
ANALYZER			
Data export	USB serial port to PC	USB port to PC	printer or via USB device, LAN port for internet cable connectivity
Printer	YES External	External	External
Barcode reader	External	Yes	External
Operating temperature	17–32°C	18–30C	10–32°C
Relative humidity	10–90%	<85% non-condensing	10–90% (non-condensing)
Power	9 V DC / 2 A	110...240 v AC, 24 V DC / 1.25A	AC mains supply (Power Input 100–240VAC 50/60Hz, 100VA)
Display	Yes	LCD Screen 70 x 40 mm	7 inch LCD colour touchscreen
Results memory capacity	1000 tests	7000 tests	5000 patient tests 5000 controls
PEER-REVIEWED DATA			
Publications	[33, 38]	[46]	[42]



ANALYZER NAME	PixoTest	Allegro	Clover A1c Plus
Manufacturer	iXensor	Nova Biomedical	OSANG
SRA approvals	CE-IVD, FDA	CE-IVD	CE-IVD, FDA
Traceable/certified	IFCC	IFCC, NGSP	IFCC, NGSP
Method	Immunoassay	Immunoassay	Boronate affinity
Test design	Colorimetric test strips	Cartridge	Cartridge
Device design	Handheld	Benchtop	Benchtop
Dimensions in mm	181 x 111 x 53	457 x 356 x 381	200 x 200 x 139
Device weight in kg	0.13	10.43	1.4
Additional tests available on analyzer	Lipid panel	Lipid panel, blood glucose, blood creatiine, PT/INR, CRP, urine creatinine, urine albumin	No
TECHNICAL			
Intended use	Quantitative measurement of HbA1c in whole blood	Quantitative measurement of HbA1c in whole blood	The CLOVER A1c Plus is an IVD device for measuring Hemoglobin A1c in whole blood. The system is designed to help in controlling diabetes.
Intended user	Professional use	Professional use	Professionals in laboratories, clinics and hospitals
Sample type	Capillary whole blood, anticoagulated venous whole blood	Capillary whole blood	Capillary whole blood, anticoagulated venous whole blood
Sample volume	5 µL	1.5 µL	4 µL
Testing time	3 min	<7 min	5 min
Reporting units	NGSP/DCCT (%) values		IFCC (mmol/mol) / NGSP/DCCT (%) / eAG (mg/dL)
PROCEDURE			
Cartridge and sample preparation	Equilibrate to room temperature prior to use.	If refrigerated, equilibrate to room temperature before use. Scan cartridge. Perform fingerstick. Remove capillary sampler from cartridge. Touch sampler to blood. Replace capillary sampler in cartridge.	If refrigerated, equilibrate to room temperature before use. The sample collection device is in the cartridge. Remove it. Collect blood from finger.
Handling	Blood sample into reagent tube. Place reagents into test cartridge.	Insert cartridge into analyzer and press "analyze"	Insert the test cartridge into the analyzer. Press the sample collector into the cartridge.
Equipment provided	PixoTest A1c test strip, PixoTest POCT analyzer, calibration Card, app	Analyzer: Allegro, power cable, companion StatStrip meter Tests: cartridge with capiallary sampler	Analyzer: Clover A1c Plus, instruction manual, DC 9 volt, 2.0A adapter, fan filters, daily check cartridge, monthly check cartridge. Tests: cartridge with sample collector
Extra equipment needed and not provided	Lancets and lancing devices	Lancet, wipes	Lancet, wipes
Control	No control solutions provided. Two level control solutions from other manufacturers can be used.	Level 1 and level 2	No control solutions provided. Two level control solutions from other manufacturers can be used.
Calibration	Calibration card - automatic notification for calibrations	Factory-calibrated Lot-specific calibration	
Cartridge storage temperature and shelf life	At 30°C, 12 months	At 2–8°C, 18 months	2–32°C, 18 months
PERFORMANCE PER IFU			
Reportable range	4–15% / 20–140mmol/mol	4.0–14.0% / 20–130 mmol/mol	4.0–14.0% / 20–130 mmol/mol
Limitations	Haemoglobin range between 7–23 g/dL, haematocrit range of 25–65%, not tested on neonates, cosmetics may interfere with results.	Diluted samples cannot be analyzed. Do not analyze hemolyzed coagulated blood samples.	The CLOVER A1c Plus assay gives accurate and precise results over a range of total Haemoglobin of 7 to 20 g/dL. Patients with severe anaemia may have Haemoglobin concentrations lower than 7 g/dL, and patients with polycythaemia may have Haemoglobin concentrations above 20 g/dL.
Precision		<4.5%	<3%
Interference	Acetylsalicylic acid >30 mg/ascorbic acid >10 mg/ acetaminophen >30 mg/bilirubin >20 mg/caffeine >30 mg/ hydroxyzine Dihydrochloride >30 mg/triglyceride >900 mg/ glyburide >20 mg/ibuprofen >20 mg/dopamine	No significant interference (<10%) was observed up to several concentration levels on most common tested substances.	
ANALYZER			
Data export	Wireless	USB port, ASTM Protocol, via serial RS232 TCP/IP, POCT1-A2, HL7	Communication with PC by cable (USB to Serial port)
Printer		Built-in thermal	Integrated
Barcode reader		Integrated	Yes
Operating temperature	15–32C	18–25°C	10–40°C
Relative humidity	10–90%	10–80%	10–90%
Power	5000 mAh battery, non removable	90–264 V AC, 50/60 Hz	DC 9V, 2A Adapter No battery
Display	Integrated touchscreen	Yes	LCD
Results memory capacity	1000 tests	Stores and presents trend data for patients over the last 9 visits	1000 tests
PEER-REVIEWED DATA			
Publications	[47]	[42]	[33, 39]



ANALYZER NAME	A1cNow+	cobas b 101	DCA Vantage
Manufacturer	PTS Diagnostics	Roche	Siemens Healthineers
SRA approvals	CE-IVD, FDA (CLIA waived)	CE-IVD, FDA	CE-IVD, FDA (CLIA waived)
Traceable/certified	IFCC, NGSP	IFCC, NGSP	IFCC, NGSP
Method	Immunoassay	Immunoassay	Immunoassay
Test design	Cartridge	Disc cartridge	Cartridge
Device design	Handheld	Benchtop	Benchtop
Dimensions in mm	51 x 63.5 x 10	184 x 135 x 234	287 x 277 x 254
Device weight in kg	0.18	2	3.88
Additional tests available on analyzer	No	Lipid panel, CRP	ACR
TECHNICAL			
Intended use	The A1cNow+ test provides quantitative measurement of glycated haemoglobin levels in whole blood. This test can be used to monitor glycaemic control in people with diabetes and as an aid to diagnose diabetes and identify patients at risk of developing diabetes	The cobas b 101 is an in vitro diagnostic test system designed to quantitatively determine the % hemoglobin A1c (DCCT/NGSP) and mmol/mol hemoglobin A1c (IFCC) in human capillary and venous whole blood.	The DCA Vantage HbA1c assay provides a convenient, quantitative method for measuring the percent concentration of hemoglobin A1c in blood. The measurement of hemoglobin A1c, recommended for monitoring the long-term care of persons with diabetes.
Intended user	Professional use	Professional use in a clinical laboratory or at point of care locations	Professional use in a physician's office or hospital laboratory
Sample type	Capillary whole blood, anticoagulated venous whole blood	Capillary whole blood, anticoagulated venous whole blood	Capillary whole blood, anticoagulated venous whole blood
Sample volume	5 µL	2 µL	1 µL
Testing time	5 min	5 min 20 sec	6 min
Reporting units	IFCC (mmol/mol) / NGSP/DCCT (%) values	IFCC (mmol/mol) / NGSP/DCCT (%) values	IFCC (mmol/mol) / NGSP/DCCT (%) values
PROCEDURE			
Cartridge and sample preparation	Equilibrate to room temperature. Apply collection device to a shaker, shake briefly and apply to cartridge.	Equilibrate to room temperature prior to use. Sample is applied directly from the fingerstick or via a pipette when testing venous whole blood. The operator applies the sample to the disc.	Equilibrate to room temperature prior to use. Obtain sample using capillary holder device. Add capillary holder device to test cartridge. Scan cartridge bar code. Load and pull foil tab.
Handling	Blood collector measuring 5 uL blood sample (located in pouch 1). After sample application is applied, the test cartridge will activate the 5 minute countdown.	Place the disc in the analyzer	Testing begins when compartment door is closed
Equipment provided	A1CNow+ analyzser, A1CNow+ test cartridges. Each test cartridge contains 2 dry-reagent strips, shaker kit, blood collector, instructions for use, patient result labels	Analyzer: cobas b 101, power adapter, power cable, optical check disc. Tests: individually-wrapped test discs	Analyzer: DCA Vantage, cleaning kit, optical test cartridge, power cord, air filter replacement kit, spare fuses, quick reference guides, documentation CD, paper roll, self adhesive label stock. Tests: test cartridges, sample capillary holders, calibration card
Extra equipment needed and not provided	Lancet or other blood fingerstick collection device	Single-use disposable lancets, germicidal wipes, powder-free gloves, cotton swabs, lint-free cloths	Lancing devices, gloves, gauze, bandages, sharps bin, alcohol wipes
Control	Over 50 internal chemical and electronic quality control checks, including potential hardware and software errors, and potential test strip errors. The analyzer has been programmed to report an error if these quality checks are not passed. Liquid control solutions and reagent test strip available.	Built-in quality controls Level 1 and level 2 liquid controls. An optical check is also available	DCA Controls Kit contains: vials of A1c Normal control, vials of A1c Abnormal control, vial of reconstitution fluid, eye-dropper caps, control card with normal and abnormal values (double-sided), instructions for use
Calibration	Analyzer is factory-calibrated. Lot-specific calibration for tests	Analyzer is factory-calibrated Calibration information is read from each reagent disc	Factory-calibrated. Lot-specific calibration
Cartridge storage temperature and shelf life	At 2–8°C, until expiration date At 18–28°C, 4 months	At 2–30°C, 22 months	At 2–8°C, 24 months
PERFORMANCE PER IFU			
Reportable range	4.0–13.0% / 20–120 mmol/mol	4.0–14.0% / 20–130 mmol/mol	2.5–14.0% / 4–130 mmol/mol
Limitations	Should not be used to replace glucose testing in persons with or suspected of having type 1 diabetes, who are pregnant, or a paediatric patient. Should not be used to diagnose diabetes in a range of cases (see package insert). Also not suitable for patients with high blood loss volume, disease affecting erythrocyte cell survival, RF factor	This test should not be used for analyzing samples from patients with conditions causing shortened red blood cell survival, such as hemolytic diseases, homozygous sickle cell trait, pregnancy and significant acute or chronic blood loss. Glycated HbF is not detected by this assay as it does not contain the glycated beta- chain that characterize HbA1c, However, HbF levels (>10%) may result in lower than expected %HbA1c values (DCCT/NGSP).	The DCA HbA1c assay gives accurate and precise results over a range of total hemoglobin of 7–24 g/dL. Patients with severe anemias may have hemoglobin concentrations lower than 7 g/dL, and patients with polycythemia may have hemoglobin concentrations above 24 g/dL. Conditions such as hemolytic anemia, polycythemia, homozygous HbS, and HbC, can result in decreased life span of the red blood cells, which causes HbA1c results to be lower than expected.
Precision	3.0 (low level), 4.02% (high level)	<4%	<3%
Interference	EDTA may cause negative bias. High levels of Haemoglobin F, Haemoglobin S, Haemoglobin C, or other haemoglobin variants may cause interference.	Heterozygous presence of the most common hemoglobin variants (HbS, HbC, HbD, HbE, and Hb2) does not interfere. Testing results indicate that there is no significant interference for HbS (≤41%), HbC (36%), HbD (42%), HbE (27%) and HbA2 (6.2%).	At levels of hemoglobin F less than 10%, the DCA system accurately indicates the patient's glycemic control. However, at very high levels of hemoglobin F (> 10%), the amount of HbA1c is lower than expected. Common HbA1c interferents have been tested. None has been found to have significant effects.
ANALYZER			
Data export	Blu-Dock available separately	by USB or direct to PC	Via USB flash drive to PC or direct to LIS/HIS or data manager
Printer	Yes	External	Integrated thermal printer. External via USB
Barcode reader	No	External	External
Operating temperature	18–25°C	15–32°C	5–40°C
Relative humidity	<80%	10–85% (non-condensing)	15–90%
Power	Battery	100 V to 240 V AC (+/-10%), 50/60 Hz	100 to 240 VAC; 50/60 Hz
Display	Yes	Integrated touchscreen	Color touch screen with 1/4 VGA resolution
Results memory capacity	N/A	5000 patient tests. 500 controls	4000 tests
PEER-REVIEWED DATA			
Publications	[48]	[33, 42, 44, 49, 50]	[33, 39, 43, 44, 50-58, 64-66, 68, 70-71]

ANALYZER NAME	A1c EZ 2.0
Manufacturer	Wuxi BioHermes
SRA approvals	CE-IVD
Traceable/certified	IFCC, NGSP
Method	Boronate affinity
Test design	Cartridge
Device design	Handheld
Dimensions in mm	123 × 62 × 25
Device weight in kg	0.11
Additional tests available on analyzer	No
TECHNICAL	
Intended use	For diagnosis of diabetes, to evaluate the effectiveness of glycaemic control of patients, screening of high-risk group of diabetes
Intended user	Professional use only in physicians' office or health clinics
Sample type	Capillary whole blood, anticoagulated venous whole blood
Sample volume	3 µL
Testing time	6 min
Reporting units	IFCC (mmol/mol) / NGSP/DCCT (%) values
PROCEDURE	
Cartridge and sample preparation	Insert the code chip, insert the test strip. Collect blood with sampler. Add 3 drops of buffer A to test strip. Press the sampler thread onto the test strip. Add 3 drops of buffer B
Handling	Read the test result
Equipment provided	Analyzer: A1c EZ 2.0, user's manual, operation guide, cleaning and maintenance guide, warranty card. Tests: test strips, buffer A, buffer B, blood sampler, code chip, package insert
Extra equipment needed and not provided	
Control	None
Calibration	Not required
Cartridge storage temperature and shelf life	At RT, 12 months
PERFORMANCE PER IFU	
Reportable range	4.0–14.0% / 20.2–129.5mmol/mol
Limitations	
Precision	<4%
Interference	No interference from HbF and haemoglobin variants or unstable glycohemoglobin
ANALYZER	
Data export	Bluetooth, USB
Printer	Yes (by data transfer or direct connection)
Barcode reader	No
Operating temperature	10–40°C
Relative humidity	30–75%
Power	Battery powered 3V CR2032
Display	LCD display
Results memory capacity	
PEER-REVIEWED DATA	
Publications	[59, 60]

NB: Images not to scale; empty fields mean no information was available

LIMITATIONS AND CONSIDERATIONS FOR HbA1c TESTING

LIMITATIONS OF HbA1c TESTING METHODOLOGIES

The quality of POC HbA1c tests has improved substantially since the introduction of standardization [14, 33]. Most current POC tests employ either immunoassay or boronate affinity chromatography analysis methods [33, 34]. Boronate affinity chromatography is generally not considered to be affected by interference from haemoglobin variants [32, 62]. However, interference has been observed with foetal haemoglobin (HbF) levels greater than 20% [62, 63]. HbF does not possess beta chains, resulting in disproportionally low glycation that can affect test results [62]. Interference from haemoglobin variants can also be an issue for immunoassay-based tests, depending on the selection of the immunological reagents [32].

LIMITATIONS OF POC HbA1c INSTRUMENTS

Possible drawbacks for POC HbA1c devices include poorer analytical performance than laboratory-based tests, particularly relating to test precision [51]. Several cross-platform comparison studies and systematic reviews have detected bias compared with laboratory-based reference test methods [34, 51, 64, 65]. Lot number dependency has also been observed for HbA1c POC tests [65].

FACTORS THAT MAY AFFECT HbA1c TEST RESULTS

The formation of HbA1c is dependent on the interaction between blood glucose concentrations and the life span of RBCs [59]. RBC age varies between individuals and can affect HbA1c measurements [59]. RBCs of people without diabetes have an average lifespan of 38 to 59 days, while those of people with diabetes have an average lifespan of 39 to 56 days; the maximum life span of an RBC is ~100–120 days [7, 59]. Factors that affect RBC life span also affect HbA1c levels [60]. Factors that may elevate HbA1c include iron deficiency, pregnancy, chronic renal failure, splenectomy and hyperbilirubinaemia [60]. Factors that may decrease HbA1c include haemolytic anaemia, chronic liver disease, antiretroviral therapy and hypertriglyceridaemia [60]. Haemoglobinopathies may increase or decrease HbA1c [60].

Whole blood is the ideal sample for HbA1c measurement, it is considered to be a dynamic sample whose characteristics can change over time [52]. Sample ageing causes lysis, glucose consumption by erythrocytes (formation of lactic acid lowers pH), spectral changes (browning), and additional haemoglobin fractions. Glycation (HbA1c formation) may also proceed during storage [52]. Shipment time and temperature can also result in different laboratory properties over wide geographical areas with different infrastructures, resulting in different HbA1c results [52].

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ACKNOWLEDGEMENTS

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APPENDICES

Footnote: Each device's IFCC-traceability and NGSP-certification status was confirmed with reference to the IFCC list of certificate manufacturers and the NGSP's list of certified methods. These lists are published monthly on the organizations' websites and comprise all analysers certified within the past 12 months. The lists informing this table were accessed in September 2021 and October 2021. Re-certification is required annually. Analysers whose most recent certification or re-certification was more than 12 months old are not shown as IFCC-traceable or NGSP-certified in this table.

APPENDIX 1

LIST OF POC HbA1c ANALYSERS ARRANGED ALPHABETICALLY

Manufacturer	Analyser	Technology	IFCC traceable	NGSP certified	SRA approved (● CE-IVD and/or FDA. ○ = Japan)	Peer-reviewed publication	Link
Abbott (USA)	Afinion 2	Boronate affinity	●	●	● ○	●	WEB
Abbott (USA)	NycoCard Reader II	Boronate affinity	●	●	●	●	WEB
Acon Diabetes (USA)	On Call A1c	Immunoassay		●			WEB
Acon Diabetes (USA)	On Call MultiCare	Immunoassay		●			WEB
Aidian Oy (Finland)	QuikRead go	Immunoassay	●	●	●	●	WEB
Apex Biotechnology Corp. (Taiwan)	Eclipse A1c	Immunoassay		●	●		WEB
Arkray Inc. (Japan)	PocketChem A1c Advanced	Boronate affinity	●	●	●		WEB
Arkray Inc. (Japan)	The Lab 001	Capillary electrophoresis	●	●	○	●	WEB
Aspen Laboratories Pvt. Ltd. (India)	FIA	Immunoassay		●			
Biosense (India)	A1Chek	Boronate affinity					WEB
biosurfit, S.A. (Portugal)	spinit	Immunoassay	●		●		WEB
Boditech Med Inc. (Republic of Korea)	ichroma II	Immunoassay		●	●	●	WEB
Boditech Med Inc. (Republic of Korea)	AFIAS-6	Immunoassay		●	●		WEB
Boditech Med Inc. (Republic of Korea)	ichroma III	Immunoassay		●	●		WEB
Boditech Med Inc. (Republic of Korea)	AFIAS-1	Immunoassay		●	●		WEB
Curofit USA)	Curo A1c	Boronate affinity					WEB
DiaSys Diagnostic Systems GmbH (Germany)	InnovaStar	Enzymatic	●	●	●	●	WEB
Dr. Müller Gerätebau GmbH (Germany)	SUPER ID clinchem	Enzymatic	●	●	●		WEB
DxGen Corp. (Republic of Korea)	Epithod 414 / Auto Dx	Boronate affinity	●	●	●		WEB

Manufacturer	Analyser	Technology	IFCC traceable	NGSP certified	SRA approved (● CE-IVD and/or FDA. ○ = Japan)	Peer-reviewed publication	Link
DxGen Corp. (Republic of Korea)	Epithod 616	Boronate affinity	●	●	●		WEB
EKF Diagnostics (United Kingdom)	Quo-Lab	Boronate affinity	●	●	●	●	WEB
EKF Diagnostics (United Kingdom)	Quo-Test	Boronate affinity	●	●	●	●	WEB
Empecs (Republic of Korea)	Asure A1c	Enzymatic					WEB
Eurolyser Diagnostica (Austria)	Cube S	Immunoassay					WEB
ForaCare, Inc. (USA)	A1C100	Immunoassay					WEB
Genrui Biotech Inc. (China)	FA50	Boronate affinity		●	●		WEB
Genrui Biotech Inc. (China)	FIA8000	Immunoassay	●	●	●		WEB
Genrui Biotech Inc. (China)	FIA8600	Immunoassay	●	●	●		WEB
Genrui Biotech Inc. (China)	Getein1100	Immunoassay	●	●	●		WEB
Genrui Biotech Inc. (China)	Getein1180	Immunoassay	●	●	●		WEB
Goldsite Diagnostics Inc. (China)	GPP-100	Immunoassay	●	●	●		WEB
Goldsite Diagnostics Inc. (China)	Nephstar Plus	Immunoassay					WEB
Green Cross MEDIS Corp. (Republic of Korea)	CERA-STAT 2000	Boronate affinity	●	●	●	●	WEB
Green Cross MEDIS Corp. (Republic of Korea)	Greencare A1c	Boronate affinity	●	●	●		WEB
Green Cross MEDIS Corp. (Republic of Korea)	LabonaCheck A1c	Boronate affinity	●	●	●		WEB
Guangzhou Wondfo Biotech Co., Ltd. (China)	Finecare FIA Meter Plus	Immunoassay	●	●			WEB
HemoCue (Sweden)	HemoCue 501	Boronate affinity	●	●	●	●	WEB
HUMAN Gesellschaft für Biochemica und Diagnostica GmbH (Germany)	HumaMeter A1c	Boronate affinity	●	●	●	●	WEB

Manufacturer	Analyser	Technology	IFCC traceable	NGSP certified	SRA approved (● CE-IVD and/or FDA. ○ = Japan)	Peer-reviewed publication	Link
i-SENS Inc. (Republic of Korea)	A1Care	Enzymatic	●	●	●	●	WEB
iXensor (Taiwan)	PixoTest	Immunoassay	●		●	●	WEB
J. Mitra & Co. Pvt Limited (India)	i-Quant	Immunoassay					WEB
Jana Care (India)	Aina	Boronate affinity			●		WEB
Labnovation Technologies Inc. (China)	LD-100/LD-120/LD-160	Boronate affinity	●	●			WEB
MED TRUST Handelsges.m.b.H. (Austria)	Wellion BONA	Boronate affinity	●	●	●		WEB
MED TRUST Handelsges.m.b.H. (Austria)	Wellion CLEVER	Boronate affinity	●	●	●		WEB
MedicalSystem (China)	MS-S100	Unknown					WEB
Menarini Diagnostics (Italy)	Linx Duo	Immunoassay					WEB
Nova Biomedical (USA)	Allegro	Immunoassay	●	●	●	●	WEB
OSANG Healthcare Co. Ltd (Republic of Korea)	CLOVER A1c	Boronate affinity	●	●	●	●	WEB
OSANG Healthcare Co. Ltd (Republic of Korea)	CLOVER A1c Plus	Boronate affinity	●	●	●	●	WEB
Path Shodh Healthcare (India)	Multi-analyte device	Unknown					WEB
Path Shodh Healthcare (India)	Glycemic status device	Unknown					WEB
PTS Diagnostics (USA)	A1CNow Self Check	Immunoassay	●	●	●	●	WEB
PTS Diagnostics (USA)	A1CNow+	Immunoassay	●	●	●	●	WEB
Roche Diagnostics International Ltd (Switzerland)	cobas b 101	Immunoassay	●	●	●	●	WEB
Sakae Corporation (Japan)	A1c Gear	Immunoassay		●	○	●	WEB
Sakae Corporation (Japan)	A1c iGear	Immunoassay		●	○		WEB

Manufacturer	Analyser	Technology	IFCC traceable	NGSP certified	SRA approved (● CE-IVD and/or FDA. ○ = Japan)	Peer-reviewed publication	Link
Sakae Corporation (Japan)	A1c iGear Quick	Immunoassay		●	○		WEB
SD Biosensor (Republic of Korea)	STANDARD F100	Immunoassay	●	●	●		WEB
SD Biosensor (Republic of Korea)	STANDARD F200	Immunoassay	●	●	●		WEB
SD Biosensor (Republic of Korea)	MultiCare System	Immunoassay	●	●	●		
Shenzhen Ultra-Diagnotics Biotec. Co. Ltd. (China)	H100	Boronate affinity		●			WEB
Siemens Healthineers (Germany)	Vantage DCA	Immunoassay	●	●	●	●	WEB
Sinocare (China)	iCARE-2100	Immunoassay	●	●			WEB
Sinocare (China)	PCH-100	Immunoassay	●	●			WEB
Sinocare (China)	PCH-50	Immunoassay	●	●			WEB
Skyla Corporation (Taiwan)	skyla Hi	Immunoassay	●	●	●		WEB
Sugentech (Republic of Korea)	INCLIX	Immunoassay		●	●		WEB
Taidoc Technology Corporation (Taiwan)	TD-4611	Immunoassay	●				WEB
TASCOM Co. Ltd (Republic of Korea)	SimplexTAS	Enzymatic	●		●		WEB
Trinity Biotech (Ireland)	Tri-stat 2	Boronate affinity	●	●	●		WEB
Vivachek (USA)	VivaDiag POCT Analyzer VIM01	Immunoassay					WEB
Vivachek (USA)	VivaDiag POCT Analyzer VIM1000	Immunoassay					WEB
Vivachek (USA)	VivaDiag POCT Analyzer VIM2000	Immunoassay					WEB
Wells Bio Inc. (Republic of Korea)	careSURE Analyzer 100	Boronate affinity	●	●			WEB
Wuxi Biohermes Bio&Medical Technology Co. Ltd (China)	A1C EZ 2.0	Boronate affinity	●	●	●	●	WEB

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