



A LEADING  
LIGHT IN  
**POINT-OF-CARE  
TESTING**

# DIABETES – ONE DISEASE THAT CAN LEAD TO MANY MORE

The majority of people with diabetes are in the dark about another great threat facing them: the comorbidities of their disease. Cardiovascular and renal complications are actually the main cause of death in people with diabetes.<sup>1</sup>

The good news? Screening programmes can detect most complications in their early stages.<sup>1</sup>

**“DIABETES COMPLICATIONS CAN BE PRESENT AT THE MOMENT OF DIAGNOSIS IN PEOPLE WITH TYPE 2 DIABETES AND EARLY (AROUND 5 YEARS) AFTER ONSET OF TYPE 1 DIABETES AND THEREFORE SHOULD BE SCREENED ACCORDINGLY.”<sup>19</sup>**

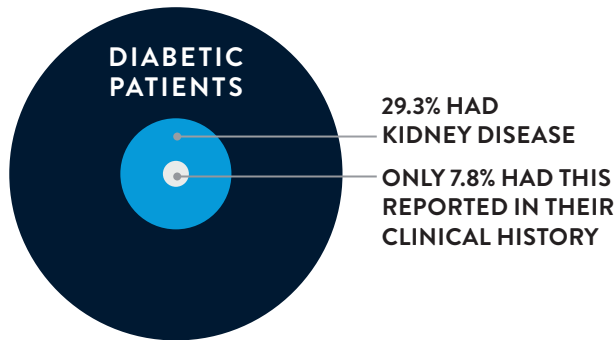
## CURRENT GUIDELINES FOR MONITORING A PATIENT WITH DIABETES

	ADA <sup>2</sup>	ESC/EASD <sup>3</sup>	IDF <sup>4,5</sup>
<b>HbA1c</b>	<ul style="list-style-type: none"> <li>Point-of-care</li> <li>2 to 4 times annually</li> <li>&lt; 7% (&lt;53 mmol/mol)</li> <li>Individualised</li> </ul>	<ul style="list-style-type: none"> <li>&lt; 7% (&lt;53 mmol/mol)</li> <li>Individualised according to duration of DM, comorbidities, age</li> </ul>	<ul style="list-style-type: none"> <li>Site-of-care or lab before clinical consultation</li> <li>Every 2–6 months</li> <li>&lt; 7% (&lt; 53 mmol/mol)</li> <li>Individualised</li> </ul>
<b>LDL</b>	<ul style="list-style-type: none"> <li>Lipid panel at diagnosis and every 5 years (&lt;40 years), annually if on lipid-lowering therapy</li> <li>&lt; 70 mg/dL established CVD (&lt; 1.8 mmol/L)</li> </ul>	<ul style="list-style-type: none"> <li>&lt; 100 mg/dL (&lt; 2.5 mmol/L) – moderate risk</li> <li>&lt; 70 mg/dL (&lt; 1.8 mmol/L) or a reduction of at least 50% – high risk</li> <li>&lt; 55 mg/dL (&lt; 1.4 mmol/L) or a reduction of at least 50% – very high risk</li> </ul>	<ul style="list-style-type: none"> <li>At diagnosis and annually</li> <li>&lt; 100 mg/dL no established CVD (&lt; 2.6 mmol/L)</li> <li>&lt; 70 mg/dL established CVD (&lt; 1.8 mmol/L)</li> </ul>
<b>Non-HDL-C</b> (secondary goal)		<ul style="list-style-type: none"> <li>&lt; 100 mg/dL (&lt; 2.6 mmol/L) – high risk</li> <li>&lt; 85 mg/dL (&lt; 2.2 mmol/L) – very high risk</li> </ul>	
<b>ACR</b>	<ul style="list-style-type: none"> <li>At least annually</li> <li>&lt; 30 mg/g Cr (&lt; 3 mg/mmol)</li> </ul>	<ul style="list-style-type: none"> <li>Annually</li> <li>&lt; 30 mg/g Cr (&lt; 3 mg/mmol)</li> </ul>	<ul style="list-style-type: none"> <li>At least annually</li> <li>&lt; 30 mg/g Cr (&lt; 3 mg/mmol)</li> </ul>
<b>eGFR</b>	<ul style="list-style-type: none"> <li>≥ 60 mL/min/1.73 m<sup>2</sup></li> </ul>	<ul style="list-style-type: none"> <li>≥ 60 mL/min/1.73 m<sup>2</sup></li> </ul>	<ul style="list-style-type: none"> <li>≥ 60 mL/min/1.73 m<sup>2</sup></li> </ul>
<b>BP</b>	<ul style="list-style-type: none"> <li>Every visit</li> <li>&lt; 140/90 mmHg</li> <li>&lt; 130/80 mmHg at higher risk</li> </ul>	<ul style="list-style-type: none"> <li>Target SBP to 130 mm/Hg, but not &lt; 120 mm/Hg</li> <li>Target DBP to &lt; 80 mm/Hg, but not &lt; 70 mm/Hg</li> <li>Individualised</li> </ul>	<ul style="list-style-type: none"> <li>At least annually and every routine visit if patient has CVD or is on associated medication</li> <li>&lt; 130 to 140/80 mmHg</li> </ul>

**ACR:** albumin/creatinine ratio; **ADA:** American Diabetes Association; **BP:** blood pressure; **Cr:** creatinine; **CV:** cardiovascular; **CVD:** cardiovascular disease; **DBP:** diastolic blood pressure; **DM:** diabetes mellitus; **EASD:** European Association for the Study of Diabetes; **eGFR:** estimated glomerular filtration rate; **ESC:** European Society of Cardiology; **IDF:** International Diabetes Foundation; **LDL:** low-density lipoprotein; **non-HDL-C:** non-HDL-cholesterol; **SBP:** systolic blood pressure

## SCREENING AND MONITORING ARE VITAL

Kidney disease is one of the most serious complications of diabetes. The prevalence of end-stage renal disease (ESRD) is up to 10 times higher in people with diabetes.<sup>1</sup> A study to assess the percentage of kidney disease amongst 1397 patients with type 2 diabetes identified 29.3% of patients with the disease, but only 7.8% had this reported in their clinical history.<sup>6</sup>



These results stress the need to screen at least once a year for the presence of diabetic renal disease by determining the presence of albuminuria and eGFR. The urinary albumin-to-creatinine ratio (ACR) aids in the early diagnosis of diabetic renal disease.

## REDUCE CVD RISK, IMPROVE OUTCOMES

People with diabetes are 2–3 times more likely to have cardiovascular disease (CVD).<sup>1</sup> Fortunately, there is good news: According to the World Health Organisation 80% of premature deaths from heart attack and stroke could be avoided by controlling high blood pressure, smoking, high cholesterol, diabetes, physical inactivity and an unhealthy diet.<sup>8</sup>

In all patients with diabetes, cardiovascular risk should be assessed at least annually.<sup>4</sup> These risk factors include obesity/overweight, dyslipidemia, hypertension, smoking, a family history of premature coronary disease, chronic kidney disease and the presence of albuminuria.

The UKPDS study found that each 1% reduction in HbA1c was associated with a 21% reduction for deaths related to diabetes, a 14% reduction for myocardial infarction and a 37% decrease of microvascular complications.<sup>9</sup>

## MANAGE DIABETES COMPLICATIONS

Diabetes is a complex disease that requires regular monitoring and care. For patients facing cardiovascular or renal complications, regular monitoring and management are truly essential.

According to the ESC Guidelines 2019, combined reduction in HbA1c, systolic blood pressure and lipids decrease Cardiovascular events by 75%.<sup>3</sup>

## REFERENCE RANGE<sup>7</sup>

CATEGORY	SPOT COLLECTION ACR	
	mg/g	mg/mmol
Normal	< 30	< 3
Microalbuminuria	30-300	3-30
Clinical albuminuria	> 300	> 30

Screening for albuminuria can be most easily performed by albumin-to-creatinine ratio (ACR) in a random spot urine collection and should be done at least annually in people with type 2 diabetes.<sup>2</sup>

**“ALBUMINURIA IS THE EARLIEST MARKER OF KIDNEY DISEASE IN DIABETES AND A STRONG PREDICTOR FOR CVD; THEREFORE IT SHOULD BE EXAMINED WHEN SCREENING FOR COMPLICATIONS.”<sup>1</sup>**

**PEOPLE WITH DIABETES ARE**



**MORE LIKELY TO HAVE CARDIOVASCULAR DISEASE**

**ACR AND CVD RISK FACTORS SHOULD BE ASSESSED AT LEAST ANNUALLY IN ALL PATIENTS WITH DIABETES.<sup>2,4</sup>**

## POINT OF CARE TESTING THAT MAKES EVERY MINUTE COUNT

Improve the way you diagnose, monitor, and manage diabetes patients with the Afinion™ 2 Analyzer. With its compact size and panel of tests, the Afinion 2 system is ideal for point-of-care testing in physician offices, clinics, community health centres, retirement homes, emergency rooms and hospital out-patient clinics. In 3 easy steps, highly accurate results for ACR, CRP, HbA1c and Lipid Panel are made available during the consultation.

**“TESTING ACR, LIPIDS AND HbA1c IN REAL TIME USING A RELIABLE AND ACCURATE POINT-OF-CARE TEST IS ESSENTIAL. IT MEANS I CAN MAKE TREATMENT DECISIONS BASED ON THE LATEST AND MOST ACCURATE INFORMATION.”**

– Prof. med. Bernd Schultes Endocrinologist/Diabetologist,  
St. Gallen Switzerland



### AFINION HbA1c

A test for quantitative determination of glycated hemoglobin (HbA1c) in human whole blood, used to monitor metabolic control in patients with diabetes.

- 1.5 µL sample volume
- 3 minutes test time
- Capillary and venous whole blood sample material
- No interference from common Hb variants
- NGSP and IFCC certified



### AFINION ACR

A test for quantitative determination of albumin, creatinine and albumin/creatinine ratio (ACR) in human urine, used for early identification of renal disease in patients with diabetes and/or hypertension.

- 3.5 µL of random/spot urine sample
- 5 minutes test time
- Measuring ACR increases diagnostic accuracy compared to urine albumin measurement only<sup>2</sup>



### AFINION LIPID PANEL

A full lipid panel for the early detection and management of cardiovascular risk in patients.

- Total Cholesterol (Chol), High Density Lipoprotein cholesterol (HDL), Low-Density Lipoprotein cholesterol (LDL), Triglycerides (Trig), non-HDL and Chol/HDL ratio.
- 15 µL sample volume
- 7-8 minutes test time
- Whole blood, serum and plasma sample material
- Traceable to CRMLN (Cholesterol Reference Method Laboratory Network)



### AFINION CRP

A rapid *in vitro* diagnostic test for quantitative determination of C-reactive protein (CRP) in blood which is valuable in the diagnosis and monitoring of infections and non-infectious inflammatory diseases.

- 2.5 µL sample volume
- 3-4 minutes test time
- Measuring range whole blood 15-200 mg/L
- Sample materials whole blood, serum or plasma
- No user calibration necessary



## PRECISION AND SPEED PROVEN IN THE FIELD

The Afinion 2 Analyzer is the result of years of continuous product innovation and refinement since 2005 and delivers actionable point-of-care results in minutes. Every single Afinion 2 system is factory calibrated and released against stringent specifications.

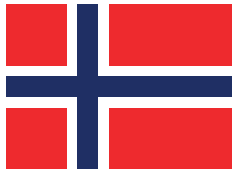
Certified by NGSP and IFCC (International Federation of Clinical Chemistry), the Afinion 2 Analyzer showed excellent results in an independent performance study from the European Reference Laboratory for Glycohemoglobin (ERL).<sup>10</sup>

Recent studies comparing the Afinion HbA1c assay to routine and reference laboratory methods have consistently shown a high degree of accuracy with bias close to zero and with precision well below 2% CV (NGSP units).<sup>10-15</sup>

EQA data from Noklus (Norway)<sup>16</sup>, the CAP survey (US)<sup>17</sup> and the EurA1c trial<sup>18</sup> demonstrate that good performance is also observed in the hands of end-users and that the Afinion HbA1c performance matches and in some cases outperforms routine laboratory methods.

Clinical assessments performed in healthcare settings also show the reliable performance in the hands of non-laboratory operators using fingerstick capillary blood.<sup>19,20</sup>

In 2018 the Afinion HbA1c Dx test\* was cleared by US FDA as an aid in the diagnosis of diabetes and in identifying patients who may be at increased risk for developing diabetes.<sup>21</sup>



- For more than 17 years, Norway has been using point of care testing to monitor patients with diabetes.<sup>22</sup>
- For the last two years Norway has used POCT to diagnose Type 2 diabetes in patients.<sup>22</sup>

**“POCT DEVICES ARE INCREASINGLY USED IN NATIONAL SCREENING PROGRAMMES OWING TO THEIR EASE OF USE AND LESS INVASIVE NATURE (FINGER PRICK VERSUS VENIPUNCTURE)”<sup>22</sup>**



**MAKE EVERY MINUTE COUNT DURING YOUR CONSULTATIONS.  
CONTACT YOUR LOCAL ABBOTT REPRESENTATIVE TODAY,  
OR VISIT ABBOTT.COM/POCT.**

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\*The Afinion HbA1c Dx test is cleared for offices that hold a moderate complexity license. The FDA categorizes diagnostic tests by their complexity—from the least to the most complex: waived tests, moderate complexity tests, and high complexity tests.

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