



# Diabetes in the U.S.

How a preventive mindset can change lives and lower cost of care



# Table of Contents

- 3 Diabetes: The basics
- 4 Type 2 diabetes
- 5 Complications from unmanaged Type 2 diabetes
- 6 The case for preventive screening: Shifting the mindset and model
- 8 Prediabetes and diabetes testing capabilities from ixlayer
- 9 Prediabetes and Type 2 diabetes: What should be screened
- 10 The cost of diabetes



### Roughly 96 million adults in the U.S. have prediabetes.

Alarmingly, 90% of those with prediabetes don't know they have it. Too often, for patients identified as having prediabetes, there is a failure to assist them in enrolling in evidence-based diabetes prevention lifestyle change programs. These programs have resulted in a 58% drop in three-year Type 2 diabetes incidence.<sup>2</sup> But without taking the first step, through preventive screening and regular testing, we perpetuate a more costly and life-threatening cycle of chronic disease management.







Alarmingly, 90% of those with prediabetes don't know they have it

Roughly 96 million adults in the U.S. have prediabetes These programs have resulted in a 58% drop in three-year Type 2 diabetes incidences

### Diabetes: The basics

Your body derives energy from the food you consume and turns it into blood glucose. Glucose from your food makes its way to your cells with the help of insulin<sup>3</sup>, a hormone made by the pancreas. If your body doesn't make enough, or any, insulin, the glucose remains in your blood, never reaching your cells. Diabetes occurs when your body doesn't produce enough insulin, resulting in too much glucose in your blood.

- 1. CDC. PREDIABETES- YOUR CHANCE TO PREVENT TYPE 2 DIABETES. DATE ACCESSED: 11/2
- 2. AMA. SEVEN STEPS TO GET PREDIABETIC PATIENTS THE PREVENTIVE HELP THEY NEED. DATE PUBLISHED: 10/4/18. DATE ACCESSED: 11/29/22
- 3. CDC. TYPE 2 DIABETES. DATE ACCESSED: 11/22/22

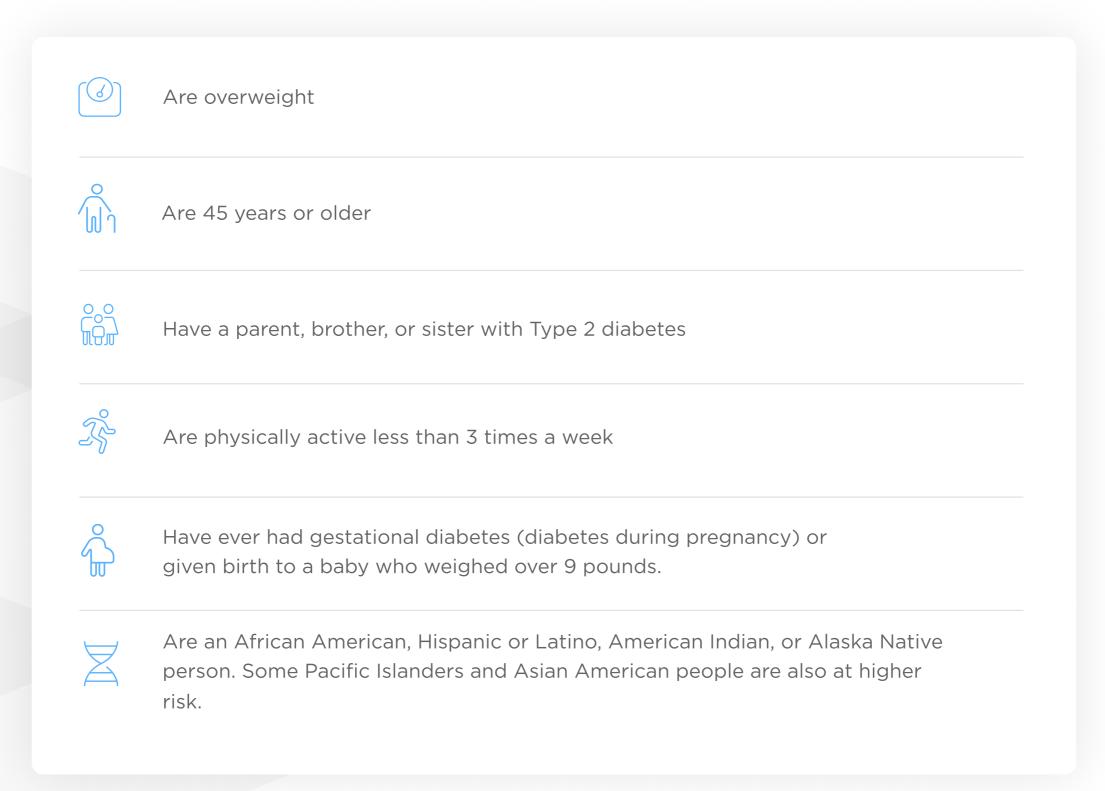
# Type 2 diabetes

While there are multiple types of diabetes, we'll focus on the most common, Type 2. Individuals with Type 2 diabetes experience insulin resistance, which occurs when cells don't respond normally to insulin. To overcompensate, the pancreas overproduces insulin in an attempt to get the body's cells to respond. Eventually, the pancreas cannot keep up, causing blood sugar to rise. In this instance, prediabetes develops and, if corrective measures are not taken, there's a high likelihood of developing Type 2 diabetes.

While Type 2 diabetes is managed mostly by the individual through diet, exercise and lifestyle choices, it can also be managed with a prescription from a doctor. Insulin, injectable medications, or oral diabetes medications may be needed to help keep blood sugar within healthy levels. Proper monitoring and management of Type 2 diabetes is essential to avoid potentially life-threatening complications.

### Who's at risk

According to the Centers for Disease Control (CDC), individuals are most at risk for developing prediabetes and Type 2 diabetes if they<sup>5</sup>:



Risk also increases for individuals in these categories who are within certain socioeconomic statuses and/or are experiencing health disparities. We'll shine a light on those factors shortly.

# Complications from unmanaged Type 2 diabetes

Not only do individuals with Type 2 diabetes need to regularly screen their blood sugar levels, but they also need to monitor their overall health to avoid complications. In fact, cardiovascular disease is the top cause of death among people living with diabetes. Those with diabetes are 2x as likely to experience heart disease or a stroke versus those without diabetes. The heart isn't the only organ that becomes stressed. Kidney disease can also develop over time among individuals with Type 2 diabetes, as high levels of blood glucose make the kidneys filter too much blood, overworking the kidneys. Without intervention, this can eventually result in end-stage renal disease.



People with Diabetes are two to three times more likely to have depression than people without diabetes.



Other complications from Type 2 diabetes include eye issues such as blindness, cataracts or glaucoma as blood vessels become damaged or fluid builds up in the eyes. Diabetes-related nerve damage, especially in the feet, can cause numbness or pain. In some more serious cases, diabetes can damage blood vessels or create infections in the leg, requiring amputation. Mental health can suffer among those with diabetes, as well. Studies have linked diabetes to increased likelihood for depression. In fact, people with diabetes are two to three times more likely to have depression than people without diabetes. Only 25% to 50% of people with diabetes who have depression get diagnosed and treated. Lastly, during the recent COVID-19 pandemic, we observed that people with diabetes were more likely to experience serious complications from the virus.

- 4. CDC. TYPE 2 DIABETES. DATE ACCESSED: 11/22/22
- <sup>5</sup>. CDC. <u>DIABETES RISK FACTORS</u>. DATE ACCESSED: 11/22/22
- <sup>6</sup>. CDC. DIABETES RISK FACTORS. DATE ACCESSED: 11/22/22
- 7. AMERICAN DIABETES ASSOCIATION. <u>CARDIOVASCULAR DISEASE</u>. DATE ACCESSED: 11/22/22.

# The case for preventive screening:

# Shifting the mindset and model

If detected in the prediabetes stage, Type 2 diabetes can often be avoided with lifestyle changes. In fact, it's estimated that between 5-10% of people with diagnosed prediabetes end up developing diabetes annually. So why do 5 million people in the United States (roughly 11%) have the disease? Part of this is a mindset shift that must occur. The practice was common to visit the doctor only when sick. We must become more open to regular preventive screenings and visits with our health care providers. For the same reason that we take our vehicle in for an oil change, we should all become more open to the concept of regular preventive measures for better health.

A preventative approach is essential if we want to start reducing the number of people diagnosed with diabetes each year. Access to simple and affordable testing is one of the key aspects of identifying people with pre-diabetes. It is thought that it takes over 10 years of dysregulated blood sugars to be diagnosed with diabetes. That's 10 years that could have been spent helping patients incorporate healthier habits into their lives with nutrition, movement, and education.

The other part of the shift that must occur is a change in the healthcare model. Our healthcare system is currently constructed to primarily treat sick people, rather than keep people well. The movement towards value-based care and the National Committee for Quality Assurance (NCQA) HEDIS®\* measures are helping health plans implement a more proactive approach to healthcare. More specifically, the HEDIS® measure for social need screening and intervention was designed to better support disadvantaged individuals who are at risk for developing Type 2 diabetes and other chronic conditions. With chronic conditions like Type 2 diabetes being the leading driver of healthcare costs in the U.S, we'd all benefit from a stronger shift to preventive care. Yet, according to AARP, only about 8% of Medicare beneficiaries use their free annual wellness check. While there are assuredly multiple factors that could influence this result, health disparities can strongly impact the emergence of a chronic condition like Type 2 diabetes.

# Social determinants of health impacting preventive diabetes care

Disparities in diabetes prevalence are the result of a variety of factors. Evidence shows substantial ties between diabetes and social factors such as socioeconomic status, food environment, and physical environment. For example, diabetes has increased among American Indian/Alaska Native (14.7%), Asian (9.2%), Hispanic/Latino (12.5%), and non-Hispanic Black (11.7%) persons than among non-Hispanic White (7.5%) persons.14



- \*HEDIS® IS A REGISTERED TRADEMARK OF THE NATIONAL COMMITTEE FOR QUALITY ASSURANCE (NCQA)
- 8. CDC. DIABETES AND MENTAL HEALTH. DATE ACCESSED: 11/22/22
- 9. NCBI. PREDIABETES, A HIGH RISK STATE FOR DEVELOPING DIABETES. 11/22/22
- <sup>10</sup>. CDC. NATIONAL DIABETES STATISTICS REPORT. DATE ACCESSED: 11/22/22
- 11. GLOBAL NEWSWIRE. NCQA UPDATES & RELEASES NEW QUALITY MEASURES FOR HEDIS® 2023 WITH A FOCUS ON HEALTH EQUITY. DATE PUBLISHED: 8/1/22. DATE ACCESSED: 11/30/22.
- <sup>12</sup>. CDC. HEALTH CARE INDUSTRY INSIGHTS: WHY THE USE OF PREVENTIVE SERVICES IS STILL LOW. DATE ACCESSED: 11/22/22
- 13. AARP. FEW MEDICARE PATIENTS MAKE USE OF FREE WELLNESS VISITS. DATE ACCESSED: 11/22/22.

A study supported by the American Diabetes Association (ADA) found that "individuals living in neighborhoods with lower educational attainment, lower annual income, and larger percentage of households receiving Supplemental Nutrition Assistance Program benefits has been associated with higher risk of progression to Type 2 diabetes among adults with prediabetes<sup>15</sup>."

Socioeconomic status, which includes one's education, income or occupation, can impact the care sought and received by an individual. Postponed or missed healthcare due to an inability to take the time off work factors into this. Housing insecurity can also impact an individual's ability to seek care. Research conducted in the Department of Veterans Affairs (VA) healthcare system found that "experiencing homelessness was associated with higher adjusted odds of an HbA1c >8.0% and >9.0%," which are elevated HbA1c levels.

Food access and insecurity can be incredibly detrimental to someone diagnosed with prediabetes or Type 2 diabetes. A study in The Journal of Rural Health found a direct relationship between higher access to quality food and lower Type 2 diabetes rates. Additionally, access to affordable, quality healthcare can influence whether someone seeks care and avoids developing Type 2 diabetes. It should come as no surprise that uninsured individuals seek healthcare less often.



"A study found that the uninsured have 60% fewer office visits with a physician, are prescribed 52% fewer medications, and have 168% more emergency department visits."

In these situations, lack of funds to pay for care up front often results in exorbitant healthcare bills down the line. At ixlayer, we believe it's incredibly important to offer affordable health testing for both preventive and chronic care that meets patients where they are, on their own terms.

In many instances, flexible testing methods like at-home screenings are the best option. According to Jasmine Gonzalvo, Director of the Center for Health Equity and Innovation at Purdue University, "If we're talking about a population who's never been diagnosed, who doesn't have access to primary care, and we can use the tests just to get a general sense of where someone's sugars are - there's huge utility".

Pairing testing with knowledgeable healthcare practitioners further maximizes the impact these screening tests can have on preventing diabetes. It's not enough for patients to just have lab results. They need to know what results mean and what to do with that information. With nearly 90% of Americans living within 5 miles of a community pharmacy and pharmacists being experts in disease state management, there's huge potential for health plans and consumers alike to leverage their local pharmacist.

- 14. HILL-BRIGGS F , ADLER NE , BERKOWITZ SA , ET AL. SOCIAL DETERMINANTS OF HEALTH AND DIABETES: A SCIENTIFIC REVIEW. DIABETES CARE. 2020;44(1):258-279. DOI:10.2337/DCI20-0053
- 15.ADA. SOCIAL DETERMINANTS OF HEALTH AND DIABETES: A SCIENTIFIC REVIEW. DATE PUBLISHED: 11/02/20. DATE ACCESSED: 11/22/22
- 16. JOURNAL OF HEALTH CARE FOR THE POOR AND UNDERSERVED. THE ASSOCIATION BETWEEN HOUSING INSTABILITY, FOOD INSECURITY, AND DIABETES SELF-EFFICACY IN LOW-INCOME ADULTS. DATE PUBLISHED: 11/11. DATE ACCESSED: 11/22/22.
- 17. THE JOURNAL OF RURAL HEALTH. A NATIONAL STUDY OF THE ASSOCIATION BETWEEN FOOD ENVIRONMENTS AND COUNTY-LEVEL HEALTH OUTCOMES. DATE PUBLISHED: 4/27/11. DATE ACCESSED: 11/22/22
- 18, ADA. ECONOMIC COSTS OF DIABETES IN THE U.S. IN 2017. DATE PUBLISHED: 5/18, DATE ACCESSED: 11/22/22.

# Prediabetes and diabetes screening from ixlayer

A self-collection kit to assess blood glucose levels, heart and kidney health

### What it Measures

- Hemoglobin A1c (HbA1c) to monitor your blood sugar levels and screen for diabetes or prediabetes.
- Total cholesterol, HDL, calculated LDL and triglycerides for optimal heart health.
- Estimated glomerular filtration rate (eGFR) and urine Albumin-creatinine ratio (uACR) for kidney health.
- Fasting blood glucose to measure blood sugar after not eating for 8 hours.

### Who Should Take This Test

- Individuals who have prediabetes or are at risk for developing prediabetes.
- Individuals diagnosed with type 2 diabetes.

(For Recommended frequency see chart on page 9)

### Collection Method

- Finger prick blood collection
- Urine sample

### Why it Matters

38% of adults have prediabetes and 11% of the U.S population has diabetes. Unfortunately, if someone has diabetes they may also be prone to other health conditions. Our self-collection kits help identify and monitor blood sugar levels for diabetes and prediabetes, as well as providing important insight into cardiovascular and kidney health.

Test results can help assess if an individual needs to connect with a healthcare provider to discuss the appropriate next steps, and whether lifestyle changes are needed to prevent diabetes and control other risk factors.

Prediabetes Dia

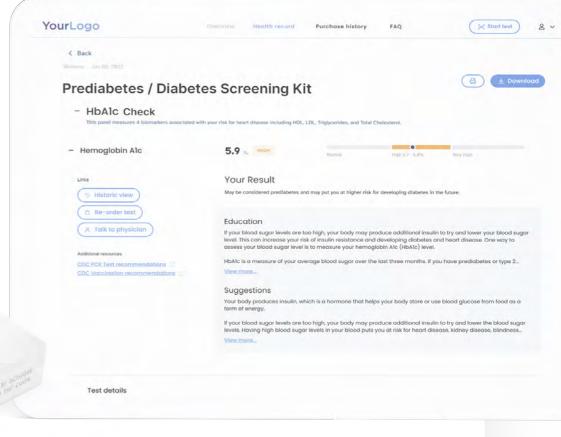
YourLogo

### How it Works

- ixlayer handles logistics of shipping kits. An individual creates an account in your patient portal and registers their kit.
- Easy step-by-step instructions guide them through the process of collecting their sample and shipping it to the lab.
- The individual can review results in a secure online patient portal. They are provided additional insights regarding results or can connect with a clinician on next steps.
   Administrators can view results, if preferred. A PDF of the results can be provided to the physician on file.

### Benefits of ixlayer

- · Affordable and convenient health testing.
- Get ahead of chronic conditions with preventative screening.
- End-to-end health testing platform, all white labeled under your brand.



https://www.cdc.gov/diabetes/data/statistics-report/index.html

# Prediabetes and Type 2 diabetes: What should be screened

Those with prediabetes who are at-risk for developing Type 2 diabetes and people with Type 2 diabetes should keep an eye on many important health indicators. A few of the most important are detailed.

Recommended Screening	Biomarker(s) Measured	Recommended Frequency for Prediabetes	Recommended Frequency for Type 2 diabetes
Hemoglobin blood sugar levels	HbA1c	Every 1-2 years <sup>20</sup>	At least twice a year 21
Kidney Health Evaluation	Estimated glomerular filtration rate (eGFR) and urine albumincreatinine ratio (UACR)	Annually for individuals in lower-risk categories (A1-A2 and G1-G3a) and more frequently for those in higher-risk groups (A3 and G3b-G5)	Annually for individuals in lower-risk categories (A1-A2 and G1-G3a) and more frequently for those in higher-risk groups (A3 and G3b-G5)  • 2-4 times per year: UACR >30 mg/mmol (A3) and eGFR <45 mL/min/1.73 m2 (G3b-G5)
Fasting blood glucose	Blood glucose	Every 1-2 years <sup>24</sup>	Yearly if normal <sup>24</sup>
Cholesterol & Lipids	Total cholesterol, HDL, calculated LDL and triglycerides	Yearly	Yearly <sup>26</sup>
Blood pressure	Systolic and diastolic blood pressure	Quarterly	Quarterly <sup>27</sup>
Eye exam	EED for diabetic retinopathy	Yearly if normal, up to monthly depending on findings ( e.g. Proliferative DR)	Yearly if normal, up to monthly depending on findings (e.g. Proliferative DR)

<sup>&</sup>lt;sup>20</sup>. CDC. ALL ABOUT YOUR A1C. DATE ACCESSED:11/30/22. | <sup>21</sup>.CDC. ALL ABOUT YOUR A1C. DATE ACCESSED:11/30/22. | <sup>22</sup>.BILOUS R (2016) <u>DIABETIC NEPHROPATHY</u>: <u>DIAGNOSIS</u>, <u>SCREENING AND</u> MANAGEMENT. DIABETES & PRIMARY CARE 18: 38-46; | 23.NATIONAL KIDNEY FOUNDATION (2020) ACR: ALBUMINURIA. NATIONAL KIDNEY FOUNDATION, NEW YORK, USA. | 24CLEVELAND CLINIC. FASTING BLOOD SUGAR TEST. | 25. SACKS DB, ARNOLD M, BAKRIS GL, BRUNS DE, HORVATH AR, KIRKMAN MS, LERNMARK A, METZGER BE, NATHAN DM; NATIONAL ACADEMY OF CLINICAL BIOCHEMISTRY; EVIDENCE-BASED LABORATORY MEDICINE COMMITTEE OF THE AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY. GUIDELINES AND RECOMMENDATIONS FOR LABORATORY ANALYSIS IN THE DIAGNOSIS AND MANAGEMENT OF DIABETES MELLITUS. DIABETES CARE. 2011 JUN;34(6):E61-99. DOI: 10.2337/DC11-9998. PMID: 21617108; PMCID: PMC3114322. | 26. MARIA P. SOLANO, RONALD B. GOLDBERG; LIPID MANAGEMENT IN TYPE 2 DIABETES. CLIN DIABETES 1 JANUARY 2006; 24 (1): 27-32. | 27. AMERICAN HEART ASSOCIATION. HEART-HEALTH SCREENINGS. DATE PUBLISHED: 6/30/17. DATE ACCESSED: 11/30/22.

# Knowing the result ranges

Result	A1c	
Normal	less than 5.7%	
Prediabetes	5.7% to 6.4%	
Diabetes	6.5% or higher	

According to the American Diabetes Association, a normal A1c result is at or below 5.7%.

Result	Fasting Blood Glucose
Normal	less than 100 mg/dl
Prediabetes	100 mg/dl to 125 mg/dl
Diabetes	126 mg/dl or higher

The American Diabetes Association states that a normal Fasting Blood Glucose level is less than 100 mg/dl.

## The cost of diabetes

In addition to the serious health impacts that can accompany Type 2 diabetes, this disease has a hefty impact on the U.S. economy. A study conducted by the ADA in 2018 found that roughly 1 of every 4 healthcare dollars spent went towards diabetes care. It's safe to assume the ratio has increased since then.

Conversely, on average, prediabetes costs only \$500 annually per person in medical costs. Diabetes is also the third most expensive chronic condition in the United States, behind cancer and heart disease. That said, it's important to acknowledge that a key complication from diabetes is heart disease. It's no surprise these two chronic conditions are intertwined.

### Conclusion

Type 2 diabetes is a costly disease with potentially life-threatening complications. Unfortunately, health inequities exacerbate disease progression, impacting the disadvantaged most. But there is tremendous potential for improved health outcomes if we make screening methods more accessible to those who need them, and in a format that is affordable and convenient. The best way to achieve this is with a shift to preventive action for the preservation of good health. A preventive approach can help detect Type 2 in the prediabetes stage, helping more people avoid disease progression and live happier, healthier lives.



The average medical expenditure of an individual diagnosed with diabetes is approximately 2x higher



Those with diabetes cost roughly \$16,750 per year.

<sup>28.</sup> AMERICAN ACADEMY OF OPHTHALMOLOGY. <u>DIABETIC RETINOPATHY SCREENING.</u> DATE PUBLISHED: 11/28/22. DATE ACCESSED: 11/29/22.

<sup>&</sup>lt;sup>29.</sup> ADA. THE COST OF DIABETES CARE- AN ELEPHANT IN THE ROOM. DATE PUBLISHED: 4/12/18. DATE ACCESSED: 11/22/22

<sup>30.</sup> NATIONAL LIBRARY OF MEDICINE. TRENDS IN MEDICAL EXPENDITURES PRIOR TO DIABETES DIAGNOSIS: THE EARLY BURDEN OF DIABETES. DATE PUBLISHED: 2/2/21. DATE ACCESSED: 11/22/22.

<sup>31.</sup> AMA. SEVEN STEPS TO GET PREDIABETIC PATIENTS THE PREVENTIVE HELP THEY NEED. DATE PUBLISHED: 10/4/18. DATE ACCESSED: 11/29/22.

<sup>32.</sup> CDC. HEALTH AND ECONOMIC COSTS OF CHRONIC DISEASES. DATE ACCESSED: 11/22/22.



# About ixlayer

People deserve easy, affordable access to the best healthcare available. ixlayer is the leading healthcare platform that seamlessly integrates with all systems and enables organizations to accelerate access to effective health testing solutions, all under their brand. We help organizations overcome barriers within the fragmented healthcare experience, creating a population that takes control of their health and resulting in an improved care continuum. The ixlayer infrastructure helps payers, retailers and biopharma organizations launch and scale health testing programs that accelerate speed to market and drive engagement and compliance, while improving brand loyalty.



# About Collaborative Therapeutics

Dr. Kristin Tallent is a pharmacist and entrepreneur on a mission to empower other pharmacists to take control of their careers by using the vast amount of testing opportunities we have at our disposal. After taking control of her own career by leveraging clinical services, Kristin decided that more pharmacists needed to know about the power testing holds, the impact it has on our communities, and how easily tests integrate with other clinical services. That's why she started Collaborative Therapeutics which houses virtual course offerings & a done-for-you policy and procedure manual to help other pharmacists implement and run profitable testing offerings. She brings a voice to testing capabilities as the host of POCTalk on the Pharmacy Podcast Network.





# Prediabetes By the Numbers

A staggering number of people in the U.S. are unaware they have prediabetes.

By providing access to simple screenings, organizations can help monitor and manage disease progression.



Alarmingly, 90% of those with prediabetes don't know they have it

People with diabetes are up to 3x more likely to experience depression, in addition to other complications.





The average medical expenditure of an individual diagnosed with diabetes is roughly 2x higher.

There's a 58% drop in three-year Type 2 diabetes incidences among people who have been enrolled in evidence-based prediabetes programs.





People with prediabetes and Type 2 diabetes should evaluate their HbA1c at least once a year.

# People deserve easy, affordable access to the best healthcare available.

ixlayer is the leading healthcare platform that seamlessly integrates with all systems and enables organizations to accelerate access to effective health testing solutions, all under their brand. We help organizations overcome barriers within the fragmented healthcare experience, creating a population that takes control of their health and resulting in an improved care continuum.

The ixlayer infrastructure helps payers, retailers and biopharma organizations launch and scale health testing programs that accelerate speed to market and drive engagement and compliance, while improving brand loyalty.

- <sup>1.</sup> CDC, PREVENTING DIABETES
- <sup>2.</sup> CDC, DIABETES RISK FACTORS
- <sup>3.</sup> CDC, HEALTH AND ECONOMIC COSTS OF CHRONIC DISEASES
- <sup>4.</sup> AMA, 7 STEPS TO GET PREDIABETIC PATIENTS THE HELP THEY NEED
- 5. CDC, ALL ABOUT YOUR A1C