



PreD Guide measures stages of pre-diabetes and progression toward Type 2 Diabetes Mellitus (T2DM) using metabolic and inflammatory biomarkers. **PreD Guide** focuses on the importance of early assessment and correction of risk factors.

PreD Guide defines stages of progression toward **Type 2 Diabetes Mellitus (T2DM)** and insulin resistance. This diagnostic tool utilizes a combination of inflammatory and metabolic biomarkers to provide an early assessment of a patient's path towards diabetes – and guide targeted therapies. CDC estimates of the US population indicate that only 40% of adults at risk for developing diabetes are obese (BMI >30). How can the other 60% be identified?

Moving beyond BMI, the **PreD Guide** assists clinicians in identifying patients at risk for developing diabetes. By integrating traditional markers of blood glucose regulation with state-of-the-art inflammatory and metabolic biomarkers, the **PreD Guide** pinpoints a patient's place within the progression to diabetes. The interplay of these biomarkers is illustrated across the stages of pre-diabetes, and results in stage-specific therapeutic interventions. In addition, an array of inflammatory markers are measured and aggregated to give the **Average Inflammation Score**.

The **PreD Guide** gives clinicians the ability to evaluate stages of pre-diabetes, determine the impact of inflammation, and individualize treatment. This clinical tool ensures, as the CDC notes, that “progression to diabetes among those with pre-diabetes is not inevitable.”

Identifying the Underlying Driver: Inflammation

Research suggests that inflammation precedes and accelerates the progression to diabetes. Five different biomarkers provide an assessment of the patient's unique expression of inflammation. Given the complex manner in which they interact, a synthesized **Average Inflammation Score** is provided to indicate severity of the degree of inflammation present.

- High Sensitivity C-Reactive Protein (hs-CRP)
- Interleukin 6 (IL-6)
- Interleukin 8 (IL-8)
- Tumor Necrosis Factor alpha (TNF α)
- Plasminogen Activator Inhibitor Type 1 (PAI-1)

Identifying the Stage of Progression

- **Adiponectin** is produced and secreted by fat cells, and regulates lipid and glucose metabolism. It influences the body's response to insulin, and has anti-inflammatory effects on the cells that line blood vessel walls. Patients with high levels of adiponectin have a reduced risk of heart attack and diabetes. Falling adiponectin levels are the hallmark of the first stage of progression to diabetes.
- **Insulin, Glucose, and Hemoglobin A_{1c}** – These markers are traditionally used to provide clinical insight into blood glucose regulation. HOMA-IR (homeostasis model assessment–insulin resistance) is a calculation based on fasting plasma glucose and fasting plasma insulin levels that was developed as a surrogate measurement of insulin resistance. Rising insulin levels in the presence of diminished adiponectin levels are the hallmark of the second stage of progression to diabetes.
- **Proinsulin** is the prohormone precursor to insulin, and is secreted by pancreatic beta cells. Rising proinsulin levels in the presence of elevated insulin levels and diminished adiponectin levels are indicative of beta-cell dysfunction, the hallmark of the third stage of progression to diabetes.

• Analytes:

hs C-Reactive Protein
Interleukin IL-6
Interleukin IL-8
TNF α
Plasminogen Activator Inhibitor Type 1
Glucose (Fasting)
Adiponectin
Insulin (Fasting)
Proinsulin
HOMA-IR
Hemoglobin A_{1c}
C-Peptide
Leptin

• Specimen Requirements:

- 4 ml EDTA (whole blood),
- 7 ml serum

• Before Patient Takes this Test:

- Fast overnight (at least 12 hours)
- See instructions inside test kit for details



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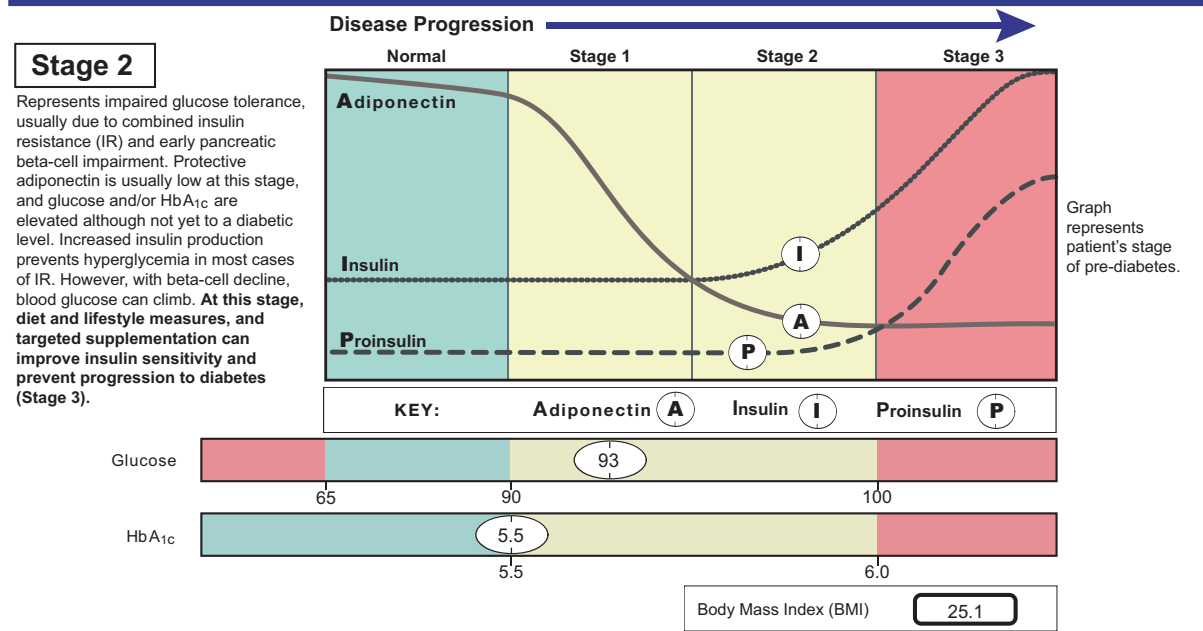


Patient: **SAMPLE PATIENT**
DOB: June 9, 1958
Sex: M
MRN:

Order Number:
Completed: April 15, 2010
Received: April 9, 2010
Collected: April 6, 2010

Sample Report

Stages of Pre-Diabetes



Average Inflammation Score

Average Inflammation = 1.0 – 3.02 (range)

1.00 – 1.50	No/Minimal inflammation
1.51 – 2.00	Moderate inflammation
>2.00	Severe inflammation

Average Inflammation Score*: 1.93

* Relative Risk Calculation of Inflammation Markers (pg 2)

This test reveals important clinical information about:

- **Stage of Progression to Diabetes** Determination of stage leads to specific treatment recommendations of diet, lifestyle, nutritional supplementation, and targeted pharmaceutical therapy.
- **The Underlying Driver of Progression: Inflammation** Evaluation of the degree of inflammation allows for identification and specific treatment of inflammation as an accelerator of insulin resistance.

For test kits, clinical support, or more information contact:

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More detailed publications with references are also available: www.GDX.net