

PreDx™ Diabetes Risk Profile

Disease Overview

- Type 2 diabetes has become the fastest growing chronic disease in the United States, affecting nearly 24 million diagnosed and undiagnosed adults, with another 57 million considered at high risk for developing the disease.¹
- Although there are several well-known risk factors for the development of type 2 diabetes, no single risk factor alone reliably discriminates between those who will develop the disease and those who will not. It has been shown that 10 percent of individuals with impaired fasting glucose and metabolic syndrome will progress to diabetes within five years.²⁻⁴
- An accurate and reliable means for assessing the risk of type 2 diabetes in a format convenient for routine clinical use would enable clinicians to more effectively identify those individuals who could benefit most from aggressive prevention strategies.

Pathophysiology

- The serum biomarkers used for the PreDx Diabetes Risk Profile are each independently associated with type 2 diabetes risk, and include biomarkers of glucose metabolism (glucose, insulin, glycated hemoglobin [HbA1c]), adipose function (adiponectin), and inflammation and atherosclerosis (C-reactive protein [CRP], interleukin-2 receptor- α [IL-2R α], and ferritin).
- When these seven serum biomarkers representing multiple pathways implicated in the development of type 2 diabetes are analyzed together by an algorithm, the resulting risk score provides statistically better discrimination than each biomarker's ability to assess risk independently.
- The PreDx Diabetes Risk Profile identifies patients 30 years and older who may be most vulnerable to developing type 2 diabetes within five years.

Indications for Ordering

To stratify at-risk populations 30 years and older (e.g., individuals with impaired fasting glucose [IFG=100 - 125 mg/dL], elevated HbA1c, or metabolic syndrome) and identify individuals with the highest risk of developing type 2 diabetes within five years. (Metabolic syndrome is identified as the presence of three or more of the following components: elevated waist circumference, elevated triglycerides, reduced HDL, elevated blood pressure, and elevated fasting glucose.)

Interpretation

- The circulating levels of each of the seven biomarkers is reported and analyzed by an algorithm to produce a single diabetes risk score that ranks a patient's diabetes risk on a scale of 1–10 (low to high).

- This diabetes risk score reflects a patient's relative risk of developing diabetes within five years and classifies patients into low-, moderate-, or high-risk categories.
- The information provided by the PreDx Diabetes Risk Profile may be used by a clinician in conjunction with other clinical indicators to develop an effective diabetes prevention program.

Limitations

- Patient must be 30 years or older and fasting at the time of blood draw.
- Conditions that shorten red cell survival, such as the presence of unstable hemoglobins (e.g., Hb SS, Hb CC, Hb SC) or other causes of hemolytic anemia may yield falsely low results for HbA1c. Iron deficiency anemia may yield falsely high results for HbA1c.

Methodology

- Test methodologies include:
 - Enzymatic (glucose)
 - Ion-exchange HPLC (HbA1c)
 - Chemiluminescent immunoassay (insulin, ferritin, interleukin 2 receptor alpha or IL2Ra)
 - Latex agglutination (hsCRP)
 - Enzyme-linked immunosorbent assay (adiponectin)
 - Diabetes risk score calculation
- Individual results for each marker and risk score are reported.
- This test is performed by Tethys Bioscience in Emeryville, CA.

References

1. Meigs JB, et al. Body mass index, metabolic syndrome, and risk of type 2 diabetes or cardiovascular disease. *J Clin Endocrinol Metab* 2006;91(8):2906–12.
2. Meigs JB, et al. Genotype score in addition to common risk factors for prediction of type 2 diabetes. *N Engl J Med* 2008;359(21):2208–19.
3. Nichols GA, Hillier TA, Brown JB. Progression from newly acquired impaired fasting glucose to type 2 diabetes. *Diabetes Care* 2007;30(2):228–33.
4. Urdea M, et al. Validation of a multimarker model for assessing risk of type 2 diabetes from a five-year prospective study of 6784 Danish people (Inter99). *J Diabetes Sci Technol* 2009;3(4):748–55.
5. 2007 National Diabetes Fact Sheet. Centers for Disease Control and Prevention. www.cdc.gov/diabetes/pubs/factsheet07.htm#contents (accessed on October 14, 2010).
6. Metabolic syndrome. National Heart, Lung, and Blood Institute. Available at <http://www.nhlbi.nih.gov/index.htm> (accessed October 14, 2010)

Test Information

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For specific collection, transport, and testing information, refer to the ARUP website at www.aruplab.com.

For information on test selection, ordering, and interpretation, refer to ARUP Consult® at www.arupconsult.com.