

Detection of glycated CD59 for the diagnosis of impaired glucose tolerance

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Technology description

Detection of glycated CD59, a Membrane Attack Complex (MAC)-associated membrane protein, may be a superior alternative to oral glucose tolerance testing for the detection of impaired glucose tolerance. Higher than normal concentrations of glycated CD59 have been associated with the development of increased insulin resistance, even when HbA1c levels are within the normal range. Recent studies link increased vascular risk in diabetic patients to increased glycation of CD59 suggest a glycated CD59 diagnostic may be able to predict elevated risk to adverse effects of diabetes, such as nephropathy and neuropathy. By enabling prophylactic care to at-risk patients, detection of glycated CD59 may extend a physician's options in managing diabetic and pre-diabetic care.

Clinical Validation:

An elevated glycated CD59 to total CD59 ratio has been clinically validated as a diagnostic marker for impaired glucose tolerance via evaluation of 38 patient samples, 10 of which were non-diabetic patients, 28 were diabetic (14 type 1, 14 type 2 diabetic). Results from Western blot analysis of concentrated urine show a strong relationship between elevated glycated CD59 levels and impaired glucose tolerance. Supporting clinical data is available on a confidential basis.

Advantages

Glycated CD59 diagnostic testing may provide evidence of pre-diabetes earlier than oral glucose tolerance testing and with greater sensitivity, dynamic range and patient convenience. When tested head to head with HbA1C in humans diagnosed with type 1 or type 2 diabetes and healthy normals, the dynamic range of the glycated CD59 diagnostic test was 3-4 fold higher and as accurate as the gold-standard HbA1c test.

The invention enables detection of impaired glucose tolerance (IGT, or "pre-diabetes") via measurement of glycated CD59 in urine and permits identification of a population at risk of developing the vascular complications associated with diabetes. This concept has been clinically validated in people by testing urine from diabetic and healthy subjects. Beyond use as a diagnostic for impaired

glucose tolerance, measuring glycated CD59 also offers a robust tool for monitoring disease progression as the glycation of CD59 can be directly linked to the pathophysiology of disease. As such, detection of glycated CD59 represents a significant advance in the detection, monitoring and prediction of diabetes and associated complications. Moreover, the single-marker urine-based test provides patients and doctors a convenient, non-invasive test with greater sensitivity, dynamic range and disease relevance than current measures of glycemic load (Hba1c, OGTT).

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