New Biomarkers for early diagnoses of type 2 diabetes mellitus improve the accuracy of current diagnostics and allow a differentiation of patients

**Background /Medical Problem**
Diabetes mellitus (DM) refers to a group of metabolic disorders characterized by elevated blood glucose concentrations. The majority (90-95%) of DM patients have type 2 DM (T2DM), which is characterized by peripheral insulin resistance and an inability of pancreatic beta cells to compensate that by increasing insulin secretion. Recent epidemiological studies indicate that only 30 to 50% of undiagnosed type 2 diabetes mellitus (T2DM) patients are identified using glycated hemoglobin (HbA\textsubscript{1c}) and elevated fasting plasma glucose (FPG) levels. Furthermore, even longitudinally measured HbA\textsubscript{1c} levels do not allow the prediction or retrospective attribution of individual T2DM-associated complications or mortality. Therefore, there is an unmet need to better predict the individual chronic hyperglycemia-related diabetes outcomes.

**Technology /Solution**
- To overcome these limitations, we studied the modification degrees of 27 glycation sites representing nine plasma proteins in newly diagnosed male T2DM patients and non-diabetic men matched for age (range: 35-65 years) and evaluated their diagnostic value alone and in combination with current WHO criteria of HbA\textsubscript{1c} and FPG levels. Selection of glycation sites relied on a list of 52 candidates we previously identified and studied.
- The new biomarkers are quantified by mass spectrometry using internal standards providing high precisions and reproducibility.
- Currently, the MS-based technology is transferred to an immunoassay to provide a higher throughput in a clinical setup.
- The combination of glycated lysine-141 of haptoglobin (HP K141) and HbA\textsubscript{1c} provide a sensitivity of 94%, a specificity of 98%, and an accuracy of 96% to identify T2DM.

**Benefits**
- High accuracy (>98%) of new biomarker set
- Classification of T2DM patients using a combination of biomarkers and clinical parameters

**Potential Application**
- Early diagnoses of T2DM
- Control of therapeutic inventions
- Prognostic marker to predict clinical complications

![Figure 1](image-url)
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Project: 16060

Development Status

Idea
Identification of glycation-dependent biomarkers in serum proteins for early diagnosis of type-2 diabetes

Demonstrator
Haptoglobin improves the accuracy of diabetes diagnostics
Combination with established clinical parameters allows a subgrouping of diabetes patients

Prototype
Sensitive analytics for 20 biomarkers established (mass spectrometry).
Development of immunoassays (ELISA) in progress

Series Production

Intellectual Property Rights
Grant of patent is intended
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Cooperation Options
- License Agreement
- R&D Agreement
- Ownership Agreement

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