

(12) **United States Patent**
Nagalla et al.(10) **Patent No.:** **US 8,476,008 B2**(45) **Date of Patent:** **Jul. 2, 2013**

- (54) **METHODS FOR DETECTING PRE-DIABETES AND DIABETES**
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- (73) Assignee: **DiabetOtics, LLC**, Beaverton, OR (US)
- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 45 days.

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C12Q 1/00 (2006.01)(52) **U.S. Cl.**
USPC **435/4**(58) **Field of Classification Search**
USPC **435/4**
See application file for complete search history.(56) **References Cited****U.S. PATENT DOCUMENTS**

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Primary Examiner — Ralph Gitomer(74) *Attorney, Agent, or Firm* — Schwabe, Williamson & Wyatt(57) **ABSTRACT**

Non-invasive methods are provided herein for the diagnosis of pre-diabetes and diabetes using biomarkers identified in a biological fluid, such as saliva. These biomarkers can be identified using proteomic methods, including but not limited to antibody based methods, such as an enzyme-linked immunosorbant assay (ELISA), a radioimmunoassay (RIA), or a lateral flow immunoassay.

16 Claims, 5 Drawing Sheets

(12) **United States Patent**
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(10) **Patent No.:** **US 8,497,077 B2**
(45) **Date of Patent:** **Jul. 30, 2013**

(54) **METHODS FOR DETECTING
PRE-DIABETES AND DIABETES USING
DIFFERENTIAL PROTEIN GLYCOSYLATION**

(75) Inventors: **Srinivasa R. Nagalla**, Hillsboro, OR
(US); **Charles T. Roberts**, Portland, OR
(US)

(73) Assignee: **DiabetOmics, LLC**, Beaverton, OR
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G01N 33/53 (2006.01)

(52) **U.S. Cl.**
USPC **435/7.1**; 435/7.2

(58) **Field of Classification Search**
None
See application file for complete search history.

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Wyatt

(57) **ABSTRACT**

Methods for identifying individuals who are not yet diabetic (pre-diabetic), but who are at significant risk of developing diabetes, such as type 2 diabetes, are disclosed herein. Methods are also provided for the identification of diabetic subjects. Also disclosed are methods for identifying individuals with diabetic complications. The methods include the identification of an overall glycosylation profile of proteins in a biological fluid, such as saliva, urine, or serum. In some examples, the methods include determining the amount of one or more protein in a biological fluid or determining the glycosylation pattern of one or more proteins in a biological fluid.

15 Claims, 7 Drawing Sheets

(12) **United States Patent**
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USPC **435/7.1**; 436/518(58) **Field of Classification Search**
None

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Primary Examiner — Jacob Cheu(74) *Attorney, Agent, or Firm* — Schwabe, Williamson &
Wyatt(57) **ABSTRACT**

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