Diabetomics' point-of-care test portfolio enables a precision medicine approach to diabetes diagnosis, monitoring, and therapy

- **Precision (or personalized) medicine is based on detailed classification of disease type or stage for the individual patient to allow more tailored and effective intervention or therapy to prevent or delay disease progression.**

- **The diabetes spectrum encompasses a wide array of clinical characteristics beyond the extremes of classical type 1 and 2 diabetes, including pre-type-1 and 2 diabetes.**

- **Precision medicine for diabetes requires comprehensive assessment of glycemic control, autoantibody status, and insulin secretory capacity.**

The use of precision medicine in diabetes is gaining increased attention (1-8) but is still in its infancy. Its application to type-1 diabetes in particular is being driven by an increased appreciation of the importance of the asymptomatic phase of the disease (9-14). Thus, a more sophisticated determination of where a specific at-risk individual is in the progression from asymptomatic to frank diabetes requires knowledge of: 1) the number and type of diabetes-associated autoantibodies; 2) the levels of C peptide that reflect insulin secretion capacity; and 3) evidence of hyperglycemia (15, 16). This more accurate classification of disease stage can allow more optimal implementation of interventions to delay or reduce disease symptoms.

An important additional aspect of accurately defining the exact nature of diabetes in young patients with suspected type-1 or 2 diabetes is the potential diagnosis of monogenic diabetes, particularly Maturity-Onset Diabetes of the Young (MODY). Optimal treatment depends on the specific MODY gene (17). A combination of C peptide and autoantibody screening can indicate confirmatory molecular genetic diagnostic testing to correctly identify MODY, allowing appropriate subsequent treatment (18).

A recent clustering analysis of Scandinavian cohorts of adult-onset diabetes defined five subgroups that were generally distinguished by autoantibody positivity, metabolic control and insulin levels, and age and BMI that were associated with distinct outcomes such as development of diabetes complications (19). Autoantibody, C-peptide, and glycemic testing along with easily obtainable measures such as age and BMI also delineates between these newly identified clusters.

DiabetOmics' Insudex™ autoantibody and C-peptide and Glucema™ short-term glycemic control (20) point-of-care tests allow convenient assessment of disease stage using the criteria above. Specifically, the combination of autoantibody, C peptide, and short-term glycemia tests provides the information necessary to employ a personalized medicine approach to diabetes screening and management.

Diabetomics, Inc. | 2345 NW Amberbrook Drive, Suite #140 | Hillsboro, OR 97006
TF: 877.748.9355 | P: 503.924.5110 | F: 503.924.5111 | www.diabetomics.com

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LITERATURE CITED

1. Ahima, RS. Editorial: rethinking the definition of diabetes for precision medicine. Mol Endocrinol 29:335-337, 2015

2. Klonoff DC. Precision medicine for managing diabetes. J Diabetes Sci Tech 9:3-7, 2015

3. Yensen J, Naylor S. The complementary iceberg tips of diabetes and precision medicine. J Precision Med Jan-Feb:21-39, 2016

4. Scheen AJ. Precision medicine: the future in diabetes care? Diabetes Res Clin Prac 117:12-21, 2016

5. Rich SS, Cefalu WT. The impact of precision medicine in diabetes: a multidimensional perspective. Diabetes Care 39:1854-1857, 2016

6. Florez JC. Precision medicine in diabetes: is it time? Diabetes Care 39:1085-1088, 2016

7. Merino J, Florez JC. Precision medicine in diabetes: an opportunity for clinical translation. Ann NY Acad Sci 1411:140-152, 2018

8. Gloyn A, Drucker DJ. Precision medicine in the management of type 2 diabetes. Lancet Diabet Endocrinol. Published April 23, 2018

9. Atkinson M, von Herrath M, Powers AC, Clare-Salzler M. Current concepts on the pathogenesis of type 1 diabetes- considerations for attempts to prevent and reverse the disease. Diabetes Care 38:979-988, 2015

10. Bonifacio E. Predicting type 1 diabetes using biomarkers. Diabetes Care 38:989-996, 2015

11. Ziegler A-G, Bonifacio E, Powers AC, et al. Type 1 diabetes prevention: a goal dependent on accepting a diagnosis of an asymptomatic disease. Diabetes 65:3233-3239, 2016

12. Bonifacio E, Mathieu C, Nepom G, et al. Rebranding asymptomatic type 1 diabetes: the case for autoimmune beta cell disorder as a pathological and diagnostic entity. Diabetologia 60:35-38, 2017

13. Regnell SE, Lernmark A. Early prediction of autoimmune (type 1) diabetes. Diabetologia 60:1370-1381, 2017

14. Jacobsen LM, Haller MJ, Schatz DA. Understanding pre-type 1 diabetes: the key to prevention. Front Endocrinol 9:70, 2018

15. Dabelea D, Pihoker C, Talton JW, et al. Etiological approach to characterization of diabetes type. Diabetes Care 34:1628-1633, 2011232.

16. Redondo MJ, Rodriguez LM, Escalante M, et al. Types of pediatric diabetes mellitus defined by anti-islet autoimmunity and random C-peptide at diagnosis. Ped Diabetes 14:333-340, 2013

17. McDonald TJ, Ellard S. Maturity onset diabetes of the young: identification and diagnosis. Ann Clin Biochem 50:403-415, 2013

18. Shields BM, Shepherd M, Hudson M et al. Population-based assessment of a biomarker-based screening pathway to aid diagnosis of monogenic diabetes in young-onset patients. Diabetes Care 40:1017-1025, 2017

19. Ahlqvist E, Storm P, Karajamaki A, et al. Novel subgroups of adult-onset diabetes and their association with outcomes: a data-driven cluster analysis of six variables. Lancet Diabet Endocrinol 6:361-369, 2018

20. Rao PV, Laurie A, Bean ES, et al. Salivary protein glycosylation as a noninvasive biomarker for assessment of glycemia. Journal of Diabetes Science and Technology. 9:97-104, 2015