Diabetomics Insudex™ Multiple Autoantibody Point-of-Care Test Facilitates Differential Diagnosis and Screening in Type 1 Diabetes

The concept of diabetes as a complicated spectrum of disorders has emerged over the last several years. Long divided into juvenile type-1 diabetes (T1D) and adult type-2 diabetes (T2D), it was realized that there were many cases of diabetes with intermediate characteristics such as adult onset and lack of immediate insulin requirement. This intermediate category was originally termed latent autoimmune diabetes of adults, or LADA[1], although the distinction between LADA and adult-onset T1D is controversial. More recently, T1D itself has been subdivided into categories based on age at diagnosis[2] or on a combination of parameters in adult-onset T1D[3]. It is also becoming apparent that adult-onset T1D is distinct in certain aspects from juvenile-onset T1D[4], and that the worldwide incidence of adult-onset T1D is substantial[5]. Accurate diabetes diagnosis is also complicated by the obesity epidemic, which has increased the incidence of obesity in children and adolescents, leading to misclassification of early-onset T2D as T1D.

Another important aspect of T1D is the presence of a significant presymptomatic stage[6-8] that represents a window for the implementation of new monoclonal and small-molecule approaches that delay disease progression[9,10]. The emergence of these new therapeutic agents has resulted in increased interest in expanding screening for T1D from at-risk groups to the general population[11,12]. In fact, the availability of interventions to delay frank T1D has resulted in T1D generally meeting all of the standard criteria for justification of population screening[12,13]. The cost-effectiveness of general screening in a pediatric population was recently demonstrated[14].

The principal biomarkers for T1D risk are diabetes-associated autoantibodies, whose number and, in some cases, affinity, can predict the risk for T1D[15]. The main autoantibodies employed in screening are those directed at insulin, GAD65, and IA-2. Antibodies against ZnT8 are also present in a proportion of at-risk individuals, but their measurement does not appreciably increase the rate of detection[16]. The number of antibodies reflects disease risk in pediatric populations, with 2 or more indicating significant risk. GAD65 is the predominant antibody in adult-onset T1D, but recent studies suggest that screening for GAD65 as well as IA-2 antibodies is justified in this group as well[17].

Diabetomics Insudex™ autoantibody test enables rapid, quantitative, point-of-care testing of insulin, GAD65, and insulin antibodies as well as C-peptide in fingerstick whole blood, serum, or plasma. The test employs proinsulin, N-terminally truncated GAD65, and the IA-2 intracellular domain as capture antigens, as these versions have been demonstrated to increase detection of progression-associated autoantibodies[15, 18-22].

The Insudex™ test:

- **Identifies individuals at risk for development of T1D**
- **In conjunction with C-peptide, allows staging of presymptomatic T1D**
- **In conjunction with C peptide, BMI, blood glucose, and age of onset, stratifies adult-onset T1D**
- **Aids in distinguishing T1D from T2D in adolescents and children with dysglycemia**

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