For Healthcare Professionals

EARLY DETECTION

of Type-1 Diabetes (T1D) and Latent Autoimmune Diabetes in Adults (LADA)

INSUDEX®

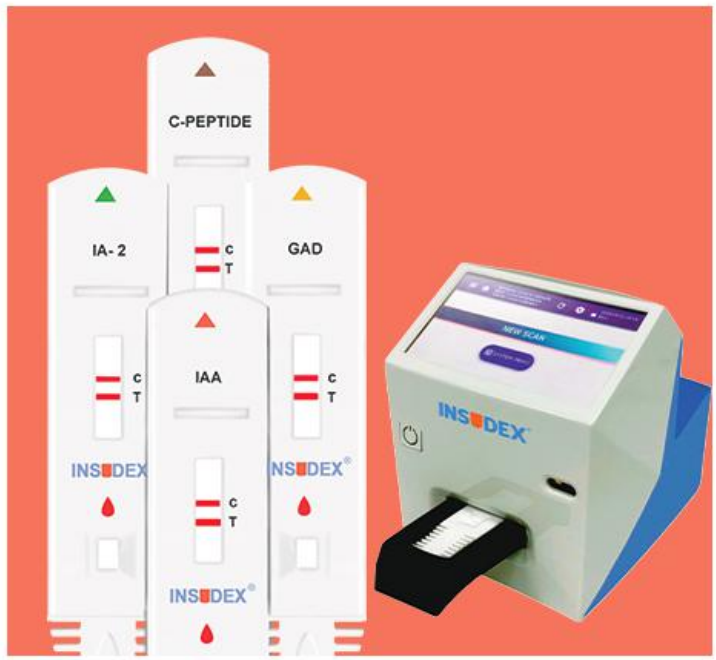
INSUDEX® OFFERS POINT-OF-CARE DIABETES TESTING AND MONITORING

Easy to use: Portable, quantitative reader for in-office or field screening

Minimally invasive: Easily obtained sample types include fingerstick, serum or plasma

Rapid results: Results in 20 minutes

Quality controlled: Data matrix codes for lot and test specification ensures test quality



TWO PRIMARY CLINICAL INDICATIONS

Early detection of type 1 diabetes (T1D)
Autoimmune T1D is preceded by a pre-clinical period characterized by the appearance and persistence of islet cell autoantibodies. For children, the number of these autoantibodies is a better predictor of disease risk than the presence of any single autoantibody.

Accurate diagnosis of latent autoimmune diabetes in adults (LADA)
Adults with presumed type 2 diabetes (T2D) have islet cell autoantibodies characteristic of T1D in children. This "mixed" form of diabetes is called LADA, Type 1.5 diabetes or double diabetes.

4-14% of T2D subjects are actually LADA and often mis-diagnosed and mis-treated

The only confirmatory diagnosis of LADA is to screen for autoantibodies (GAD, IA2) and C-peptide

Currently there is no simple and rapid way to screen and identify LADA subjects

Laboratory based tests are minimally available and results take up to two weeks

INSUDEX® provides a rapid and reliable solution to LADA diagnosis

WHO SHOULD BE TESTED?

- Children with suspected classical T1D and their siblings
- Children or adolescents who present with putative T2D, but who may, in fact, have T1D. These patients are a distinct group that is indistinguishable without autoantibody screening, and may benefit from different interventions.
- Adults suspected of having T1D, since a significant porportion of T1D patients are diagnosed as adults.
- Patients with established or pre(type-2) diabetes, in which the presence of autoantibodies in addition to insulin resistance may predict a more rapid progression to insulin deficiency.
- Diabetes patients who have autoimmune complications such as celiac disease or autoimmune thyroid disease.
- Pregnant women with putative gestational diabetes who may have undiagnosed T1D.

SPECIFICATIONS

Product	Cut-off value	Sensitivity	Specificity	PPV	NPV
Insudex® GAD Test	29 IU/mL	88% (95% C.I= 82-93%)	98% (95% C.I= 96-99%)	95% (95% C.I= 90-99%)	94% (95% C.I= 91-97%)
Insudex® IA-2 Test	38 IU/mL	62% (95% C.I= 54-69%)	97% (95% C.I= 92-98%)	95% (95% C.I= 88-98%)	73% (95% C.I= 66-78%)
Insudex® IAA Test	30 IU/mL	56% (95% C.I= 47-65%)	97% (95% C.I= 93-99%)	93% (95% C.I= 84-97%)	75% (95% C.I= 69-80%)

Published literature shows the clinical sensitivity of GAD antibodies in the range of 60 to 85%, IA-2 and IAA antibodies in the range of 50 26 to 7045% (depending on the clinical characteristics of the cohort). Diabetes Antibody Standardization Program: evaluation of assays for insulin autoantibodies M Schlosser et al, PMID:20871974 DOI:10.1007/s00125-010-1915-5
Comparison with predicate diabetes autoantibody assays (Kronus GAD and IA-2 ELISA tests) demonstrated a Positive Percent Agreement (PPA) of 88%-92% and Negative Percent Agreement (NPA) of 97%-98%. (Data on File)

Product	LOQ	Normal Value	Measurable Range
Insudex® C-peptide Test	0.17 ng/ml	0.5-2.0 ng/ml	0.17ng/ml-11ng/ml

INSUDEX®

diabetomics.com| insudexpoc.com

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Pending FDA approval in the USA