INSUDEX®

UTILITY OF INSULIN C-PEPTIDE POINT-OF-CARE TESTING IN DIABETES MANAGEMENT

Insulin deficiency is the proximal cause of hyperglycemia in type-1 diabetes and in advanced type-2 diabetes, although the specific mechanisms responsible differ (1). In the case of classical type 1 diabetes, this is the result of immune destruction of β cells (2). In long-standing type-2 diabetes, β cell exhaustion resulting from the demands of compensatory hyperinsulinemia to overcome insulin resistance and the deleterious effects of glucolipotoxicity combine to reduce functional β cell mass, leading to insulinopenia (3).

C peptide is the amino acid sequence between the β and a chain of mature insulin that is cleaved from proinsulin and is stored in equimolar amounts with mature insulin in the β cell secretory granule and that is released with insulin following glucose stimulation. Since C peptide is not subject to post-secretion processes that alter circulating levels of insulin, such as first-pass hepatic clearance, degradation by insulin-degrading enzyme, etc., C peptide levels are considered a superior clinical biomarker for β cell function (4) as they more directly reflect initial insulin granule release and, thus, functional β cell mass. A practical advantage of C peptide determination over insulin is that the former can be evaluated in patients undergoing insulin therapy.

The decline in C peptide during type-1 diabetes is well characterized, although many patients with long-standing type-1 diabetes can exhibit residual C peptide production that suggests persistent β cell function (5). Thus, assessment of C peptide levels in diagnosed type 1 diabetes patients may identify those for whom β cell-sparing therapies are most likely to be efficacious.

More recently, C peptide levels have emerged as an important parameter in the management of type-2 diabetes, since they can predict the need for future insulin therapy, especially when combined with postprandial glucose levels (6).

While most patients with diabetes can be accurately classified as type 1 or type 2, a substantial proportion of patients with presumed type-2 diabetes exhibit diabetes autoantibody positivity, generally to GAD65 or IA-2. This intermediate category of diabetes is termed Latent Autoimmune Diabetes in Adults, or LADA (7). Earlier studies showed that patients in this group more often failed therapy with secretagogues and progressed to insulin dependency faster (8). Determination of C peptide levels has been shown to facilitate discrimination of LADA from type-2 diabetes and to predict β cell failure in GAD65 antibody-positive LADA patients (9).

THESE DATA SUGGEST THAT C PEPTIDE DETERMINATION CAN BE AN IMPORTANT ASPECT OF DIAGNOSIS AND MANAGEMENT OF TYPE-1 AND TYPE-2 DIABETES AS WELL AS LADA.

DIABETOMICS' C PEPTIDE POC TEST WILL GREATLY FACILITATE THE INCORPORATION OF C PEPTIDE STATUS INTO ROUTINE CLINICAL CARE OF PEOPLE WITH DIABETES

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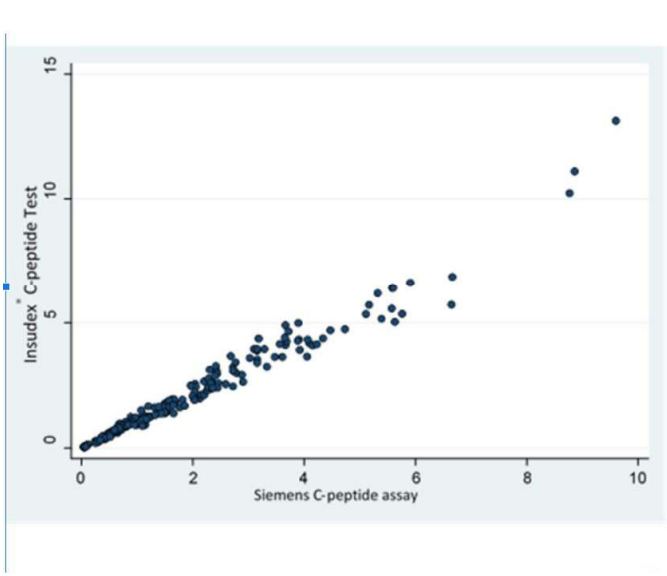
DIABETOMICS™

Product Code	Product	LoQ	Normal Value	Measurable range
2013	**Insudex® C-peptide Test**	0.17ng/mL	0.5-2.0ng/ml	0.17 -11ng/mL

Figure 1a. Correlation between results obtained in the Insudex® C-peptide POC test and the Siemens CpS assay. Insudex® C-Peptide test was compared to the Siemens ADVIA Centaur CpS assay on 200 subjects. The correlation coefficient r=0.9831.

Figure 1b. Insudex® C-peptide POC Test system.



Insudex® C-peptide lateral-flow test strip housed in a cassette(left) and quantitatuve reader (right).

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