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Autor(en) des Beitrags: Bonifacio, E; Yu, L; Williams, AK; Eisenbarth, GS; Bingley, PJ; Marcovina, SM; Adler, K; Ziegler, AG; Mueller, PW; Schatz, DA; Krischer, JP; Steffes, MW; Akolkar, B

Titel des Beitrags: Harmonization of glutamic acid decarboxylase and islet antigen-2 autoantibody assays for national institute of diabetes and digestive and kidney diseases consortia.

Abstract: Autoantibodies to islet antigen-2 (IA-2A) and glutamic acid decarboxylase (GADA) are markers for diagnosis, screening, and measuring outcomes in National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) consortia studies. A harmonization program was established to increase comparability of results within and among these studies. Large volumes of six working calibrators were prepared from pooled sera with GADA 4.8-493 World Health Organization (WHO) units/ml and IA-2A 2-235 WHO units/ml. Harmonized assay protocols for IA-2A and GADA using (35)S-methionine-labelled in vitro transcribed and translated antigens were developed based on methods in use in three NIDDK laboratories. Antibody thresholds were defined using sera from patients with recent onset type 1 diabetes and healthy controls. To evaluate the impact of the harmonized assay protocol on concordance of IA-2A and GADA results, two laboratories retested stored TEDDY study sera using the harmonized assays. The harmonized assays gave comparable but not identical results in the three laboratories. For IA-2A, using a common threshold of 5 DK units/ml, 549 of 550 control and patient samples were concordantly scored as
positive or negative, specificity was greater than 99% with sensitivity 64% in all laboratories. For GADA, using thresholds equivalent to the 97th percentile of 974 control samples in each laboratory, 1051 (97.9%) of 1074 samples were concordant. On the retested TEDDY samples, discordance decreased from 4 to 1.8% for IA-2A (n = 604 samples; P = 0.02) and from 15.4 to 2.7% for GADA (n = 515 samples; P< 0.0001). Harmonization of GADA and IA-2A is feasible using large volume working calibrators and common protocols and is an effective approach to ensure consistency in autoantibody measurements.

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