Abstract:

Autoantibodies to IA-2? (IA-2?A) are important risk markers of type 1 diabetes. We report the first Diabetes Antibody Standardization Program (DASP) evaluation of IA-2?A assays. Thirteen laboratories from nine countries received coded sera from 50 patients with newly diagnosed type 1 diabetes and 100 healthy blood donors. IA-2?A results were analyzed using receiver operating characteristic (ROC) curves. Concordance of antibody levels was compared using counts per minute (cpm), local and standard curve-derived common units. Median laboratory-assigned sensitivity was 47% (interquartile range [IQR] 45-51), specificity 98% (IQR 95-99), adjusted sensitivity at 95% specificity 50% (IQR 49-53), and area under the ROC curve 0.70 (IQR 0.69-0.73). Use of common IA-2?A units improved concordance between assays compared with local units and cpm (P < 0.0001). IA-2?A assays in multiple laboratories worldwide achieved good concordance and high specificity for type 1 diabetes. IA-2?A are suitable for inclusion in autoantibody testing for risk assessment in prediabetes.