Background
Insulin autoantibodies are often the first autoantibody to appear prior to the development of Type 1A diabetes in children after birth. Almost all children developing Type 1A diabetes prior to age five express insulin autoantibodies, while children developing after age 12 and adults much less often express insulin autoantibodies. However, the detection of human insulin autoantibodies that are associated with the development of Type 1A diabetes has proven problematic. Although testing using radioactive insulin can be used to measure concentrations of antigens, the variations in specificity and sensitivity between laboratories have remained a major problem.

Enzyme-linked immunosorbent assays (ELISAs) are plate-based assays designed for detecting substances such as peptides, proteins, and antibodies. Standard ELISA assays bind insulin to solid mediums such as ELISA plates and attempt to detect anti-insulin antibody binding to the plate bound insulin. However, standard ELISA formats are unable to detect insulin autoantibodies of non-insulin treated new onset diabetic patients or individuals progressing to Type 1 diabetes.

Technology
A research team led by Drs. George Eisenbarth and Liping Yu at the University of Colorado has developed a novel method for the diagnosis and prediction of Type 1A diabetes in prediabetic patients. By exchanging the radioactive insulin with biotinylated and sulfo-tagged proinsulin, they were able to detect insulin autoantibodies with a plate-based non-radioactive assay. This new method of plate capture for highly reproducible, non-radioactive testing for insulin autoantibodies can lead to the development of multiple assay formats to improve the prediction of Type 1A diabetes.

Data Update
In recent testing, all but one of the patient samples exceeded the control samples, with one control having a high level of antibody to proinsulin. This assay has now been extended to detection of GAD65 and is being applied to other auto-immune antibodies.

Key Documents