Innovations
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

Multiplex Assays for Simultaneous Screening of Type 1 Diabetes and Comorbidities

Category

Diagnostics

Problem

Mass screening of Type 1 Diabetes (T1D) and its comorbidities is a laborious and inefficient process

Technology Overview

Assays for simultaneous screening of T1D and its comorbidities using autoantibodies

IP Status

- Available for Exclusive or Non-Exclusive Licensing

Value Proposition

- Accurate, simultaneous screening of multiple diseases
- Can detect up to ten autoantibodies at the same time
- Can detect autoantibodies at an earlier stage than current techniques

Market Attractions

- Immunoassay market to read $27B by 2023 with CAGR of 6.1%

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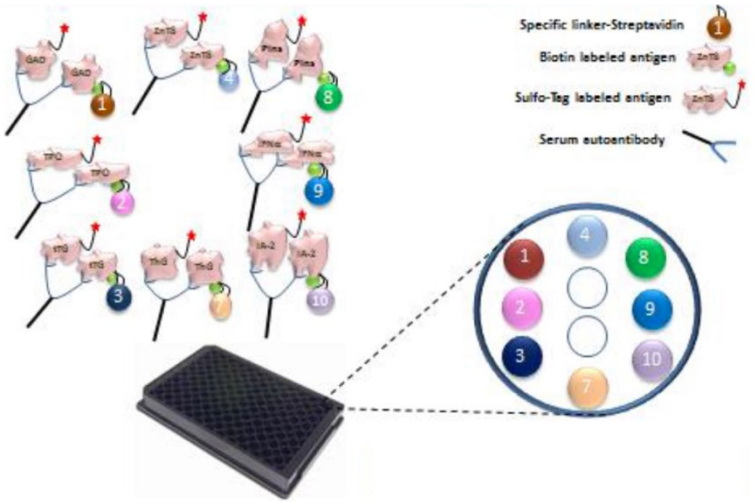
Problem: The incidence of type 1 diabetes (T1D) had doubled over the last 20 years and it affects at least 1.4 million people in the US alone. Early detection, before symptom onset, can improve outcomes, decrease hospitalizations, and allow those diagnosed with T1D to participate in studies. Preventative trials for T1D are underway, but mass screening for eligible subjects remains a laborious and inefficient process. Nearly all children positive for two or more islet autoantibodies (iAbs), including insulin, glutamic acid decarboxylase, islet antigen 2 and zinc transporter 8, develop clinical T1D. There are multiple diseases frequently seen in children with T1D that can also be diagnosed using autoantibodies including celiac disease, autoimmune thyroiditis, and autoimmune polyglandular syndrome type 1 (APS-1). There is a need for efficient diagnostics which can screen for T1D and its comorbidities simultaneously.

Solution: Physicians from the University of Colorado have developed multiplex assays which can be used for high throughput, simultaneous screening of T1D and its comorbidities using autoantibodies. These assays can measure up to ten autoantibodies using separate linkers for each labeled antigen and electrochemiluminescence detection. They require a small volume and can be performed with as little as 6ul of blood. The inventors successfully created an 8-plex assay which allowed for screening of T1D, celiac disease, autoimmune thyroiditis, and APS-1 in a single well of a 96 well plate as shown in the figure. This multiplex assay was validated using T1D and healthy patient samples and retained 100% sensitivity for all autoantibodies.



Advantages and Value Propositions: This novel multiplex assay allows for accurate, simultaneous and quantitative screening for type 1 diabetes and celiac disease in a single well. In comparison with the standard autoantibody radio assay, this method is nonradioactive, more sensitive, can detect iAbs at an earlier stage, and can measure whether multiple antibodies are present in a sample. In addition, there are less false positive results due to interference from other autoantibodies present. It can also be used to screen for other diseases in which autoantibodies play a role including rheumatoid arthritis, and Systemic lupus erythematosus and the autoimmune hepatitis.

Additional Documents and Sources:

"Software that identifies sleep states from deep brain signals." Provisional patent application No. 62/256,624 filed November 17, 2015; available under NDA.

Zhao Z, Miao D, Michels A, et al. A multiplex assay combining insulin, GAD, IA-2 and transglutaminase autoantibodies to facilitate screening for pre-type 1 diabetes and celiac disease. *Journal of Immunological Methods*. 2016;430:28-32. doi:10.1016/j.jim.2016.01.011

About CU Innovations

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