

DIABETES AUTOANTIBODY STANDARDIZATION PROGRAM (DASP)

<http://www.idsoc.org/DASPhome.html>

Description of Project

- The fundamental aim of DASP is to improve the measurements of the autoantibodies predictive of Type 1 Diabetes Mellitus (T1DM).
- Autoantibodies are the best predictive tests for type 1 diabetes of any presently available tests, and they are being used extensively in a variety of international consortia in combination with genetic screening to identify individuals at an elevated risk of developing type 1 diabetes. These tests serve as the current “gold” standard for prediction and diagnosis of T1DM.
- The DASP sets of sera are characterized by data from the best international T1DM autoantibody laboratories and serve as reference materials for the evaluation of new serum based methods for the prediction and diagnosis of type 1 diabetes.
- The specific aims:
 - Help laboratories improve methods by providing technical support, training, and information about the best methods;
 - Evaluate laboratory performance of the assays with extensive analysis of assay characteristics, sensitivity, and specificity;
 - Support the development of highly sensitive and specific measurement technologies;
 - Develop reference methods and reference materials as an accuracy base.

Accomplishments

- Three DASP Workshop Evaluations have occurred (DASP 2000, DASP 2002, DASP 2003) and a fourth is planned for early 2005.
- 47 key laboratories in 17 countries participated in DASP 2003, including 11 in the United States.
- Extensive data analysis has been done for DASP 2000 and DASP 2002 and presented at the IDS meetings in Chennai, India in 2001, in Denver, Colorado in 2002, and in Cambridge, U.K. in 2004.
- For the first time, a commercial ELISA assay in the hands of two different laboratories demonstrated the best performance for GAD autoantibodies of all laboratories.
- Performance of other commercial kits was documented and reported to manufacturers to serve as a basis of further product development.
- The insulin autoantibody (IAA) assay performance still varies greatly among laboratories, but certain laboratories that have participated in DASP for at least two workshops and that participated in the 2003 insulin autoantibody training demonstrated improvement in sensitivity and specificity.
- DASP Reference laboratories have been designated based on those with the highest demonstrated assay sensitivity and specificity.
- A second insulin autoantibody training program is planned for the fall of 2004.

- Additional factors have been identified that improved insulin autoantibody assay performance.
- Publication of a summary of the results of the DASP 2000 workshop (Mueller PW, et. al. Diabetes Technology & Therapeutics 4:397-400, 2002).
- Publication of the full DASP 2000 workshop analysis (Bingley PJ, et. al. Diabetes 52:1128-1136, 2003).
- Establishment of extensively characterized sets of reference sera.

Future directions

- Continue evaluation of laboratory autoantibody analysis performance and evaluation of new methods to predict type 1 diabetes.
- Continue reference method development and identification of key methodological factors.
- Continue to create reference material sets to evaluate new methods and new analytes.
- Continue support for designated reference laboratories to provide reference values and training.
- Establish DASP collaborations with investigators studying new technological approaches to improve the prediction and diagnosis of type 1 diabetes.
- Prepare sets of 500 healthy controls with the same demographic distribution as the controls in DASP to: 1) to aid laboratories in investigating why some samples from the population are positive while not resulting in the development of diabetes, 2) to provide samples to aid in establishing cut-offs, and 3) to provide for long-term quality control of assay specificity in on-going studies such as TEDDY.

Materials to be made available to researchers

- Evaluation and reference sera sets consisting of sera from newly diagnosed type 1 diabetes patients and population controls.
- Sets of 500 control sera with the same demographic distribution as the controls in DASP.
- Results of performance provided to the individual participants.
- Results of data analyses and data summaries.
- Comparisons of results from newly developed methods with those from the best currently available methods.

The access policy for these materials is currently being established. In the interim, please direct requests for information to:

Dr. Patricia Mueller
Centers for Disease Control and Prevention
Phone: (770) 488-4015
E-mail: PMueller@cdc.gov

Participants

Sponsors: Centers for Disease Control and Prevention
 Immunology of Diabetes Society
 Research Triangle Institute