



# SUGGESTED PROCEDURAL GUIDELINE

## Autoantibody Screening Protocol

### IA-2 and GADA

### OPPC-GDL-24

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**Network for Pancreatic Organ Donors with Diabetes (nPOD)**

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nPOD OPPC - Suggested Procedural Guideline	
GDL Number and Version: 24.1      Supersedes: nPOD 6	TITLE: IA-2 ANTIBODY PROTOCOL
Original Effective Date: 08/01/08	
Version Effective Date: 03/07/12	Page 2 of 4

## IA-2 ANTIBODY PROTOCOL

- POLICY:** Use universal safety precautions when handling human samples and personal protective equipment (e.g., face mask with shield, gloves, lab coat or apron).
- PURPOSE:** The purpose of this Suggested Procedural Guideline (GDL) is to outline process of screening for autoantibodies related to Type 1 Diabetes: GADA, IA-2A, mIAA, and ZnT8A.
- SCOPE:** This GDL will be applied to all nPOD staff and operations at any location to ensure compliance with all nPOD, University of Florida, and related institution policies and practices.
- RESPONSIBILITIES:** Managers and supervisors - are responsible for making sure that technicians are properly trained and equipment and facility are maintained in good working order.
- Laboratory personnel - are responsible for reading and understanding this GDL and related documents and to perform these tasks in accordance with the GDLs. They are responsible for following clinical laboratory and tissue banking best practices.
- EQUIPMENT & MATERIALS:** The materials, equipment and forms listed in the following list are recommendations only and alternative products as suitable may be substituted for the site-specific task or procedure. Please refer to the following GDLs for specific equipment and materials needed:
- IA-2 Antibody Protocol
  - GAD Antibody Protocol
  - Shipping: Positive Samples

### PROCEDURE:

#### 1.0 Screening Process

##### 1.1 OPO/Donors Screened

1.1.1 Serum from non-T1D donors that meet nPOD criteria (standard Operating Procedure for *Exclusion and Inclusion Criteria for nPOD Donors*) is:

1.1.1.1 Sent to the screening lab for GADA and IA-2A testing.

1.1.2 Results reported from the screening lab.

1.1.2.1 The OPO offers the case to nPOD if the screen is positive for both GADA and IA-2A.

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Original Effective Date: 08/01/08	
Version Effective Date: 03/07/12	Page 3 of 4

1.1.3 A blood sample is drawn prior to organ recovery and sent with the case to nPOD. This sample is referred to as the “recovery” sample.

## 1.2 Screening Lab

1.2.1 Serum samples received from OPOs

1.2.1.1 Run on the Kronus-ELISA to test for GADA and IA-2A, see nPOD24: IA-2 Antibody Protocol and nPOD25: GAD Antibody Protocol.

1.2.2 *Results*

1.2.2.1 Immediately reported to the OPO

1.2.2.2 Reported monthly to the nPOD lab, includes the following:

1.2.2.2.1 Accession#

1.2.2.2.2 UNOS Identifier

1.2.2.2.3 Reported Date

1.2.2.2.4 OPO

1.2.2.2.5 GADA

1.2.2.2.6 IA2

1.2.2.3 500µl aliquot from all positive screens and 10% of the negative screens are sent to the nPOD lab.

1.2.2.3.1 For shipment specifics, refer to the SOP for Shipping.

## 1.3 POD Lab (Gainesville, FL)

1.3.1 5.3.1 Receives the screen sample aliquot from the screening labs.

1.3.2 Receives the recovery sample aliquot from nPOD OPPC (Case Processing).

1.3.3 All samples are run on the Kronus-ELISA for GADA, IA-2A, and ZnT8A.

1.3.4 An aliquot from each sample is sent to the Autoantibody Core.

## 1.4 Autoantibody Core (Denver, CO)

1.4.1 Receives screen and recovery sample aliquots.

1.4.2 Runs all samples on the RIA for GADA, IA-2A, mIAA, and ZnT8A.

1.4.3 Reports results to the nPOD lab.

## 1.5 Quality Assurance/Quality Control

1.5.1 Islet Autoantibody Standardization Program (IASP)

1.5.1.1 Both the nPOD lab and the Autoantibody Core participate.

1.5.2 Proficiency Testing

1.5.2.1 Twice per year the nPOD lab sends 5 blinded samples to all screening labs and the Autoantibody Core.

1.5.2.2 Results are collected and compared for concordance. See Appendix B for results from April 2012.

## 1.6 Decision and Reporting

1.6.1 *Results*

1.6.1.1 All data is tracked by nPOD.

1.6.1.2 Data is shared with City of Hope and uploaded to the autoantibody database.

1.6.2 *Decision*

1.6.2.1 When all labs agree on all samples within a case, the decision is clear.

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1.6.2.2 When discrepancy between labs on a sample occurs, the results are reviewed by Mark Atkinson, George Eisenbarth, and Alberto Pugliese for an official decision.

1.6.3 *Reporting*

1.6.3.1 Within each case in Spectrum, autoantibodies that are positive are reported.

1.6.3.2 Upon request, all data for a sample is available.

**REFERENCES:**

**1.0 Appendices and Related Documents**

- 1.1 Autoantibody Screening Process Diagram (Appendix A)
- 1.2 Exclusion and Inclusion Criteria for nPOD Donors
- 1.3 OPPC-GDL-24.1 IA-2 Antibody Protocol
- 1.4 OPPC-GDL-25.1 GAD Antibody Protocol
- 1.5 OPPC-GDL-33 Shipping from Autoantibody Screening Labs
- 1.6 OPPC-GDL-57.5 Case Processing
- 1.7 Eisenbarth, G.S. and McCulloch, D.K. (2008). Pathogenesis of type 1 diabetes mellitus.
- 1.8 Bonifacio, E., Yu, L., Williams, A.K., Eisenbarth, G.S., Bingley, P.J., Marcovina, S.M., Adler, K., Ziegler, A.G., Mueller, P.W., Schatz, D.A., Krischer, J.P., Steffes, M.W. & Akolkar, B. (2010). Harmonization of glutamic acid decarboxylase and islet antigen-2 autoantibody assays for national institute of diabetes and digestive kidney diseases consortia. *Journal of Clinical Endocrinology & Metabolism*, 95:3360-7.

**REVISION HISTORY:**

Version	Date	Revision
0	03/07/12	Added a reference. AW

	Name	Signature	Date
Prepared by	Clive Wasserfall		
Approved by	Mark Atkinson		