

# SOP-NOD-0009 Blood Collection

## STANDARD OPERATING PROCEDURE

### Pre-clinical Consortium on Combination Therapies for Type I Diabetes

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Document #: SOP-NOD-0009.03

Version #: 03

Supersedes: 02

Effective Date: September 1, 2011

Applicable to: ITN Project 1

Category:

**Title: Blood Collection**

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#### INTRODUCTION/PURPOSE

The goal of this study is to determine the efficacy of anti-CD20 monoclonal antibody therapy (alone), oral insulin (alone), or the combination of anti-CD20 plus oral insulin to reverse hyperglycemia in NOD mice with recent onset autoimmune diabetes.

The purpose of this Standard Operating Procedure is to describe the timing of blood collections and quantities required for this study. This SOP does not apply to blood collection for blood glucose monitoring. Refer to *SOP-NOD-005.00: Blood Glucose Monitoring* for the schedule of blood glucose assessments.

#### DEFINITIONS

Therapy failure: For purposes of removing animals from the study for euthanasia. Maximum weight loss as permitted by each site's IACUC (or 20% weight loss if IACUC does not have a weight loss restriction) or 3 consecutive maximum blood glucose measurements as permitted by each site's IACUC (or 3 consecutive blood glucose measurements of  $\geq 500$  mg/dl (28 mmol/L) if IACUC does not have a guideline for blood glucose measurements).

Therapy success: Two consecutive blood glucose measurements of  $< 250$  mg/dl or 14 mmol/L after 120 days post-onset of diabetes.

#### PROCEDURES

1. Blood collection will be performed on days 1, 30, 60 and 90 post-onset, and at study endpoint.
2. On days 1, 30, 60, and 90, collect 25-50 microliters of serum (from 50-100ul whole blood). Store serum at -20 degrees Celsius for future assessment.
3. At study endpoint, collect maximum attainable volume of whole blood via cardiac puncture during necropsy as described in SOP-NOD-0011 Mouse Necropsy. Separate out serum from whole blood. Store serum at -20°C for future assessment.

#### DOCUMENTATION TO BE MAINTAINED

#### REFERENCES TO OTHER APPLICABLE SOPS

SOP-NOD-0003.00: Study Endpoints

SOP-NOD-0005.00: Blood Glucose Monitoring

SOP-NOD-0010.00: Schedule of Assessments

SOP-NOD-0011.00: Mouse Necropsy

**REFERENCES**

**FORMS/ATTACHMENTS**

**REVISION HISTORY**

<b>Effective Date</b>	<b>Revision</b>	<b>Author</b>	<b>Description of Changes</b>
8/22/11	01	T Kupfer	Corrected symbols that did not import into the program properly and added the volume of serum to be collected and storage criteria.
8/23/11	02	A Posgai	Corrected blood collection schedule and added description of terminal blood collection.
9/1/2011	03	T Kupfer	Changed definition of therapy failure to be consistent with <a href="#">SOP-NOD-0003 Study Endpoints</a> .