

CIT-03: PERITRANSPLANT DEOXYSPERGUALIN IN ISLET TRANSPLANTATION IN TYPE 1 DIABETES

LABORATORY MANUAL FOR CIT-03 STUDY-SPECIFIC CENTRAL ASSESSMENTS

**VERSION 7.0
MAY 14, 2013**

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1. CIT-03 DCC COORDINATOR INFORMATION

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2. CIT-03 CENTRAL LABORATORY SPECIMEN SCHEDULE

Central Laboratory Assessments					
Assessment	Laboratory	Visit / Time-point	Volume	Collection Container	Shipping Instructions
Hemoglobin A1c (HbA1c)	University of Washington	Visits 15, 18, 19, 20, 1Y, 21, 22, 23, 24, Y2	2 mL Blood	(1) 2-mL Lavender top EDTA Vacutainer	Ship on cold pack within 24 hours of collection. Ship Monday-Thursday only.
Fasting serum glucose and c-peptide / serum creatinine	University of Washington	Visits 12, 14, 15†, 16, 17, 18*, 19*, 20, 1Y, 22, 24, Y2	2 mL Blood	(1) 3.5-mL Gold SST	Ship on dry ice in batches at least weekly. Ship Monday – Thursday only.
MMTT: Stimulated serum glucose and c-peptide	University of Washington	Visits 15†, 18, 19, 20, 1Y, 22, 24, Y2	4 mL Total Blood <ul style="list-style-type: none"> • 2 mL at 60 minutes (only if checking for graft failure) • 2 mL at 90 minutes (Note: the Fasting serum glucose and c-peptide/serum creatinine is the 0 hour sample for the MMTT)	(2) 3.5-mL Gold SST	Ship on dry ice in batches at least weekly. Ship Monday – Thursday only.
Insulin Modified FSIGT	University of Washington	Visits 15†, 20, 1Y	48 mL Total Blood <ul style="list-style-type: none"> • 2 mL each at -10, -5, and -1 minutes pre-injection of glucose • 2 mL each at 1, 2, 3, 4, 5, 7, 10, 12, 14, 16, 18, 20, 22, 25, 30, 40, 50, 70, 100, 140, and 180 minutes post injection of glucose 	(24) 3.5-mL Gold SST	Ship on dry ice in batches at least weekly. Ship Monday – Thursday only.
Atherogenic Profile	University of Washington	Visit 1Y, 24	8.5 mL Blood	(1) 8.5 mL Gold SST	Ship on dry ice in batches at least weekly. Ship Monday-Thursday only.
Alloantibodies	University of Pennsylvania	Visits 03 ^o , 15, 18, 19, 20, 1Y, 22, 24	2 mL Blood	(1) 3-mL Red-top Vacutainer	Ship on dry ice in batches at least quarterly. Ship Monday – Thursday only.
Autoantibodies	Barbara Davis Center	Visits 15, 18, 19, 20, 1Y, 22, 24	2 mL Blood	(1) 3-mL Red-top <u>OR</u> (1) 3.5 mL Gold SST	Ship on dry ice in batches at least quarterly. Ship Mon. – Wed only. If collected on Thurs or Fri, freeze serum at -20°C or -70°C until Mon, Tues, or Wed. in dry ice.
Serum to Archive	NIDDK Repository	Visits 15, 18, 19, 20, 1Y	4 mL Blood	(1) 4-mL Gold SST	Ship in batches at least quarterly.

Central Laboratory Assessments					
Assessment	Laboratory	Visit / Time-point	Volume	Collection Container	Shipping Instructions
Plasma to Archive (see below)	NIDDK Repository	Visits 15, 18, 19, 20, 1Y	10 mL Blood	(1) 10-mL Na Heparin Vacutainer	Ship in batches at least quarterly.
GFR	University of Minnesota	Visits 12, 15, 20, 1Y, 24	10 mL Blood 2 mL each at 120, 150, 180, 210 and 240 minutes	(5) 2-mL Na Heparin Tube	Ship in batches weekly on dry ice. Ship Mon – Thurs.
Albumin/Creatinine Ratio	University of Minnesota	Visits 12, 15, 20, 1Y, 22, 24	5 mL Urine	Sterile Urine Container	Ship in batches weekly, frozen on dry ice. Ship Monday – Thursday.

* If blood is drawn locally at Months 7, 8, 10 and 11 (Visits 18a, 18b, 19a and 19b, respectively), sample should be sent from local lab to study site and then shipped to the central laboratory.

† Do not collect these samples at Day 75 for subjects with confirmed graft failure.

° Collect these samples beginning on Day -2 (pre-IS) for Visit 03.

Plasma to Archive Note– Specimen kits will not be modified to reflect the changes to archived samples. To collect Plasma to Archive samples, use one of the three PBMC/Plasma to Archive primary tubes that are currently in the kits. Draw only one green-top and discard the other two. To aliquot, take (3) 1.8 mL cryovials from bulk supply. Label each with an extra barcode label from the set inside the kit lid. In the STS (Process and Aliquot step), you will scan each of these aliquots as an extra sample and choose “Plasma to Archive” as the specimen type. On the kit requisition form, add (write in) a section for the Plasma to Archive samples. Ship the Plasma to Archive with the Serum to Archive to the NIDDK Repository.

Serum to Archive
 1 x 4 ml Gold top SST tube

Collect 4 ml of blood. Process serum according to CIT General Laboratory Manual and aliquot equally into 3 x 1.8 ml cryovials. Freeze at -70C. Batch ship on dry ice at least quarterly Monday-Thursday to NIDDK Repository.



Plasma to Archive

3

on the requisition, under Serum to Archive, write in Plasma to Archive with 3 aliquots

3. CIT-03 KIT COMPONENTS

Visit 03 Day -2 through Day 0	Kit #3	TAT, C3a and c-peptide (5) 2 mL EDTA Vacutainer (Lavender top) (5) 1.8 mL cryovials	Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial
Visit 12 Day 28	Kit #4	Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials Albumin/Creatinine Ratio (1) Urine Specimen Container (1) 4-mL cryovial	GFR (5) 2-mL Na Heparin Vacutainer Tubes (5) 1.8-mL cryovials
Visit 14 Day 56	Kit #5	Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials	
Visit 15 Day 75	Kit #6	*Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials *MMTT (stimulated glucose and c-peptide) (2) 3.5-mL Gold SST (4) 1.8-mL cryovials HBA1C (1) 2-mL EDTA Vacutainer Tube Albumin/Creatinine Ratio (1) Urine Specimen Container (1) 4-mL cryovials *FSIGT (24) 3.5-mL Gold SST (58) 1.8-mL cryovials	GFR (5) 2-mL Na Heparin Tubes (5) 1.8-mL cryovials Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial Autoantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial RNA to Archive (NIDDK) (3) 3-mL Tempus RNA Tube (discard) Serum to Archive (1) 4-mL Gold SST Tube (3) 1.8-mL cryovials PBMC and Plasma to Archive (3) 10-mL Na Heparin Tubes <i>Use (1) 10-mL Na Heparin Tube for Plasma and discard the other 2</i> <i>(3) 1.8-mL cryovial from bulk supply</i>
Visit 16 Day 120	Kit #5	Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials	

Visit 17 Day 150	Kit #5	Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials		
Visit 18 Day 180	Kit #7	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials MMTT (stimulated glucose and c-peptide) (2) 3.5-mL Gold SST (4) 1.8-mL cryovials HBA1C (1) 2-mL EDTA Vacutainer Tube Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial </td> <td style="width: 50%; vertical-align: top;"> Autoantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial RNA to Archive (NIDDK) (3) 3-mL Tempus RNA Tube (discard) Serum to Archive (1) 4-mL Gold SST Tube (3) 1.8-mL cryovials PBMC and Plasma to Archive (3) 10-mL Na Heparin Tubes <i>Use (1) 10-mL Na Heparin Tube for Plasma and discard the other 2</i> (3) 1.8-mL cryovial from bulk supply </td> </tr> </table>	Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials MMTT (stimulated glucose and c-peptide) (2) 3.5-mL Gold SST (4) 1.8-mL cryovials HBA1C (1) 2-mL EDTA Vacutainer Tube Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial	Autoantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial RNA to Archive (NIDDK) (3) 3-mL Tempus RNA Tube (discard) Serum to Archive (1) 4-mL Gold SST Tube (3) 1.8-mL cryovials PBMC and Plasma to Archive (3) 10-mL Na Heparin Tubes <i>Use (1) 10-mL Na Heparin Tube for Plasma and discard the other 2</i> (3) 1.8-mL cryovial from bulk supply
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Visit 18a Day 210	Kit # 5	Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials		
Visit 18b Day 240	Kit # 5	Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials		
Visit 19 Day 270	Kit #7	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials MMTT (stimulated glucose and c-peptide) (2) 3.5-mL Gold SST (4) 1.8-mL cryovials HBA1C (1) 2-mL EDTA Vacutainer Tube Autoantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial </td> <td style="width: 50%; vertical-align: top;"> RNA to Archive (NIDDK) (3) 3-mL Tempus RNA Tube (discard) Serum to Archive (1) 4-mL Gold SST Tube (3) 1.8-mL cryovials PBMC and Plasma to Archive (3) 10-mL Na Heparin Tubes <i>Use (1) 10-mL Na Heparin Tube for Plasma and discard the other 2</i> (3) 1.8-mL cryovial from bulk supply Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial </td> </tr> </table>	Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials MMTT (stimulated glucose and c-peptide) (2) 3.5-mL Gold SST (4) 1.8-mL cryovials HBA1C (1) 2-mL EDTA Vacutainer Tube Autoantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial	RNA to Archive (NIDDK) (3) 3-mL Tempus RNA Tube (discard) Serum to Archive (1) 4-mL Gold SST Tube (3) 1.8-mL cryovials PBMC and Plasma to Archive (3) 10-mL Na Heparin Tubes <i>Use (1) 10-mL Na Heparin Tube for Plasma and discard the other 2</i> (3) 1.8-mL cryovial from bulk supply Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial
Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials MMTT (stimulated glucose and c-peptide) (2) 3.5-mL Gold SST (4) 1.8-mL cryovials HBA1C (1) 2-mL EDTA Vacutainer Tube Autoantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial	RNA to Archive (NIDDK) (3) 3-mL Tempus RNA Tube (discard) Serum to Archive (1) 4-mL Gold SST Tube (3) 1.8-mL cryovials PBMC and Plasma to Archive (3) 10-mL Na Heparin Tubes <i>Use (1) 10-mL Na Heparin Tube for Plasma and discard the other 2</i> (3) 1.8-mL cryovial from bulk supply Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial			

Visit 19a Day 300	Kit # 5	Fasting Serum Glucose, C- Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials	
Visit 19b Day 330	Kit # 5	Fasting Serum Glucose, C- Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL	
Visit 20 Day 365	Kit #6	Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL cryovials MMTT (stimulated glucose and c-peptide) (2) 3.5-mL Gold SST (4) 1.8-mL cryovials HBA1C (1) 2-mL EDTA Vacutainer Tube Albumin/Creatinine Ratio (1) Urine Specimen Container FSIGT (24) 3.5-mL Gold SST (58) 1.8-mL cryovials	GFR (5) 2-mL Na Heparin Tubes (5) 1.8-mL cryovials Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial Autoantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL cryovial RNA to Archive (NIDDK) (3) 3-mL Tempus RNA Tube (Discard) Serum to Archive (1) 4-mL Gold SST Tube (3) 1.8-mL cryovials PBMC and Plasma to Archive (3) 10-mL Na Heparin Tubes <i>Use (1) 10-mL Na Heparin Tube for Plasma and discard the other 2</i> <i>(3) 1.8-mL cryovial from bulk supply</i>

<p>Visit Y1 Day 365 post- initial transplant</p>	<p>Kit #8</p>	<p>Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials MMTT (stimulated glucose and c-peptide) (2) 3.5-mL Gold SST (4) 1.8-mL Cryogenic Vials HBA1C (1) 2-mL EDTA Vacutainer Tube Albumin/Creatinine Ratio (1) Urine Specimen Container (1) 4-mL Cryogenic Vial FSIGT (24) 3.5-mL Gold SST (58) 1.8-mL Cryogenic Vials GFR (5) 2-mL Na Heparin Tubes (5) 1.8 ml Cryogenic Vials</p>	<p>Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8mL cryovial Autoantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8mL cryovial RNA to Archive (NIDDK) (3) 3-mL Tempus RNA Tube (discard) Serum to Archive (1) 4-mL Gold SST Tube (3) 1.8-mL Cryogenic Vials PBMC and Plasma to Archive (3) 10 ml Na Heparin Tubes <i>Use (1) 10-mL Na Heparin Tube for Plasma and discard the other 2</i> (3) 1.8-mL cryovial from bulk supply Atherogenic Profile (1) 8.5-mL Gold SST Tube (4) 1.8-mL Cryogenic Vials</p>
<p>Visit 21 Month 15</p>	<p>Kit #12</p>	<p>HBA1C (1) 2-mL EDTA Vacutainer Tube</p>	
<p>Visit 22 Month 18</p>	<p>Kit #9</p>	<p>Albumin/Creatinine Ratio (1) Urine Specimen Container (1) 4-mL Cryogenic Vial HBA1C (1) 2-mL EDTA Vacutainer Tube Autoantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8mL cryovial</p>	<p>MMTT (stimulated glucose & c-peptide) (2) 3.5-mL Gold SST (4) 1.8-mL Cryogenic Vials Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8mL cryovial</p>
<p>Visit 23 Month 21</p>	<p>Kit #12</p>	<p>HBA1C (1) 2-mL EDTA Vacutainer Tube</p>	

Visit 24 Month 24	Kit #10	Albumin/Creatinine Ratio (1) Urine Specimen Container (1) 4-mL Cryogenic Vial HBA1C (1) 2-mL EDTA Vacutainer Tube Atherogenic Profile (1) 8.5-mL Gold SST (4) 1.8-mL Cryogenic Vials Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8mL cryovial Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials	GFR (5) 2-mL Na Heparin Tubes (5) 1.8 ml Cryogenic Vials Autoantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8mL cryovial MMTT (stimulated glucose & c-peptide) (2) 3.5-mL Gold SST (4) 1.8-mL Cryogenic Vials
Visit Y2	Kit #11	HBA1C (1) 2-mL EDTA Vacutainer Tube Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials	MMTT (stimulated glucose & c-peptide) (2) 3.5-mL Gold SST (4) 1.8-mL Cryogenic Vials
Reduced Follow-Up (Year 1 and 2 post Initial transplant)	Kit #50	Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8mL cryovial HBA1C (1) 2-mL EDTA Vacutainer Tube	90 min c-peptide post-MMTT & serum creatinine (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials
Reduced Follow-Up (Monthly and Quarterly)	Kit #50x	Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8mL cryovial	
Suspected Graft Failure	Kit #50z	Fasting Serum Glucose, C-Peptide, Creatinine (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials MMTT (stimulated glucose and c-peptide) (2) 3.5-mL Gold SST (4) 1.8-mL Cryogenic Vials	Alloantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8mL cryovial Autoantibody (1) 3-mL Red-top Vacutainer Tube (1) 1.8mL cryovial

*Do not collect these samples at Day 75 for subjects with confirmed graft failure.

SEE APPENDIX 1 FOR KIT SUPPLY ORDER FORM

4. CIT-03 BLOOD VOLUME TABLE

CIT03 - MAXIMUM RESEARCH BLOOD VOLUME TABLE																										
TIME POINTS/VISITS																										
TIMING OF STUDY PARTICIPATION	Days							Weeks						Months												
	SCRN	BL	TX 0	1	2	3	5	1	1.5	2	3	4	6	2	2.5 (Day 75)	4	5	6, 7, 8	9, 10, 11	12	1 yr post initial tx	15	18	21	24	2 yrs post initial tx
VISIT	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18*	19**	20	1Y	21	22	23	24	2Y
BLOOD VOLUMES																										
LOCAL LABORATORY ASSESSMENTS																										
CBC (WBC + Diff & Plat)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5		5	5	5	5	
Chemistry (P18 + Mg or P20)	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4		4	4	4	4	
Lipids	4	4													4			4	4	4			4		4	
Thyroid Function	4	4																								
Serum β-HCG (females)	4																									
Serology	7	7																			7					
EBV IgG	2																									
CMV IgG, CMV IgM		4																			4					
Coagulation (PT, PTT, INR)	5	5	5																							
Blood Type & HLA		11																								
Crossmatch		10																								
PRA		10																								
Fasting and 2 post-prandial (1-3 hrs) c-pep						9		9																		
Sirolimus drug levels (trough)			4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Tacrolimus drug level (trough)					4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
CMV by PCR		4													4			4								
EBV py PCR		4																								
CENTRAL LABORATORY AND METABOLIC ASSESSMENTS																										
GFR (5 timed specimens/timept; 2 ml each)	10	10										10			10					10	10				10	
HbA1c	2	2													2			2	2	2	2		2		2	2
Fasting glucose & c-pep / serum creatinine	2	2										2		2	2	2	2	6	6	2	2					
60, 90 min c-pep, gluc (MMTT) / serum creat	4																									
90 min c-pep, gluc (MMTT) / serum creat															2			2	2	2	2		2		2	2
Insulin modified FSIGT (c-pep, insulin, gluc)		48													48					48	48					
Atherogenic profile		8.5																			8.5				8.5	
CENTRAL MECHANISTIC ASSAYS																										
Alloantibody	2	2													2			2	2	2	2		2		2	
Autoantibody		2													2			2	2	2	2		2		2	
CENTRAL ARCHIVED SAMPLES																										
Serum		4													4			4	4	4	4					
PBMC / Plasma		10													10			10	10	10	10					
TOTALS (mLs)	55.0	160.5	18.0	13.0	13.0	26.0	17.0	26.0	17.0	17.0	17.0	29.0	17.0	19.0	107.0	19.0	19.0	53.0	49.0	103.0	109.5	17.0	29.0	17.0	47.5	4.0
BL - WK 6 TOTAL (mLs)	370.5																									
YEAR TOTAL (mLs)	904.0																									

* 18, 18a, and 18b
 ** 19, 19a, and 19b

5. Kit Usage

Kit #6 (Visit 15 and Visit 20), kit #7 (Visit 18 and Visit 19), kit #8 (Visit Y1), kit #9 (Visit 22), kit #10 (Visit 24) and kit #11 (Y2) contain two 3.5-mL Gold SST tubes for the MMTT. Only one of these two tubes will be filled (at 90 minutes), unless it is suspected that the participant has suffered graft failure (in which case, the second tube should be filled at 60 minutes). If there is no suspicion of graft failure, one of the two 3.5-mL Gold SST tubes can be discarded.

Appendix 1: KIT SUPPLY ORDER FORM

Please complete form and fax to University of Iowa @ +1-319-335-6580

Protocol #: _____

Site Name: _____ Site Number: _____

Order Date: _____ Due Date @ Site: _____

Requested By: _____ Requestor's phone: _____

Requestor's FAX: _____ Requestor's email: _____

Kit(s) #	QUANTITY
Kit(s) # _____	_____
Kit(s) # _____	_____
Kit(s) # _____	_____
Kit(s) # _____	_____
Kit(s) # _____	_____

You will receive an initial supply of kits for 10 participants upon notice of your site activation. The initial supply of kits will include (1) Kit #1 through Kit# 5, per subject.

Please check your kits' expiration dates and DO NOT order more than a 6 month supply of kits.