

PPD Study Code: Sponsor: Protocol Number:
Version 1.1 10-January-2008

TITLE :

			WEEK														PHASE						PPD will provide urine dipsticks to the site. PPD will provide urine pregnancy kits to the site.					
			VISIT														Visit Designation											
			Screen	Random	Week 2	Random	Random	Week 1	Week 6	Week 12	Week 14	Week 16	Week 20	Week 24	Week 40	Discontinuation	Stop-up	Optional Visit	Optional Visit	24hr CCI	Serology	ALT, AST, ECC	ALT, AST, ECC					
			1	1.1	2	2.1	3	4	5	6	7	8	9	10	11	12	DIS	SU	OV1	OV2	OV3	OV4	OV5	OV6				
Collection Tube	Transfer Vial	Transfer Method	Lab Services																								Shipping Condition	Chemistry:
10mL Red Top	5mL transfer	Large serum filter	Chemistry																								Refrigerated	ALT, AST, Albumin, Alkaline Phosphatase, BUN;
	(off chem)		Thyroid Stimulating Hormone (visit 1 onl)																									Potassium, Protein; Sodium, Uric Acid
	(off chem)		HCG (WOCBP w/positive urine pregnancy only)																									Bicarbonate ; Bilirubin, Direct; Bilirubin, Total; Calcium;
3mL Red Top (SP)	5mL transfer (SP)	Small serum filter (SP)	Serum HCG (WOCBP w/positive urine pregnancy only)																								Refrigerated	Chloride; Creatinine; Creatinine Clearance (Estimated by Weight);
3mL Red Top (SP)	5mL transfer (SP)	Small serum filter (SP)	Thyroid Stimulating Hormone (rescreen)																								Refrigerated	
3mL Red Top (SP)	5mL transfer (SP)	Small serum filter (SP)	C Peptide (ONLY if PI suspects Type 1 Diabetes)																								Refrigerated/Frozen if shipment time is > 24 hrs	
3mL Red Top (SP)	5mL transfer (SP)	Small serum filter (SP)	ALTA/AST (rescreen)																								Refrigerated	FFPG:
3mL Red Top (SP)	5mL transfer (SP)	Small serum filter (SP)	Serum Creatinine/Estimated Creatinine Clearance (rescreen)																								Refrigerated	Glucose
			Creatinine Clearance (Classic)																								Refrigerated	
			Urine Creatinine																									Hematology auto diff:
3mL Red Top (SP)	5mL transfer (SP)	Small serum filter (SP)	Serum Creatinine (for 24hr creatinine clearance)																								Refrigerated	Basophils; Eosinophils; Hematocrit ; Hemoglobin; Lymphocytes;
2mL Oxalate Fluoride	5mL transfer	Small serum filter	FFPG																								Refrigerated	MCH; MCHC; MCV; Monocytes; Platelet; RBC; Total Neutrophils; WBC
2mL EDTA	None	None	Hemoglobin A1c																								Refrigerated	
2mL EDTA	None	None	Hematology auto diff																								Ambient	Hematology Manual diff:
Slide w/malial	None	None	Hematology Manual diff																								Ambient	Band Neutrophils; Basophils; Eosinophils; Lymphocytes;
2mL EDTA (SP)	None	None	Hemoglobin (rescreen)																								Ambient	Monocytes; RBC Morphology; Segmented Neutrophils
10mL EDTA	5mL transfer	Large serum filter	Lipid Panel																								Refrigerated	
			Beta Quant if Trig > 400mg/dL																									Lipid Panel:
			LDL																									Cholesterol, Total; HDL; LDL; Non HDL; Triglyceride
			Cholesterol >1.006 Fraction																									
2mL EDTA (SP)	5mL transfer (SP)	Small serum filter (SP)	Triglyceride (rescreen)																								Refrigerated	
7.5mL SST (SP)	None	None	Serology (if required)																									Serology:
(off serology)			Hepatitis C, Antibody by RIBA (if Hep C Ab is Positive)																								Refrigerated	Hepatitis A; Hepatitis B, Core Antibody, IgM;
6mL EDTA (SP)	5mL transfer (SP)	Small serum filter (SP)	Hepatitis C, Viral Load RNA (ONLY with Merck approval)																								Frozen	Hepatitis B, Surface Antigen; Hepatitis C, Antibody, Total
3.5mL SST (SP)	None	None	Cytomegalovirus Antibody IgM																								Refrigerated	
Urine collection cup	10mL UA transfer vial (SP)	Transfer pipet (SP)	Urinalysis w/Micro (if urine dipstick @ site is positive for blood, LE, nitrites, or protein)																								Refrigerated	Urinalysis (atlas):
10mL EDTA (SP)	None	None	Pharmacogenetic (consenting patients only)																								Ambient	Appearance; Bilirubin; Blood; Color; Glucose; Urine; Ketone;
			Meal Tolerance Test (MTT)																									Leukocyte Esterase; Nitrite; Protein; Specific Gravity; Urobilinogen; pH
			Glucose																									Urine Microscopy:
2mL Oxalate Fluoride	5mL transfer	Small serum filter	>> 0 Minutes																								Refrigerated/Frozen if shipment time is > 24 hrs	Bacteria; Granular Casts; Hyaline Casts; RBC; Red Blood Cell Casts;
2mL Oxalate Fluoride	5mL transfer	Small serum filter	>> 30 Minutes																								Refrigerated/Frozen if shipment time is > 24 hrs	Renal Epithelial Cells; Squamous Epithelial Cells; Transitional Epithelial Cells;
2mL Oxalate Fluoride	5mL transfer	Small serum filter	>> 2.0 Hours																								Refrigerated/Frozen if shipment time is > 24 hrs	WBC; Waxy Casts; White Blood Cell Casts;
			Insulin																									
4mL Red Top	5mL transfer	Small serum filter	>> 0 Minutes																								Refrigerated/Frozen if shipment time is > 24 hrs	
4mL Red Top	5mL transfer	Small serum filter	>> 30 Minutes																								Refrigerated/Frozen if shipment time is > 24 hrs	Samples sent to reference lab:
4mL Red Top	5mL transfer	Small serum filter	>> 2.0 Hours																								Refrigerated/Frozen if shipment time is > 24 hrs	Cytomegalovirus will be sent to Cleveland Clinic
	(off Insulin)		>> 0 Minutes																									Hepatitis C by RIBA will be sent to Cleveland Clinic
	(off Insulin)		>> 30 Minutes																									Hepatitis C by PCR (qualitative) will be sent to Cleveland Clinic
	(off Insulin)		>> 2.0 Hours																									
			Storage Services																									
10mL EDTA	2.5mL cryovia	Transfer pipet	Plasma Archive Storage @ -70C aliquot 1																								Frozen	
	2.5mL cryovia		Plasma Archive Storage @ -70C aliquot 2																								Frozen	
	2.5mL cryovia		Plasma Archive Storage @ -70C aliquot 3																								Frozen	
10mL Red Top	2.5mL cryovia	Transfer pipet	Serum Archive Storage @ -70C aliquot 1																								Frozen	
	2.5mL cryovia		Serum Archive Storage @ -70C aliquot 2																								Frozen	
	2.5mL cryovia		Serum Archive Storage @ -70C aliquot 3																								Frozen	
			Clinical Data																									Requisition labels:
			FASTING																									Visit 1: 9-digit baseline #, Confirmatory serum preg test required, weight, fasting
			TIME																									Visit 1.1: Fasting, weight, time & volume for 24hr urine (if applicable)
			VOLUME																									Visit 2: Fasting
			WEIGHT																									Visit 2.1: Fasting
			MEAL TOLERANCE TEST																									Visits 3, 6, 12 & DIS: 5-digit allocation # (V3 only), Fasting, weight, confirmatory serum preg test required, MTT
			CONFIRMATORY SERUM PREG TEST REQUIRED																									
			Laboratory Package																									Visits 4 & 7: Fasting

R - Reported M - Mandatory SP - Spare Supplies
 NR - Not Reported C - Conditional Blinded results (FFPG, HbA1C, and MTT @ visits > 3, including Optional Visits)
 CL - Collected O - Optional

Reviewed By (Sponsor Initials) :
 Date:

Visits 5, 8, 10, & 11: Fasting
 Visit SU: Fasting, MTT
 Visit 9: Fasting, Weight, Confirmatory serum pregnancy test required
 OV1, & OV2: Fasting, Weight, Confirmatory serum pregnancy test required
 Visit OV3: Time & volume for 24hr urine, weight, Fasting
 Visit OV4: Fasting
 Visits OV5 & OV6: Fasting, Weight

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Reference Values for

Laboratory Test	Conventional Units			SI Units		
	Unit	Male	Female	Unit	Male	Female
Alanine Aminotransferase (ALT)	U/L	5-25	5-25	U/L	5-25	5-25
Albumin	g/dL	3.5-5.5	3.5-5.5	g/L	35-55	35-55
Alkaline Phosphatase	U/L	32-72	32-72	U/L	32-72	32-72
Amorphous Crystals	#HPF	Absent	Absent	#HPF	Absent	Absent
Aspartate Aminotransferase (AST)	U/L	8-22	8-22	U/L	8-22	8-22
Band Neutrophils	%	0-11	0-11	%	0-11	0-11
Band Neutrophils (Absolute Ct)	K/cu mm	0.0-1.2	0.0-1.2	x 10 ⁹ /L	0.0-1.2	0.0-1.2
Basophils	%	0-1	0-5	%	0-3	0-3
Basophils (Absolute Ct)	K/cu mm	0.0-0.3	0.0-0.3	x 10 ⁹ /L	0.0-0.3	0.0-0.3
Bicarbonate	mEq/L	21-33	21-33	mmol/L	21-33	21-33
Blood Urea Nitrogen	mg/dL	5-20	5-20	mmol/L	1.78-7.14	1.78-7.14
C Peptide	ng/mL	0.81-3.86	0.81-3.86	nmol/L	0.27-1.27	0.27-1.27
Calcium	mg/dL	8.5-10.5	8.5-10.5	mmol/L	2.12-2.62	2.12-2.62
Calcium Carbonate Crystals	#HPF	None	None	#HPF	None	None
Calcium Oxalate Crystals	#HPF	None	None	#HPF	None	None
Calcium Phosphate Crystals	#HPF	None	None	#HPF	None	None
Cholide	mEq/L	95-110	95-110	mmol/L	95-110	95-110
Cholesterol > 1.006 Fraction	mg/dL	0.7-1.4	0.7-1.4	mmol/L	0.2-1.4	0.2-1.4
Creatinine	mg/dL	0.7-1.4	0.7-1.4	mmol/L	0.2-1.4	0.2-1.4
Creatinine Clearance (Classic)	ml/min	75-135	65-125	ml/min	75-135	65-125
Creatinine Clearance (Estimated by Weight)	ml/min	85-125	75-115	ml/min	85-125	75-115
Cystine Crystals	#HPF	None	None	#HPF	None	None
Cytomegalovirus Antibody IgM	#HPF	Negative	Negative	Negative	Negative	Negative
Direct Bilirubin	mg/dL	0.0-0.4	0.0-0.4	mmol/L	0.0-6.8	0.0-6.8
Eosinophils	%	0-7	0-7	%	0-7	0-7
Eosinophils (Absolute Ct)	K/cu mm	0.0-0.8	0.0-0.8	x 10 ⁹ /L	0.0-0.8	0.0-0.8
Glucose	mg/dL	60-115	60-115	mmol/L	3.33-6.38	3.33-6.38
Granular Casts	#LPF	None	None	#LPF	None	None
HDL	mg/dL	30-60	30-60	mmol/L	0.78-1.55	0.78-1.55
Hematocrit	%	37.0-51.0	33.0-47.0	%	37.0-51.0	33.0-47.0
Hemoglobin	g/dL	12.5-17.0	11.0-15.5	g/L	125-170	110-155
Hemoglobin A1c	%	4.0-6.0	4.0-6.0	%	4.0-6.0	4.0-6.0
Hepatitis A	Negative	Negative	Negative	Negative	Negative	Negative
Hepatitis B Core IgM	Negative	Negative	Negative	Negative	Negative	Negative
Hepatitis B Surface Antigen	Negative	Negative	Negative	Negative	Negative	Negative
Hepatitis C Antibody	Negative	Negative	Negative	Negative	Negative	Negative
Hepatitis C Antibody RIBA	Negative	Negative	Negative	Negative	Negative	Negative
Hepatitis C, Viral Load RNA (Qualitative)	#HPF	Negative	Negative	#HPF	None	None
Hyaline Casts	#LPF	None	None	#LPF	None	None
Insulin	mcU/mL	2.0-30.0	2.0-30.0	pmol/L	14-208	14-208
LDL Cholesterol (Calc)	mg/dL	50-160	50-160	mmol/L	1.30-4.14	1.30-4.14
LDL Cholesterol (Ultracentrifugation)	mg/dL	50-160	50-160	mmol/L	1.30-4.14	1.30-4.14
Leucine Crystals	#HPF	None	None	#HPF	None	None
Lymphocytes	%	12-46	12-46	%	12-46	12-46
Lymphocytes (Absolute Ct)	K/cu mm	0.4-5.1	0.4-5.1	x 10 ⁹ /L	0.4-5.1	0.4-5.1
MCH	pg	27.0-34.0	27.0-34.0	pg	27.0-34.0	27.0-34.0
MCHC	g/dL	31.0-36.0	31.0-36.0	g/dL	31.0-36.0	31.0-36.0
MCV	fL	78.0-100.0	82.0-102.0	fL	78.0-100.0	82.0-102.0
Monocytes	%	0-11	0-11	%	0-11	0-11
Monocytes (Absolute Ct)	K/cu mm	0.0-1.2	0.0-1.2	x 10 ⁹ /L	0.0-1.2	0.0-1.2
MPV	fL	7-10	7-10	fL	7-10	7-10
Non-HDL Cholesterol	mg/dL	65-165	65-165	mmol/L	1.68-4.27	1.68-4.27
Platelet Count	K/cu mm	125-375	125-375	x 10 ⁹ /L	125-375	125-375
Platelet Estimate	Normal	Normal	Normal	Normal	Normal	Normal
Potassium	mEq/L	3.5-5.0	3.5-5.0	mmol/L	3.5-5.0	3.5-5.0
Promisulin	pmol/L	3-28	3-28	pmol/L	3-28	3-28
Protein	g/dL	6.0-8.0	6.0-8.0	g/L	60-80	60-80
RBC Morphology	%	Normal	Normal	Normal	Normal	Normal
RDW	%	11.5-14.5	11.5-14.5	%	11.5-14.5	11.5-14.5
Red Blood Cell Casts	#LPF	None	None	#LPF	None	None
Red Blood Cells	x 10 ⁶ /cu mm	4.00-5.60	3.70-5.20	x 10 ¹² /L	4.00-5.60	3.70-5.20
Renal Epithelial Cells	#HPF	None	None	#HPF	None	None
Segmented Neutrophils	%	46-61	46-61	%	46-61	46-61
Segmented Neutrophils (Absolute Ct)	K/cu mm	1.7-6.7	1.7-6.7	x 10 ⁹ /L	1.7-6.7	1.7-6.7
Sodium	mEq/L	133-145	133-145	mmol/L	133-145	133-145
Squamous Epithelial Cells	#HPF	None	None	#HPF	None	None
Thyroid Stimulating Hormone	mcU/mL	0.300-5.000	0.300-5.000	mIU/L	0.300-5.000	0.300-5.000
Total Bilirubin	mg/dL	0.1-1.1	0.1-1.1	mmol/L	1.7-18.8	1.7-18.8
Total Cholesterol	mg/dL	125-200	125-200	mmol/L	3.24-5.18	3.24-5.18
Total Neutrophils	%	46-72	46-72	%	46-72	46-72
Total Neutrophils (Absolute Ct)	K/cu mm	1.7-7.9	1.7-7.9	x 10 ⁹ /L	1.7-7.9	1.7-7.9
Transitional Epithelial Cells	#HPF	None	None	#HPF	None	None
Triglyceride	mg/dL	45-200	45-200	mmol/L	0.51-2.26	0.51-2.26
Triple Phosphate Crystals	#HPF	None	None	#HPF	None	None
Tyrosine Crystals	#HPF	None	None	#HPF	None	None
Uric Acid	mg/dL	4.0-8.0	2.0-6.0	mmol/L	0.238-0.478	0.119-0.357
Uric Acid Crystals	#HPF	None	None	#HPF	None	None
Urinary Bacteria	#HPF	Absent	Absent	#HPF	Absent	Absent
Urinary Bilirubin	Negative	Negative	Negative	Negative	Negative	Negative
Urinary Blood	Negative	Negative	Negative	Negative	Negative	Negative
Urinary Color	Yellow - Amber Yellow - Amb	Yellow - Amber Yellow - Amb	Yellow - Amber Yellow - Amb	Yellow - Amber Yellow - Amber	Yellow - Amber Yellow - Amber	Yellow - Amber Yellow - Amber
Urinary Creatinine	mg/dL	45-278	28-206	mmol/L	3.5-24.6	2.8-20.0
Urinary Glucose	mg/dL	Negative	Negative	mg/dL	Negative	Negative
Urinary Ketones	mg/dL	Negative	Negative	mg/dL	Negative	Negative
Urinary Mucus	mg/dL	Absent	Absent	mg/dL	Absent	Absent
Urinary Nitrite	mg/dL	Negative	Negative	mg/dL	Negative	Negative
Urinary Protein	mg/dL	Negative	Negative	mg/dL	Negative	Negative
Urinary Red Blood Cells	#HPF	None-1-2	None-1-2	#HPF	None-1-2	None-1-2
Urinary White Blood Cells	#HPF	None-1-6	None-1-6	#HPF	None-1-6	None-1-6
Urinary Yeast	Absent	Absent	Absent	Absent	Absent	Absent
Urine Appearance	Clear	Clear	Clear	Clear	Clear	Clear
Urine Leukocyte Esterase	Negative	Negative	Negative	Negative	Negative	Negative
Urine pH	pH	5.0-8.0	5.0-8.0	pH	5.0-8.0	5.0-8.0
Urine Specific Gravity	1.002-1.035	1.002-1.03	1.002-1.035	1.002-1.035	1.002-1.035	1.002-1.035
Urobilinogen	mg/dL	0.2-1.0	0.2-1.0	mg/dL	0.2-1.0	0.2-1.0
Waxy Casts	#LPF	None	None	#LPF	None	None
White Blood Cell Casts	#LPF	None	None	#LPF	None	None
White Blood Cells	K/cu mm	3.7-11.0	3.7-11.0	x 10 ⁹ /L	3.7-11.0	3.7-11.0

PPD Study Code: Sponsor: Protocol Number:		
VISIT	RULE NAME	RULE
1	C-peptide V1	if(C Peptide < 0.7 ng/mL) { Add Comment to DSR: Patient meets exclusion criteria. One repeat determination allowed. for Tests: C Peptide }
1.1	C-peptide V1.1	if(C Peptide < 0.7 ng/mL) { Add Comment to DSR: Patient meets exclusion criteria. for Tests: C Peptide }
1	HbA1C V1	if(((Hemoglobin A1c, (Glycated hemoglobin) > 12 %) OR ((Hemoglobin A1c, (Glycated hemoglobin) < 7.5 %))) { Add Comment to DSR: Patient meets exclusion criteria. One repeat determination allowed. for Tests: Hemoglobin A1c, (Glycated hemoglobin) }
1.1	HbA1C V1.1	if(((Hemoglobin A1c, (Glycated hemoglobin) > 12 %) OR ((Hemoglobin A1c, (Glycated hemoglobin) < 7.5 %))) { Add Comment to DSR: Patient meets exclusion criteria. for Tests: Hemoglobin A1c, (Glycated hemoglobin) }
1	Hemoglobin Male, Female V1	if((((CBC, Hemoglobin (Hgb) < 11 g/dL) AND ((GENDER = Female))) OR (((CBC, Hemoglobin (Hgb) < 12.5 g/dL) AND ((GENDER = Male)))) { Add Comment to DSR: Patient meets exclusion criteria. One repeat determination allowed. for Tests: CBC, Hemoglobin (Hgb) }
1.1	Hemoglobin Male, Female V1.1	if((((CBC, Hemoglobin (Hgb) < 11 g/dL) AND ((GENDER = Female))) OR (((CBC, Hemoglobin (Hgb) < 12.5 g/dL) AND ((GENDER = Male)))) { Add Comment to DSR: Patient meets exclusion criteria. for Tests: CBC, Hemoglobin (Hgb) }

1	HCG V1	if(((HCG (Human Chorionic Gonadotrophin) = Positive)) AND ((GENDER = Female))) { Add Comment to DSR: Patient meets exclusion criteria. for Tests: HCG (Human Chorionic Gonadotrophin) }
1.1	ALT, AST V1.1	if(((Alanine Aminotransferase (ALT) > 50 U/L)) OR ((Asparate Aminotransferase (AST) > 44 U/L))) { Add Comment to DSR: Patient meets exclusion criteria. for Tests: Alanine Aminotransferase (ALT), Asparate Aminotransferase (AST) }
1	Creatinine male, female V1	if((((Creatinine >= 1.4 mg/dL) AND ((GENDER = Male))) OR (((Creatinine >= 1.3 mg/dL) AND ((GENDER = Female))))) { Add Comment to DSR: Patient meets exclusion criteria. One repeat determination allowed within 7 days. for Tests: Creatinine }
1.1	Creatinine male, female V1.1	if((((Creatinine >= 1.4 mg/dL) AND ((GENDER = Male))) OR (((Creatinine >= 1.3 mg/dL) AND ((GENDER = Female))))) { Add Comment to DSR: Patient meets exclusion criteria. for Tests: Creatinine }
1	ECC V1	if(Creatinine Clearance (Estimated by Weight) < 60 ml/min) { Add Comment to DSR: Refer to protocol Table 2-1. for Tests: Creatinine Clearance (Estimated by Weight) }
1.1	ECC V1.1	if(Creatinine Clearance (Estimated by Weight) < 60 ml/min) { Add Comment to DSR: Patient may be ineligible. Refer to protocol Table 2-1. for Tests: Creatinine Clearance (Estimated by Weight) }
OV4	Hep C +Ab RIBA trigger	if(Hepatitis C, Antibody, Total = Positive) { Order New Test: Hepatitis C, Antibody by RIBA CCF }
2.1	Trig V2.1	if(Triglyceride > 500 mg/dL) { Add Comment to DSR: Patient meets exclusion criteria. for Tests: Triglyceride }

1, 3, 6, 9, 12, DIS, OV1, OV2	Confirm HCG trigger	if(((Confirmatory Serum Pregnancy Test Required = Yes)) AND ((GENDER = Female))) { Order New Test: HCG (Human Chorionic Gonadotrophin) }
3, 5, 6, 8, 9, 10, 11, 12, OV1, OV2, OV5, OV6	HCG DIS	if(((HCG (Human Chorionic Gonadotrophin) = Positive)) AND ((GENDER = Female))) { Add Comment to DSR: Patient meets discontinuation criteria. for Tests: HCG (Human Chorionic Gonadotrophin) }
2	FPG V2	if(Glucose > 320 mg/dL) { Add Comment to DSR: Repeat test and confirm within 7 days. for Tests: Glucose }
1, 1.1, 2, 2.1, 3, 6, 12, DIS, OV1, OV2	Lipid panel TG beta quant	if(Triglyceride > 400 mg/dL) { Order New Test: Cholesterol >1.006 Fraction AND Order New Test: Cholesterol, Low Density Lipoprotein (LDL by Ultracentrifugation, Beta-Quant) }
1.1	TSH <0.300 V1.1	if(Thyroid Stimulating Hormone (TSH) < 0.300 mIU/mL) { Add Comment to DSR: Patient meets exclusion criteria. Refer to protocol Table 2-1. for Tests: Thyroid Stimulating Hormone (TSH) }
1.1	TSH >5.000 V1.1	if(Thyroid Stimulating Hormone (TSH) > 5.000 mIU/mL) { Add Comment to DSR: Patient meets exclusion criteria. Refer to protocol Table 2-1. for Tests: Thyroid Stimulating Hormone (TSH) }
1.1	Measured Creatinine Clearance V1.1	if(Creatinine Clearance (Classic) < 60 ml/min) { Add Comment to DSR: Patient ineligible. for Tests: Creatinine Clearance (Classic) }
3, 6, 9, 12, OV1, OV2, OV5, OV6	Creatinine male, female V>=3	if((((Creatinine >= 1.5 mg/dL) AND ((GENDER = Male))) OR (((Creatinine >= 1.4 mg/dL) AND ((GENDER = Female)))))) { Add Comment to DSR: Patient may meet discontinuation criteria. Repeat test and confirm within 3-7 days. Refer to protocol Table 2-5. for Tests: Creatinine }

3, 6, 9, 12, OV1, OV2, OV5, OV6	ECC V>=3	if(Creatinine Clearance (Estimated by Weight) < 60 ml/min) { Add Comment to DSR: Patient may meet discontinuation criteria. Repeat test and confirm within 3-7 days. Refer to protocol Table 2-5. for Tests: Creatinine Clearance (Estimated by Weight) }
3, 6, 9, 12, OV1, OV2, OV5, OV6	ALT >75, <=125 V>=3	if(((Alanine Aminotransferase (ALT) > 75 U/L)) AND ((Alanine Aminotransferase (ALT) <= 125 U/L))) { Add Comment to DSR: Patient may meet discontinuation criteria. Refer to protocol Appendix 6.1. for Tests: Alanine Aminotransferase (ALT) }
3, 6, 9, 12, OV1, OV2, OV5, OV6	ALT >125 V>=3	if(Alanine Aminotransferase (ALT) > 125 U/L) { Add Comment to DSR: Patient may meet discontinuation criteria. Refer to protocol Appendix 6.1. for Tests: Alanine Aminotransferase (ALT) }
3, 6, 9, 12, OV1, OV2, OV5, OV6	AST >66, <=110 V>=3	if(((Asparate Aminotransferase (AST) > 66 U/L)) AND ((Asparate Aminotransferase (AST) <= 110 U/L))) { Add Comment to DSR: Patient may meet discontinuation criteria. Refer to protocol Appendix 6.1. for Tests: Asparate Aminotransferase (AST) }
3, 6, 9, 12, OV1, OV2, OV5, OV6	AST >110 V>=3	if(Asparate Aminotransferase (AST) > 110 U/L) { Add Comment to DSR: Discontinue study drug. Repeat test within 3 days. Refer to protocol Appendix 6.1. for Tests: Asparate Aminotransferase (AST) }
1	TSH V1 <0.300	if(Thyroid Stimulating Hormone (TSH) < 0.300 mIU/mL) { Add Comment to DSR: Patient meets exclusion criteria. One retest allowed. For patients on thyroid replacement therapy see protocol Table 2-1 for Tests: Thyroid Stimulating Hormone (TSH) }
1	TSH V1 >5.000	if(Thyroid Stimulating Hormone (TSH) > 5.000 mIU/mL) { Add Comment to DSR: Patient meets exclusion criteria. For patients on thyroid replacement therapy see protocol Table 2-1. for Tests: Thyroid Stimulating Hormone (TSH) }
1	ALT, AST V1	if(((Alanine Aminotransferase (ALT) > 50 U/L)) OR ((Asparate Aminotransferase (AST) > 44 U/L))) { Add Comment to DSR: Patient meets exclusion criteria. One repeat determination allowed. for Tests: Alanine Aminotransferase (ALT), Asparate Aminotransferase (AST) }

1, 1.1, 2	TG V1, 1.1, 2	if(Triglyceride > 500 mg/dL) { Add Comment to DSR: Patient meets exclusion criteria. One repeat determination may be allowed. Refer to protocol Table 2-1. for Tests: Triglyceride }
1.1	MCC V1.1	if(Creatinine Clearance (Classic) >= 60 ml/min) { Add Comment to DSR: Patient may meet inclusion criteria. Refer to protocol and contact Merck Medical Monitor. for Tests: Creatinine Clearance (Classic) }
OV4	Hep C RIBA viral load approval	if(Hepatitis C, Antibody by RIBA CCF = Indeterminate) { Add Comment to DSR: Hepatitis C viral load may be allowed. Contact Merck for approval. for Tests: Hepatitis C, Antibody by RIBA CCF }
Reviewed By (Sponsor Initials) : _____		
Date: _____		

PPD Study Code: Sponsor: Protocol Number:

Visit	Test	Value	Comment
if OV3<V3	Measured Creatinine Clearance (24-hr)	<60mL/min	Patient meets exclusion criteria.
if OV3<V3	Measured Creatinine Clearance (24-hr)	>=60mL/min	Patient may meet inclusion criteria. Refer to protocol and contact Merck Medical Monitor.
if OV3>V3	Measured Creatinine Clearance (24-hr)	<60mL/min	Patient meets discontinuation criteria.
Consecutive Visit>=3, including OV	Creatinine	>=1.5mg/dL (133umol/L) (Male)	Patient meets discontinuation criteria. Refer to protocol Table 2-5.
Consecutive Visit>=3, including OV	Creatinine	>=1.4mg/dL (124umol/L) (Female)	Patient meets discontinuation criteria. Refer to protocol Table 2-5.
Consecutive Visit>=3, including OV	Estimated Creatinine Clearance	>=50 and <60mL/min	Patient meets discontinuation criteria. Refer to protocol Table 2-5.
Consecutive Visit>=3, including OV	Estimated Creatinine Clearance	<50mL/min	Patient meets discontinuation criteria.
Consecutive Visit V>=2 and <V3 including OV	FPG	>320mg/dL (17.76mmol/L)	Patient does not meet inclusion criteria
Visit >3, <=5 including OV	FPG	>300mg/dL (16.65mmol/L)	Value needs to be repeated at an unscheduled visit and confirmed within 7 days. Report actual FPG value in the result field.
Consecutive Visit V>=3, <=5 including OV	FPG	>300mg/dL (16.65mmol/L)	Refer to protocol for initiation of step-up therapy
Visit >5, <= Visit 6, including OV	FPG	>270mg/dL (14.99mmol/L)	Value needs to be repeated at an unscheduled visit and confirmed within 7 days. Report actual FPG value in the result field.
Consecutive Visit >5, <=6 including OV	FPG	>270mg/dL (14.99mmol/L)	Refer to protocol for initiation of step-up therapy
>V3, <=V5 with SU1 + 4 weeks, including OV	FPG	>300mg/dL (16.65mmol/L)	Value needs to be repeated at an unscheduled visit and confirmed within 7 days. Report actual FPG value in the result field.
Consecutive visit >V3, <=V5 with SU1 + 4 weeks, including OV visits	FPG	>300mg/dL (16.65mmol/L)	Patient meets discontinuation criteria. Refer to protocol Table 2-4.
>V5, <=V6 with SU1 + 4 weeks, including OV	FPG	>270mg/dL (14.99mmol/L)	Value needs to be repeated at an unscheduled visit and confirmed within 7 days. Report actual FPG value in the result field.
Consecutive visit >V5, <=V6 with SU1 + 4 weeks, including OV visits	FPG	>270mg/dL (14.99mmol/L)	Patient meets discontinuation criteria. Refer to protocol Table 2-4.
>V6, <=V9, including OV	FPG	>240mg/dL (13.32mmol/L)	Value needs to be repeated at an unscheduled visit and confirmed within 7 days. Report actual FPG value in the result field.
Consecutive Visit >6, <=V9, including OV visits	FPG	>240mg/dL (13.32mmol/L)	Patient meets discontinuation criteria. Refer to protocol Table 2-4.
>V9, including OV	FPG	>200mg/dL (11.10mmol/L)	Value needs to be repeated at an unscheduled visit and confirmed within 7 days. Report actual FPG value in the result field.
Consecutive visit >V9, including OV visits	FPG	>200mg/dL (11.10mmol/L)	Patient meets discontinuation criteria. Refer to protocol Table 2-4.
Consecutive Visit >=V3, including OV1, OV2	FPG	>=50 and <70mg/dL	Patient may meet discontinuation criteria. Refer to protocol.
Consecutive Visit >=V3, including OV1, OV2	FPG	<50mg/dL	Patient meets discontinuation criteria. Refer to protocol.
Consecutive Visit >=3, including OV1, OV2, OV5, OV6	ALT	>75U/L (3 X ULN)	Patient meets discontinuation criteria. Refer to protocol Appendix 6.1.
Consecutive Visit >=3, including OV1, OV2, OV5, OV6	AST	>66U/L (3 X ULN)	Patient meets discontinuation criteria. Refer to protocol Appendix 6.1.

OV = Optional Visit DIS = Discontinuation Visit
 SU = Step-Up Therapy

Project Management

PPD Study Code: Sponsor: Protocol Number:

Version 1.1 10-January-2008

PROJECT ACCOUNT MANAGER

PRIMARY PROJECT MANAGER
SECONDARY PROJECT MANAGER

MEDICAL MONITOR

Email:

CLINICAL TRIAL LEAD

Phone:

Email:

SITES

RANDOMIZATION

<i>Patients Screened:</i>	1223
<i>Patients Randomized:</i>	579
<i>Patients Completed:</i>	579
<i>First Patient In:</i>	25-Jan-08
<i>Last Patient Randomized</i>	6-Jan-09
<i>Last Patient Out</i>	13-Oct-09

Reviewed By (Sponsor Initials) : _____

Date: _____

PPD Study Code: Sponsor: Protocol Number:
Version 1.1 10-January-2008

_____ Date: _____

_____ Date: _____

Head of Project Management: _____ Date: _____

Head of Data Management: _____ Date: _____

