










Subjects should fast overnight for at least 8 hours (except water) prior to all study visits			Screening	24-Week Treatment Period										
			Visit 1 (Screen)	Visit 2 (Baseline)	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 (Study Termination)				
Label	Tube	Testing	Day -7 (±3 day)	Day 1	Day 28 (±3 day)	Day 56 (±3 day)	Day 84 (±3 day)	Day 112 (±3 day)	Day 140 (±3 day)	Day 168 (±3 day)				
Chemistry & Lipids		7.0mL SST Glucose, BUN, Creatinine, TP, Alb, UA, Total/Direct/Indirect Bilirubin, ALP, ALT, AST, GGT, CPK, CK-MB(if CPK is elevated), Na, K, Chloride, Bicarbonate, Phosphate, Ca, Mg, eGFR (MDRD), Anion Gap	X	X	NO SAMPLES TO MRL	NO SAMPLES TO MRL	X	NO SAMPLES TO MRL	NO SAMPLES TO MRL	X				
				X			X							
				X			X							
				X										
Biomarkers		5.0mL SST Exploratory Biomarkers		X	NO SAMPLES TO MRL	NO SAMPLES TO MRL	X	NO SAMPLES TO MRL	NO SAMPLES TO MRL	X				
Hematology & HbA1C		3.0mL K2 EDTA RBC, Hemoglobin, Hematocrit, WBC w/ Diff (% and Absolutes), Platelets, MCV, MCH, MCHC	X	X			NO SAMPLES TO MRL			NO SAMPLES TO MRL	X	NO SAMPLES TO MRL	NO SAMPLES TO MRL	X
				X							X			
Urinalysis		Urine Collection Cup pH, SG, Glucose, Blood, Ketones, Protein, Micro	X	X			NO SAMPLES TO MRL			NO SAMPLES TO MRL		NO SAMPLES TO MRL	NO SAMPLES TO MRL	X
Urine Drug & Alcohol Screen														
FOOTNOTES			Order & Volume of Draw											
1. For all female subjects, regardless of childbearing status (unless subject has had a hysterectomy)			1: 7.0mL SST	1: 7.0mL SST	NO SAMPLES TO MRL	NO SAMPLES TO MRL		1: 7.0mL SST	NO SAMPLES TO MRL		NO SAMPLES TO MRL			1: 7.0mL SST
				1: 5.0mL SST			1: 5.0mL SST	1: 5.0mL SST						
			1: 3.0mL K2 EDTA	1: 3.0mL K2 EDTA			1: 3.0mL K2 EDTA	1: 3.0mL K2 EDTA						
			1: Urine Collection	1: Urine Collection				1: Urine Collection						

Sample	Tube	Collection & Processing	Aliquots	Shipping	Notes
Chemistry & Lipids	 7.0mL SST	<p>Fill tube completely.</p> <p>Gently invert 5 times.</p> <p>Allow blood to clot for 45 minutes.</p> <p>Centrifuge at 1800g for 15 minutes.</p> <p>Allow tube to sit upright for 1 hour at ambient temperature prior to shipment. Do NOT open tube.</p>	None	Refrigerated Day of Collection	
Biomarkers	 5.0mL SST	<p>Fill tube completely.</p> <p>Gently invert 5 times.</p> <p>Allow blood to clot for 45 minutes.</p> <p>Within 6 hours of collection, centrifuge at 1500g for 10 minutes at ambient temperature.</p> <p>Using a pipette, transfer serum equally into two cryovials and freeze at -75°C ± 10°C. Discard cells.</p>	2 - 2.5mL Cryovial (Green Capped)	Frozen Day of Collection	Frozen shipments should only be sent Monday - Wednesday. For collections Thursday - Sunday, shipment should be held until the following Monday. If an ultralow freezer is unavailable, storage at 20°C ± 5°C is acceptable.
Hematology & HbA1C	 3.0mL K2 EDTA	<p>Fill tube completely.</p> <p>Gently invert 10 times.</p> <p>Do NOT centrifuge.</p> <p>Do NOT open tube.</p>	None	Ambient Day of Collection	
Urinalysis	 10.0mL Urine Transport Tube	<p>Collect midstream sample in urine collection cup.</p> <p>Using a pipette, aliquot urine into Yellow Capped Urine Transport Tube w/ preservative tablet.</p> <p>Discard urine collection cup. Do NOT send urine collection cup to lab.</p>	1 - Urine Transport Tube w/Preservative Tablet (Yellow Capped)	Ambient Day of Collection	Do NOT send urine cup to lab.
Urine Drug & Alcohol Screen	 5.0mL Urine Transport Vial	<p>Collect midstream sample in urine collection cup.</p> <p>Urine collected in collection cup from Urinalysis may be used for this sample.</p> <p>Using a pipette, aliquot urine into two(2) White Capped Urine Transport Vials.</p> <p>Discard urine collection cup. Do NOT send urine collection cup to lab.</p>	2 - Urine Transport Vials (White Capped)	Refrigerated Day of Collection	Do NOT send urine cup to lab.