










































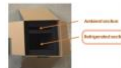








SONOMA BIOTHERAPEUTICS PROTOCOL: <u>SBT777101-02</u> MRL LAB MANUAL VERSION: 3			VISIT																				MRL LAB MANUAL (PG. #) (FOR REFERENCE)
			SCREENING	APHERESIS	PRE-INFUSION	WEEK 1 DAY 1	WEEK 1 DAY 2	WEEK 1 DAY 4 OR 5	WEEK 1 DAY 7 ± 1	WEEK 2 DAY 11 ± 1	WEEK 2 DAY 14 ± 2	WEEK 3 DAY 21 ± 2	WEEK 4 DAY 28 ± 2	WEEK 6 DAY 42 ± 2	WEEK 8 DAY 56 ± 2	WEEK 10 DAY 70 ± 2	WEEK 12 DAY 84 ± 3	WEEK 18 DAY 126 ± 7	WEEK 24 DAY 168 ± 7	WEEK 36 DAY 252 ± 7	WEEK 48 DAY 336 ± 7 OR END OF STUDY	EARLY TERMINATION	UNSCHEDULED
	ADA			①								①		①		①	①			①	①	①	
	EXPLORATORY BIOMARKER SERUM	①		①		①		①		①	①	①	①	①	①	①	①	①	①	①	①	①	
	PBMC	②		④		②	②	②	②	②	②	③	②	③	②	③	②	③	②	③	②	④	
	EXPLORATORY BIOMARKER PLASMA	①		②		①		①		①	①	①	①	①	①	①	①	①	①	①	①	①	
	PK ddPCR			①		①	①	①	①	①	①	①	①	①	①	①	①	①	①	①	①	①	
	FFPE SKIN BIOPSY	① L		① L								① L				① L					① L		
				① P								① P				① P							
(KIT TYPE)	A	-	B	-	C	D	C	D	C	C	E	C	E	C	E	F	G	C	E	F	XS		
L – LESIONAL P – PERILESIONAL OPTIONAL																							

SONOMA BIOTHERAPEUTICS PROTOCOL: SBT777101-02 MRL LAB MANUAL VERSION: 3			PROCESSING								
			DRAW TUBE CAP COLOR	BLOOD VOLUME (mL)	INVERT	TIME ELAPSED (MIN) POST COLLECTION PRIOR TO CENTRIFUGATION (MIN)	CENTRIFUGATION SETTINGS	TRANSFER DEVICE	STORAGE TUBES	TRANSFERRED VOLUME (mL)	STORAGE CONDITION
ORDER OF DRAW 	ADA	 7mL		ALLOW BLOOD TO CLOT IN UPRIGHT POSITION FOR 30 TO 60 MINUTES CENTRIFUGE WITHIN 60 MINUTES	1800 – 2200g or RCF (NOT RPM)  AT ROOM TEMPERATURE			1 ST : 0.5mL INTO FIRST 2 x 2.0mL SARSTEDT CRYOVIALS 2 ND : DIVIDE REMAINING SERUM INTO REMAINING 2 x 2.0 mL SARSTEDT CRYOVIALS LEAVE SMALL AMOUNT LEFT ABOVE SEPARATOR GEL	≤-20°C UNTIL SHIPMENT	31	
	EXPLORATORY BIOMARKER SERUM	 4mL		ALLOW BLOOD TO CLOT IN UPRIGHT POSITION FOR 30 TO 60 MINUTES CENTRIFUGE WITHIN 60 MINUTES	1800 – 2200g or RCF (NOT RPM)  AT ROOM TEMPERATURE			1 ST : 0.5mL INTO FIRST 2 x 2.0mL SARSTEDT CRYOVIALS 2 ND : DIVIDE REMAINING SERUM INTO REMAINING 2 x 2.0 mL SARSTEDT CRYOVIALS LEAVE SMALL AMOUNT LEFT ABOVE SEPARATOR GEL	≤-20°C UNTIL SHIPMENT	32	
	PBMC	 10mL		DO NOT CENTRIFUGE AND DO NOT OPEN TUBE						ROOM TEMPERATURE UNTIL SHIPMENT	33
	EXPLORATORY BIOMARKER PLASMA	 4mL		IMMEDIATELY PLACE ON WET ICE CENTRIFUGE WITHIN 60 MINUTES	1800 – 2200g or RCF (NOT RPM)  AT 4°C			0.5mL INTO 4 x 2.0mL SARSTEDT CRYOVIALS <u>PER TUBE</u>	≤-20°C UNTIL SHIPMENT	34	
	PK ddPCR	 3mL		DO NOT CENTRIFUGE					DIVIDE EVENLY INTO 2 x 2.0 SARSTEDT CRYOVIALS	≤-70°C UNTIL SHIPMENT	35
	FFPE SKIN BIOPSY		(PLEASE REFER TO SONOMA BIOPSY LAB MANUAL)						TRANSFER INTO 1 X 10% NBF prefilled tube 20 mL/10 mL WITHIN 30 MINUTES OF COLLECTION. IF UNABLE TO SHIP WITHIN DAY OF COLLECTION, TRANSFER TO PROVIDED 20mL CONTAINER PREFILLED WITH 70% REAGENT GRADE ALCOHOL	REFRIGERATE UNTIL SHIPMENT	36

SONOMA BIOTHERAPEUTICS		SHIPPING										DESTINATION	
PROTOCOL: SBT777101-02		MRL SHIPPER	PACKAGING	FEDEX AIRWAY BILL	DAYS OF OPERATION NOTIFICATIONS	MRL LAB MANUAL (PG. #) FOR REFERENCE							
MRL LAB MANUAL VERSION: 3													
TEST	PBMC	AMBIENT	<p>*IMPORTANT! UNPACK SHIPPER 24 HOURS BEFORE USE TO ALLOW FOAM EXPANSION FOR ADEQUATE INSULATION</p> 	<p>PLACE TUBES IN SPECIMEN BAG AND SEAL</p> 	<p>FOLD BAG ONCE LENGTHWISE AND AGAIN WIDTHWISE</p>  + 	<p>PLACE BAG IN AMBIENT COMPARTMENT</p>  	<p>PLACE FOAM LID ON TOP OF FOAM INSERT WITH SAMPLE FORM ON TOP</p> 	<p>SECURE WITH PROVIDED SEAL AND TAPE AROUND OPENINGS OF OUTER BOX PACKAGING</p> 		MEDPACE REFERENCE LABORATORY MON - SAT	14 - 16		
	ADA	FROZEN		<p>PLACE TUBES IN SPECIMEN BAG AND SEAL</p> 	<p>FILL STYROFOAM INSERT WITH LAYER OF DRY ICE, FILLING ABOUT A QUARTER OF THE TOTAL SPACE</p> 	<p>PLACE SEALED SPECIMEN BAG ON TOP OF DRY ICE LAYER</p> 	<p>FILL REMAINING SPACE OF STYROFOAM CONTAINER WITH DRY ICE AND CLOSE WITH STYROFOAM LID AND SAMPLE FORM ON TOP</p> 	<p>SECURE WITH PROVIDED SEAL AND TAPE AROUND OPENINGS OF OUTER BOX PACKAGING</p> 		MEDPACE REFERENCE LABORATORY MON - SAT	16 - 19		
	EXPLORATORY BIOMARKER SERUM												
	EXPLORATORY BIOMARKER PLASMA												
	PK ddPCR												
FFPE SKIN BIOPSY	REFRIGERATED	<p>*IMPORTANT! UNPACK SHIPPER 24 HOURS BEFORE USE TO ALLOW FOAM EXPANSION FOR ADEQUATE INSULATION</p> 	<p>PLACE TUBE IN SPECIMEN BAG AND SEAL</p> 	<p>FREEZE PROVIDED GEL PACK IN -20°C FREEZER (DO NOT FREEZE IN ULTRALOW -80°C FREEZER). PLACE IN LARGER REFRIGERATED SECTION OF SHIPPER</p>  	<p>PLACE PROTECTIVE FOAM OVER FROZEN GEL PACK</p>  	<p>PLACE SPECIMEN BAG ON TOP OF PROTECTIVE FOAM AND CLOSE INSERT WITH FOAM LID WITH SAMPLE FORM ON TOP</p>  	<p>SECURE WITH PROVIDED SEAL AND TAPE AROUND OPENINGS OF OUTER BOX PACKAGING</p> 		MOSAIC LABORATORIES MON - SAT	19 - 22			