LABORATORY MANUAL

Sonoma Biotherapeutics

Protocol ID: SBT777101-02

Study: A Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Activity of Single Ascending Doses of SBT777101 in Subjects with Hidradenitis Suppurativa

Date: 28Jul2025

Version: V 4

Region: US

Summary of Changes

Version	Section	Changes	Reason for Change
V2	Multiple	Removed RNALater Biopsy sample and renamed FFPE Skin Biopsy 1 and 2 to FFPE Skin Biopsy Lesional and Peri-lesional	Per Sponsor Request
	Multiple	Added reminder to unpack ambient/refrigerated combo shipper 24hrs prior to shipping to let foam expand.	Per Sponsor Request
	4.2	Split ambient and refrigerated packing instructions and added note about folding kPa bags	Per Sponsor Request
	6.2	Removed Riley Steward	Administrative Update
	8	Added hardcoded diagnosis	Per Sponsor Request
	10	Updated CAP & CLIA Certificate added	Administrative Update
	15	Updated V2 QRC added	Per Sponsor Request
	16	Updated V2 Resupply Form added to remove RNALater tubes and change size of Reagent Grade Alcohol Bottle	Per Sponsor Request
V3	7	Added total blood volume (624mL)	Clerical Error
	9.1.1	Corrected order of draw to match QRC SST>>NaHep>>EDTA	Clerical Error
	9.1.6	Added reminder to send requisition forms	Per Sponsor Request
	15	Updated V3 QRC added with correct tube picture and additional centrifugation notes from manual	Per Sponsor Request
	16	Updated V2 Resupply Form added which includes ambient gel packs for hot/cold months	Per Sponsor Request
	17	PMBC submission form added (was missing previously)	Clerical Error
V4	1.2	2024-2025 holidays updated to 2025-2026	Administrative Update
	2.1	Updated language to reflect scheduled resupplies	Per sponsor request
	4.2	Ship ambient/refrigerated samples samples in hard foam. Updated box labeling and number of gel packs.	Per Sponsor Request
	9.1.9	Updated biopsy instructions	Per Sponsor Request
	15	V4 QRC added	Per Sponsor Request
	16	Updated V6 Resupply Form added which includes new shipping materials	Per Sponsor Request
	18	Added Appendix I | Lab Kit Resupply Schedule	Per Sponsor Request

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GENERAL LAB INFORMATION

This section provides an overview of basic laboratory information such as contact information, specimen collection and processing instructions, shipping guidelines, laboratory reporting details, and accreditation certificates. Refer to Sections 6–8.1 of this manual for detailed instructions related to a particular study.

1 Laboratory Information

1.1 Contact Information

Medpace Reference Laboratories (MRL)

5365 Medpace Way
Cincinnati, Ohio, US 45227
Phone: +1.513.366.3270 or +1.800.749.1737 (North America sites only)
Fax: +1.513.366.3273 or +1.800.705.2177 (North America sites only)

Client Services

The extension for the Project Manager assigned to your protocol is in Section **6**. Contact client services to clarify sample collection procedures or shipment temperature, request additional laboratory supplies, or re-send laboratory reports.

Critical Values Department

Contact the Critical Values Department (extension 11120) to obtain and acknowledge receipt of critical values.

You should have the following information available each time you contact MRL:

- Sponsor name
- Protocol number
- Site number
- Subject ID (laboratory number, randomization number and/or initials [where applicable])
- Date of collection and visit

1.2 MRL Hours of Operation and Holiday Observances

Monday–Friday
8:00am–5:00pm (ET)

Saturday
8:00am–4:30pm (ET)

Sunday and Public Holidays
Closed*

*Couriers do not deliver specimens on those days. Sites will be notified in advance if shipping adjustments are required because of public holidays.

2025	2026	US Laboratory Public Holiday
01 January	01 January	New Year's Day
26 May	25 May	Memorial Day
04 July	04 July	Independence Day
01 September	07 September	Labor Day
27 November	26 November	Thanksgiving Day
25 December	25 December	Christmas Day

2 Laboratory Materials

MRL provides sites with study-specific supplies, including (as applicable):

- **Laboratory Manual**: general and study-specific section
- **Quick Reference Chart**: laboratory schedule and abbreviated sample processing instructions
- Visit-specific laboratory kits
- Extra laboratory supplies
- Subject requisition forms
- Packaging and shipping materials (boxes, pre-printed air waybills (AWBs), labels)
- Letter indicating the latest time that the local courier can be contacted to ensure same-day pick-up

2.1 Specimen Collection Supplies

Each visit-specific kit is labeled with the Sponsor Name, Protocol Number, Visit(s) the kit is to be used for, and Expiration Date of the kit. Lab kit labels have a peel-off barcode label that must be removed from the used lab kit's label and affixed to the requisition form for the corresponding visit. If there are multiple pages of requisitions provided for a given visit, affix the lab kit barcode label to the first requisition page. There is space on the requisition form to place the lab kit barcode label (refer to Section 3.1).

Extra laboratory supplies are provided in the initial supply shipment for unscheduled visit testing or in cases where additional supplies are needed (e.g., vacutainer tube included in lab kit does not contain vacuum).

Prior to phlebotomy, ensure that laboratory kits are not expired. Expiry date is indicated on the laboratory kit label. Pay particular attention to the expiration date of each component taken from extra supplies prior to use.

To reduce waste and avoid duplicative ordering, there will be a change in the MRL Resupply Shipment Request process. Moving forward, please refrain from proactively ordering lab kits for your upcoming visits as lab kits will be managed through Medpace, who will automatically be distributing lab kits in multiple shipments as your site's patients progress throughout the study (refer to Appendix I)

Bulk supplies such as those used for biopsy samples and shipping supplies should still be ordered as normal when you notice you are running low. If your site requires additional kits due to damage or loss, or for any other reason, please submit a Resupply Shipment Request and note your reasoning for requesting additional shipments.

To request additional laboratory supplies, order via web at https://clintraklab.medpace.com within the **study-specific** MRL ClinTrak web portal.

As secondary/back-up options, send Appendix G | Laboratory Re-Supply Form:

- Fax: 513.366.3273
- Email: MRL-US-PA@medpace.com
- Phone: Contact the Client Services Department at 513.366.3270 ext. 11034

Allow ten (10) business days for delivery.

Sites should not place orders for kits more than 3 months in advance. MRL guarantees a 3-month minimum expiry date on resupply orders.

3 Specimen Labeling (Minimized Requisition Forms & Label Pages)

Requisition forms are generic. They do not reflect a specific subject and correlate to one among multiple visits indicated on the form.

Sample label pages **are subject-specific** and include barcoded labels for all samples for one subject across multiple visits on a single page. Labels for early termination and unscheduled visits, if applicable, are provided at the end of each set.

MRL recommends keeping the requisition and label set in a unique location per subject, like the subject file.

It is the responsibility of the site to take photocopies of all completed requisition forms for storage at site. Original requisition forms must be included in the first sample shipment.

3.1 Overview of the Requisition Form

Information collected on a requisition form will include (See Figure 1):

Visit Information Box:

- List of applicable visits
    - The correct visit must be selected prior to submission of the requisition form and samples to Medpace Reference Laboratories and Mosaic Laboratories, L.L.C.

Patient Demographic Information:

- Lab Subject ID:
    - The Subject ID must be written on the requisition form. This Subject ID must match the Subject ID on the corresponding labels utilized for samples.

Standard demographic information collected on a requisition form may include:

- Date of Collection
- Time of Collection
- Subject randomization number (if applicable)
- Subject Sex at birth
- Subject year of birth
- Subject age at time of collection
- Is Subject Fasting?
- Childbearing Potential

Samples and Information:

- Lists all samples required to be collected at each visit. In the event a sample is not collected, write “not collected” next to the applicable sample. (See Figure 2).

Refer to Section 8 for the study-specific demographic information collected on the requisition form.

Important: Incomplete or illegible information prompts immediate site contact for verification. In cases where the issue cannot be resolved promptly, sending the laboratory report may be delayed.

Space is identified in the header of the first requisition page of each visit to affix the peel-off barcode label from the lab kit used for that visit (Figure 1).

Important: Remember to provide this barcode for every subject visit so that MRL can track the number and expiration date(s) of kits remaining at the site.

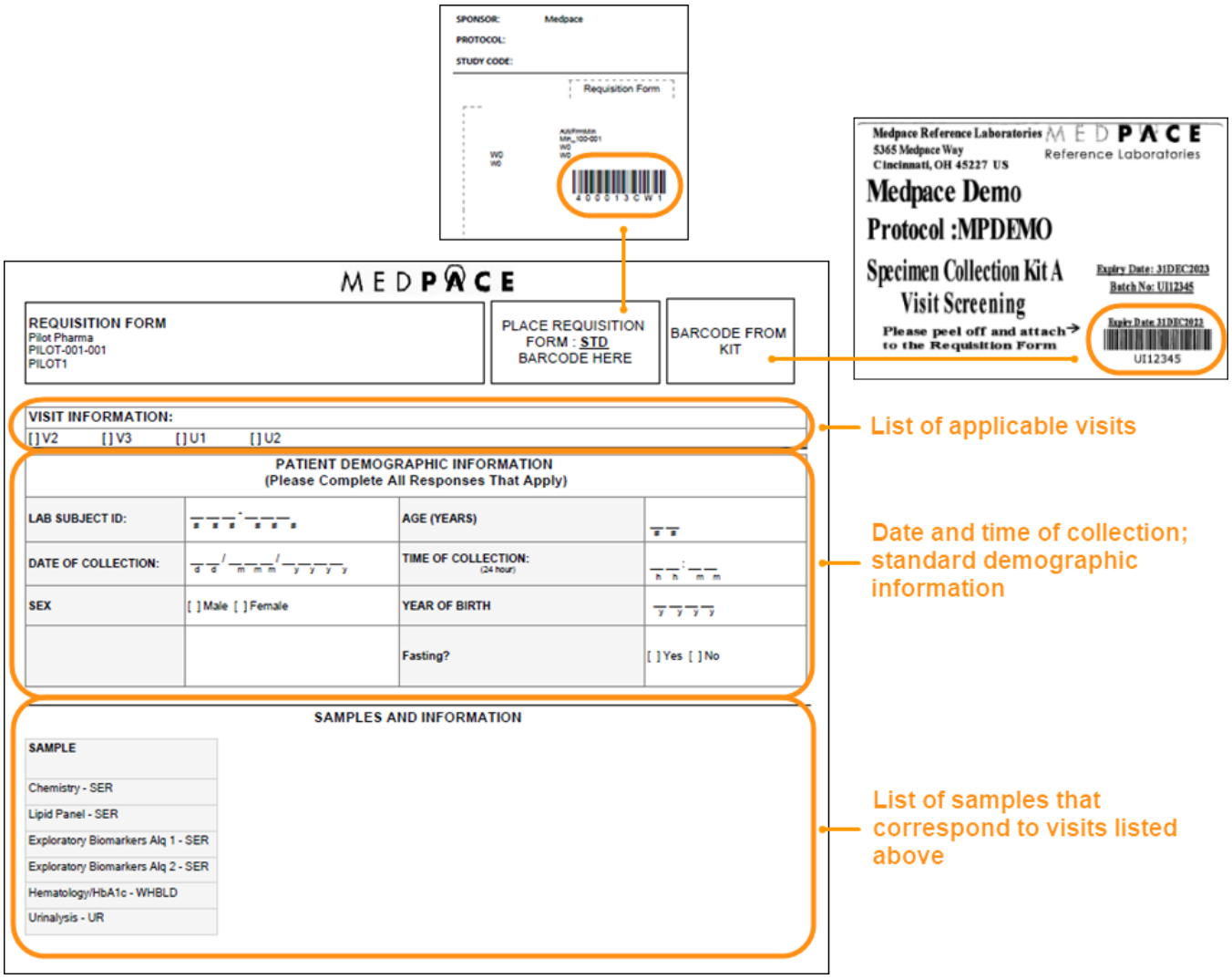
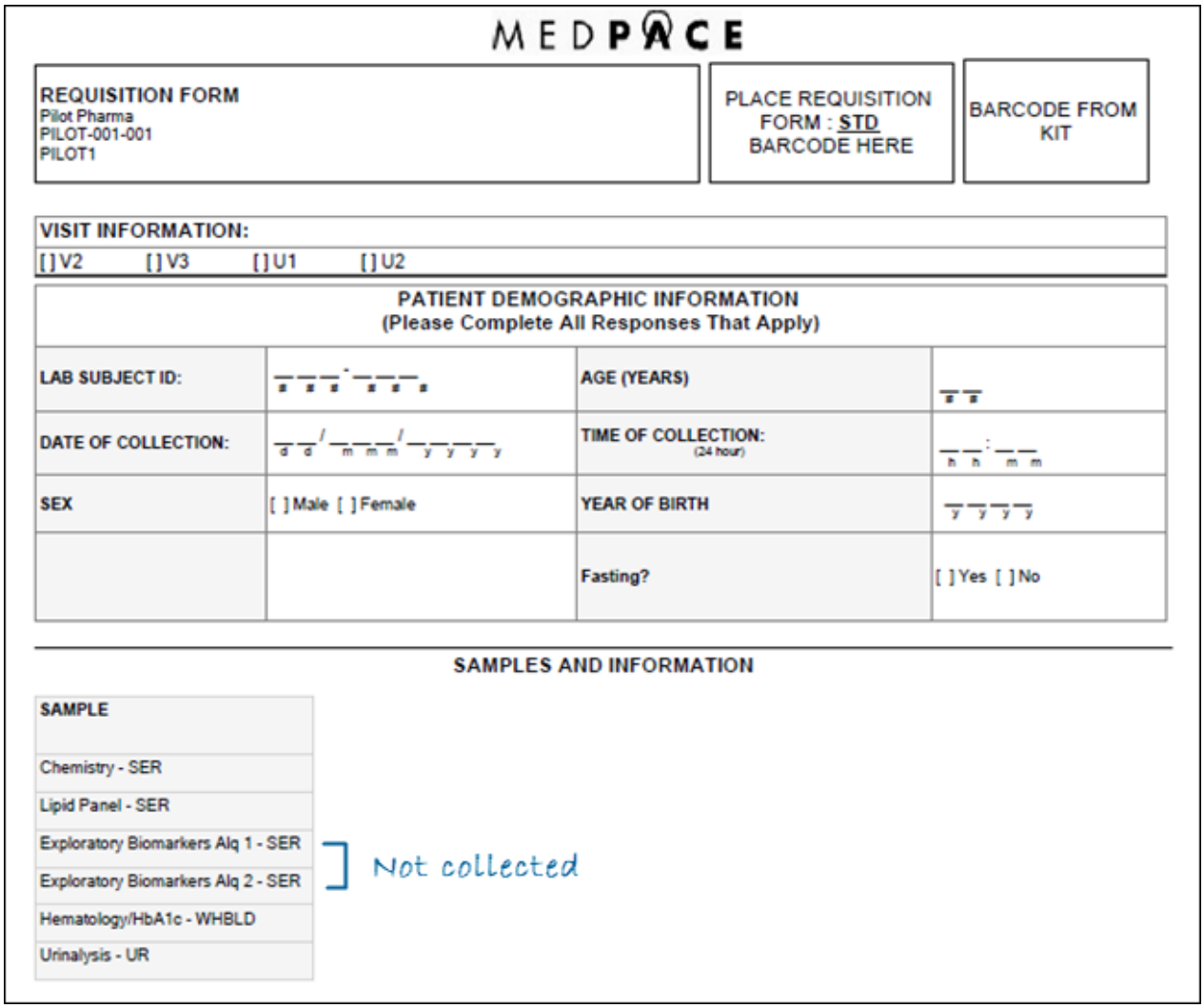


Figure 1 – Example of a Requisition Form



MEDPACE

REQUISITION FORM Pilot Pharma PILOT-001-001 PILOT1	PLACE REQUISITION FORM : STD BARCODE HERE	BARCODE FROM KIT

VISIT INFORMATION:

[ ] V2 [ ] V3 [ ] U1 [ ] U2

PATIENT DEMOGRAPHIC INFORMATION
(Please Complete All Responses That Apply)

LAB SUBJECT ID:	_ _ _ - _ _ _ _	**AGE (YEARS)**	_ _
DATE OF COLLECTION:	_ _ / _ _ _ / _ _ _ _ (d d / m m m / y y y y)	**TIME OF COLLECTION:** (24 hour)	_ _ : _ _ (h h : m m)
SEX	[ ] Male [ ] Female	**YEAR OF BIRTH**	_ _ _ _ (y y y y)
		Fasting?	[ ] Yes [ ] No

SAMPLES AND INFORMATION

SAMPLE	
Chemistry - SER	
Lipid Panel - SER	
Exploratory Biomarkers Alq 1 - SER	] Not collected
Exploratory Biomarkers Alq 2 - SER	
Hematology/HbA1c - WHBLD	
Urinalysis - UR	

Figure 2 – Notation for Sample Not Collected

3.2 Overview of the Sample Labels Page

Label Rows (see Figure 3):

Top (left to right)

- Requisition Form: Remove a sticker from this row and apply it to the “Place Requisition Form Barcode Here” box on a requisition form (See Figure 1).
- Tubes: Barcoded labels for samples to be sent to MRL and stickers for vacutainers.
- Slides: Labels for slides

Left Column (top to bottom)

- Brackets indicate the applicable visits for each collection of labels.

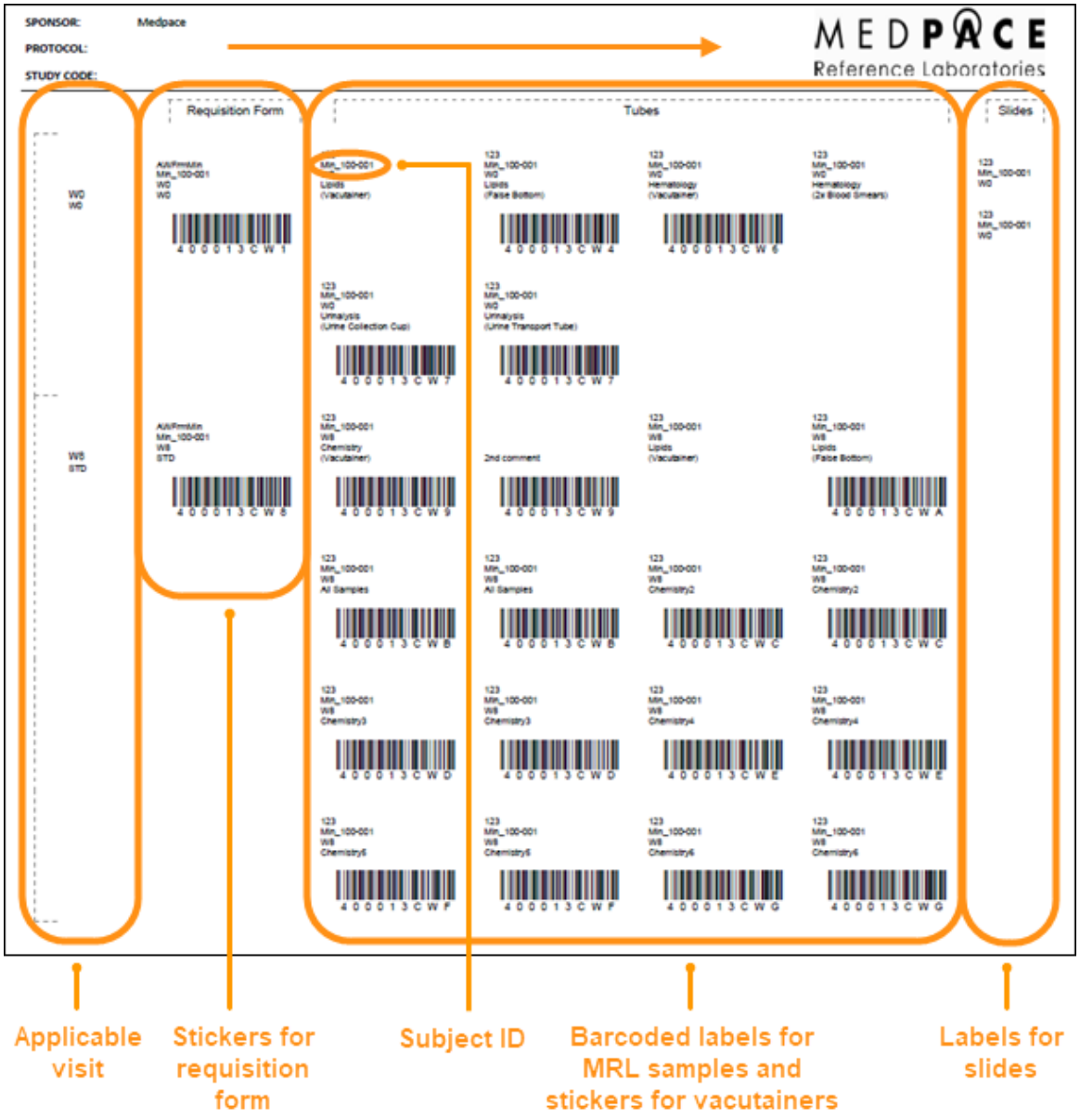


Figure 3 – Example of Sample Labels Page

3.3 Overview of Specimen Labels

Specimen labels (Figure 4) should be placed on the corresponding tube lengthwise in the middle of the tube or vial as shown in Figure 5. Labels should not cover the cap of the tube.

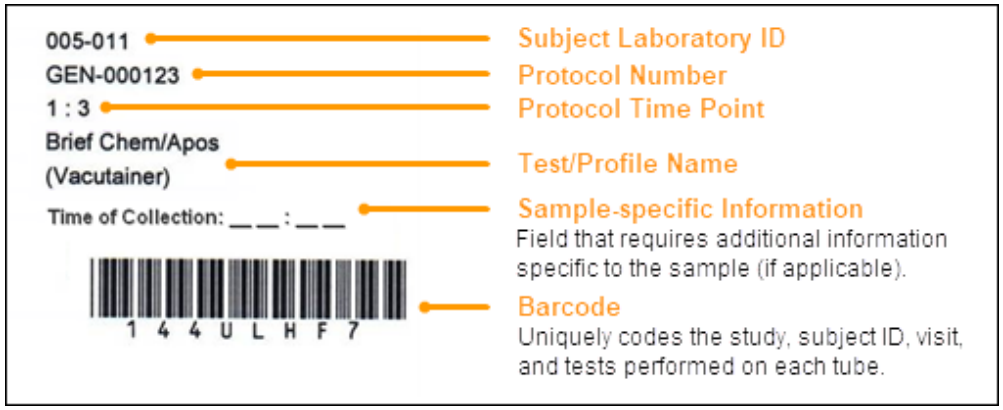


Figure 4 – Example Specimen Label

Correct labeling:

Lengthwise. Do NOT cover cap of the tube.

Figure 5 – Correct Label Placement

Incorrect labeling:

This label is not lengthwise.

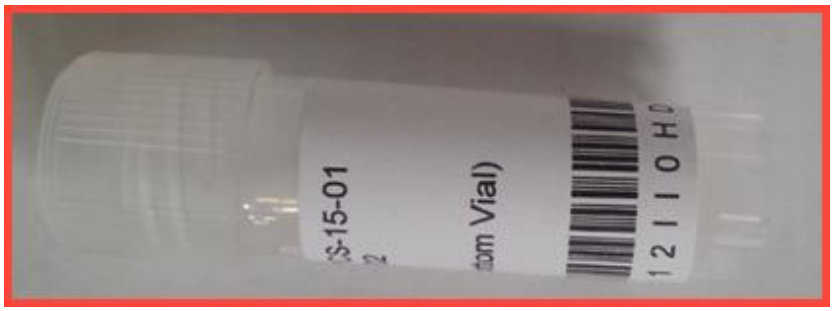


Figure 6 – Incorrect Label Placement

3.4 Submitting Requisition Forms

Submit completed requisition forms to MRL in the shipment box together with the corresponding samples. In cases where back-up aliquots are shipped separately from the primary sample, the original completed requisition form must be copied PRIOR to the first shipment and a copy included with the subsequent shipments.

Requisition forms for samples shipped periodically in batches should be kept at the site with the samples until shipment. Photocopies of completed requisition forms, along with the shipment tracking number, should be maintained in site files.

If multiple forms are available for an unscheduled visit, ALL forms should be completed with the requested demographic information and submitted to the laboratory, even if no labels from a particular page are used.

In cases where a sample is not collected (e.g., difficult venipuncture, error, or subject unable to void a urine sample), leave the barcode label for that sample affixed to the requisition and make a notation next to the label the reason why the sample was not submitted. Refer to the example in Figure 7:

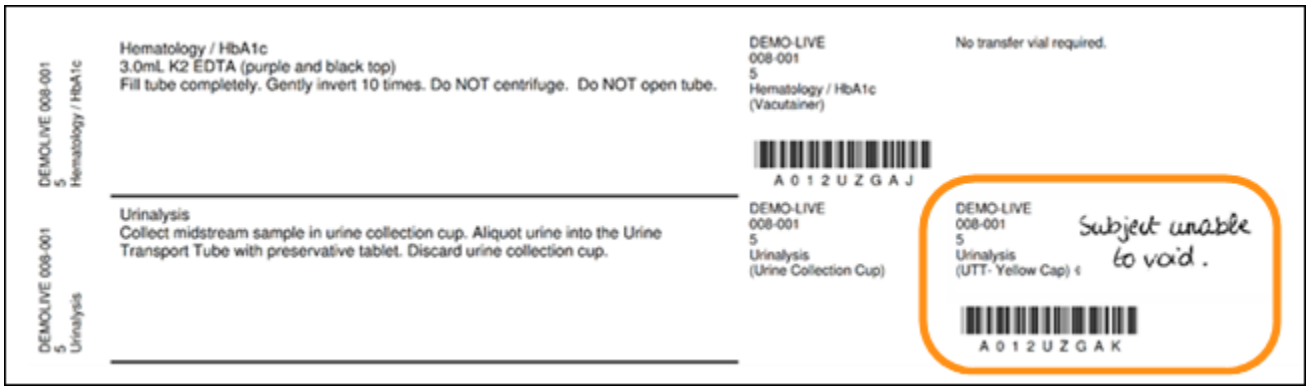


Figure 7 – Example Notation

4 Specimen Shipping

Sites are responsible to ensure their staff are appropriately trained for the shipment of diagnostic specimens.

If safe transport of ambient specimens cannot be guaranteed within 24 hours of collection, contact the study-specific MRL Project Manager. Refer to Appendix E | Alternate Specimen Handling/Shipping Arrangements for instructions on how to proceed in an emergency or other unusual circumstances that interrupt or affect normal shipping or delivery of samples to the MRL US facility.

4.1 Shipping Supplies

All shipping supplies provided by MRL are in compliance with international regulations (IATA PI650 / UN3373). Pre-printed airbills are provided that contain the site address as the shipper, MRL address or Mosaic address, description of contents, and overnight shipment designation.

4.1.1 Dry Ice

MRL US does not routinely provide sites with dry ice, although we can assist in locating dry ice providers in the vicinity of the site. Contact the study-specific MRL Project Manager should you have difficulty, or require assistance, in obtaining dry ice for specimen shipments.

4.1.2 Instructions for Completing the List of Contents

An itemized List of Contents must be included in each shipment, as required by current shipping regulations for biological substances. This complies with International rules & regulations pertaining to the transport of Diagnostic Specimens/Biological Substances Category B (IATA UN3373 – Packing Instruction 650). This is required by IATA for transportation, is valid for such purposes only, and is not subject to any internal audit or archiving obligations.

To complete the List of Contents:

1. The List of Contents is incorporated onto the **inner lid** of the shipping boxes.
2. One itemized List of Contents must be completed for the entire contents of each shipping box (one List of Contents per outer container).
3. Complete the List of Contents, indicating the Protocol number and site number associated with the samples. Check the box next to each sample type included in the shipment and enter the quantity of vials included for each sample type on the line to the right of the description.

Important: Serum separator tubes (red or gold tops) are classified as whole blood. The person who packed the shipment and completed the List of Contents must print his/her name, and sign and date the bottom of the form (Figure 8).

Packing - Shipping List (List of Contents)
Protocol Number **GEN123** Site Number **001**
Check the box next to each sample type included in this shipment and enter the number of each sample type on the line to the right of the description:
☒ Human blood (whole) x **1** tubes x **2** blood smears
☒ Human urine x **1** vials
☒ Human serum x **2** vials
☐ Human plasma x _____ vials
☐ Human tissue x _____ slides / biopsies in solution / other_____(Circle the appropriate medium)
☐ Other: _____ x _____ quantity
Specimens packed by:
Name (Printed) **Jane Smith**
Signature *Jane Smith*
Date **04Jun2023**
This document complies with International rules & regulations pertaining to the transport of Diagnostic Specimens/Biological Substances Category B (IATA UN3373 - Packing Instruction 650).
This document is required by IATA for transportation, is valid for such purposes only and is not subject to any internal audit or archiving obligations.

Figure 8 – Itemized List of Contents

4.2 Preparing Specimens for Shipment

Important: All images in this section are for illustration purposes only. Actual items may differ.

4.2.1 Ambient Shipments

Frozen Medium (Styrofoam) boxes are intended to be utilized for all shipments and should have their dry ice markings covered up and an Ambient Sticker placed on the box when shipping ambient and/or refrigerated samples to MRL.

Ambient temperature shipments are defined as shipments in the temperature range of 15°C to 25°C.

Specimens intended for refrigerated and ambient shipment should be shipped on the day of collection whenever possible.

To prepare ambient shipments:

1. Confirm that all demographic information is filled out on the requisition form(s), that the itemized List of Contents has been completed, and that all tubes are properly labeled.
2. Styrofoam boxes will arrive at your site stored and ready for use. **Set aside 3 ambient gel packs for use and ensure they are at room temperature before preparing the sample for shipment. Place the first gel pack at the bottom of the shipper.**

3. Place the tubes for ambient shipment in the 95kPa absorbent safety specimen bag(s) and seal the bag(s) (maximum 7 tubes per bag) as per the instructions on the bag.

4. **Wrap the second ambient/room temperature gel pack around the samples and them place into the shipper.**

5. IF TEMPTALES ARE PROVIDED TO THE SITE, turn on TempTale device by pressing and holding green “Start” button until the screen turns on and a sun icon appears. Then place on top of second gel pack.

6. Place third ambient room temperature gel pack on top of TempTale device or on top of the sample if no TempTale was provided.

7. Fill remaining space after final gel pack with packaging bubble wrap to prevent shuffling of samples during transit (bubble wrap is provided separately by MRL).

8. Ensure styrofoam lid is secured tightly and seal.
9. Complete the List of Contents on the inner lid of the box, close the box, and secure with tape.
10. Complete the courier AWB as outlined in Section 4.3.2.

4.2.2 Refrigerated Shipments

Frozen Medium (Styrofoam) boxes are intended to be utilized for all shipments and should have their dry ice markings covered up when shipping ambient and/or refrigerated samples to MRL.

Refrigerated temperature shipments are defined as shipments in the temperature range of 2°C to 8°C.

Specimens intended for refrigerated and ambient shipment should be shipped on the day of collection whenever possible.

Important: At least 24h prior to a shipment, actions are required with the refrigerant packs as detailed below.

To prepare refrigerated shipments:

1. Confirm that all demographic information is filled out on the requisition form(s), that the itemized List of Contents has been completed, and that all tubes are properly labeled.
2. **Refrigerant packs should be frozen for a minimum of 24 hours at -20°C ±5°C prior to use**.

   Warning: Do not freeze the refrigerant pack at ultra low temperatures (-75˚C ±10°C), as this will result in the samples freezing in transit.

3. **Prepare a Styrofoam shipper and 2 refrigerant packs. Place 1 refrigerant pack at the bottom of the shipper.**

4. Place tissue container in specimen bag, then wrap bag with provided foam pad followed by bubble wrap.

5. Place a the wrapped tissue container in the box and then place the 2nd refrigerant pack on top.

6. Fold and place the requisition form(s) on top of the foam lid.
7. Complete the List of Contents on the inner lid of the box, close the box, and secure with tape.
8. Complete the courier AWB as outlined in Section 4.3.2.

4.2.3 Frozen Shipments

Frozen temperature shipments are defined as shipments <-20ºC ±5°C. Frozen shipments are shipped Monday through Wednesday only (or Thursday if expected transit time does not exceed 24 hours) to ensure receipt during normal business hours.

Refer to Section 9.1.3 for study-specific instructions for the frequency of frozen shipments.

To prepare frozen shipments:

1. Confirm that all demographic information is filled out on the requisition form(s), that the itemized List of Contents has been completed, and that all tubes are properly labeled.

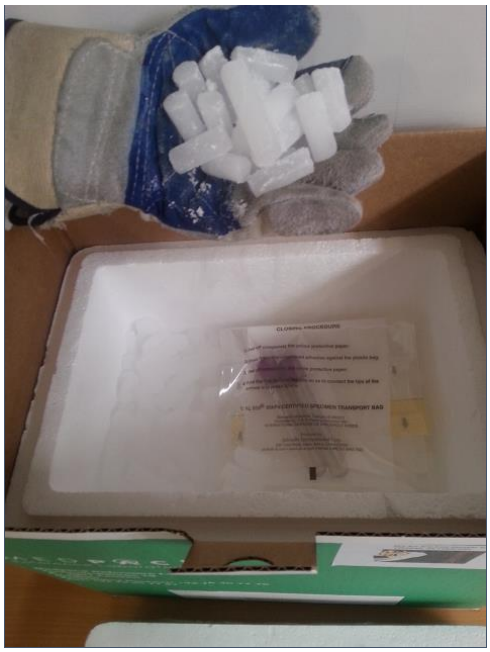
2. Place the tubes for frozen shipment in the 95kPa absorbent safety specimen bag(s) (maximum 7 tubes per bag) and seal the bag(s).

3. Line the bottom of the insulated cooler with at least 4 pounds (2 kg) of dry ice.

4. Place the safety specimen bag(s) into the insulated cooler on top of the dry ice.

5. Place at least an additional 4 pounds (2 kg) of dry ice in the insulated cooler around the specimens. Care should be taken not to overfill with dry ice so as to prevent the lid from being tightly fitted onto the cooler.

Warning: Use granular dry ice—NOT chunks of dry ice—because chunks can damage samples in transit.



6. Place the lid on the insulated cooler, ensuring that it is inserted securely.

7. Place the completed requisition form(s) on top of the insulated cooler.
8. Complete the List of Contents on the inner lid of the box, close the box, and secure with tape.
9. Record information on the dry ice label as outlined in Section 4.3.1.
10. Complete the courier AWB as outlined in Section 4.3.2.

4.3 Box Labeling and Courier Instructions

4.3.1 Box Labeling

When labeling boxes:

- The outside of each shipping bag or box must clearly display the UN3373 and Biohazard symbols, as detailed below. All supplies provided by MRL for use as outer containers have these labels applied already.
- Shipments sent on a Thursday or Friday should be labeled with a Saturday Delivery label.
- For ambient and refrigerated shipments, cover dry ice label on the side of the box with provided blank sticker and for the ambient shipment, additionally apply an “Ambient” sticker on the side of the box

Figure 9 – UN3373 and Biohazard Symbols

If shipping dry ice, record the information in Figure 10 on the dry ice label on the side of the box:

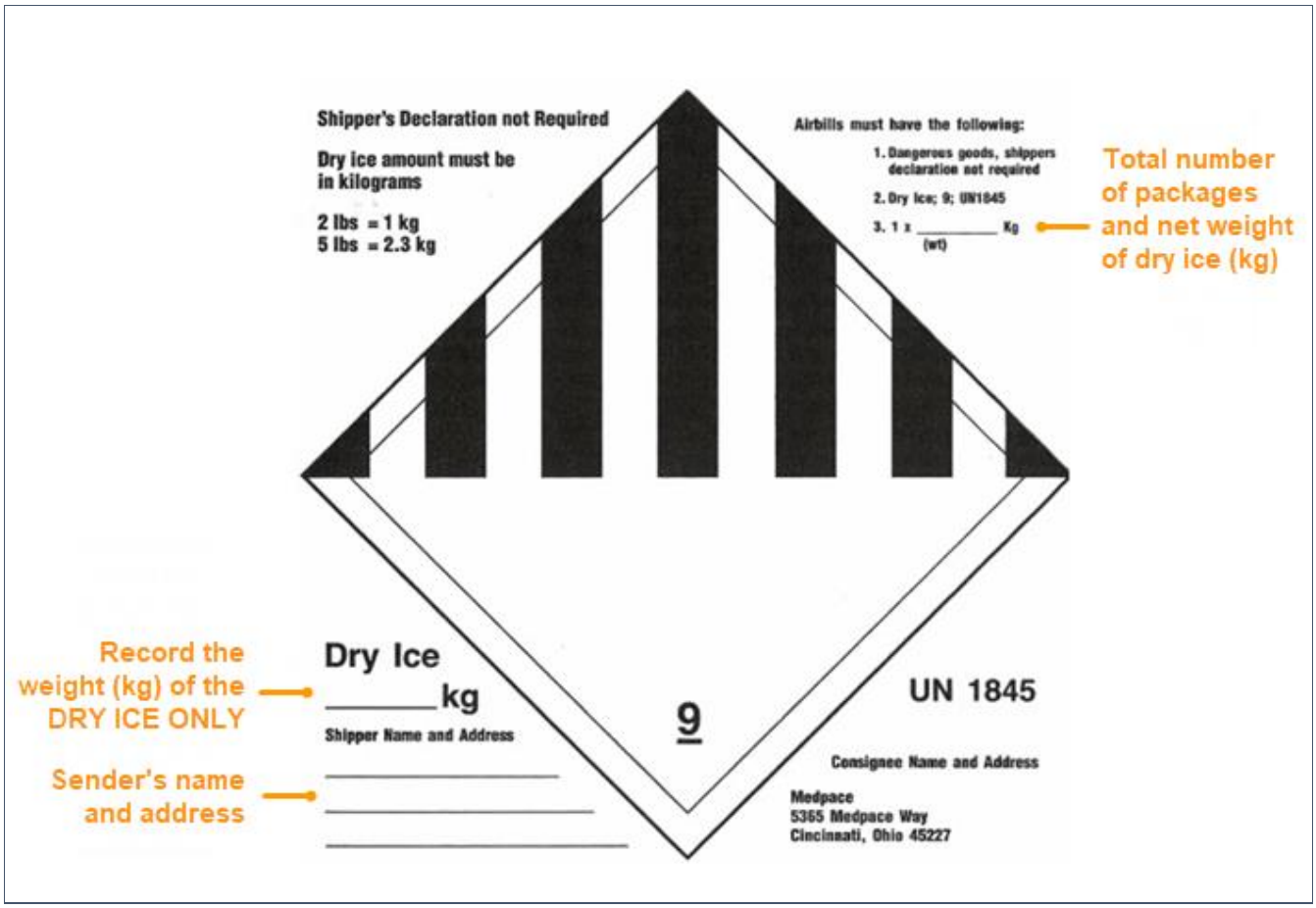


Figure 10 – Dry Ice Shipment Information

4.3.2 FedEx Airbill Instructions

Important: Thermal label airbills contain a billing reference to the protocol and site number for tracking purposes; therefore, use airbills **ONLY** for shipping samples for the study for which they are provided.
One airbill tracking ID is utilized per box. Do not make photocopies of airbills for use on multiple packages.

Ambient or Refrigerated Shipments, Thermal Label Airbill (US)

For ambient or refrigerated shipments:

- Remove the thermal label from the backing.
- Keep the top portion of the label for your records (Figure 11).
- Place the adhesive label on the side of the bag or box. Place a Saturday Delivery sticker on the package if mailed on Thursday or Friday.

Figure 11 – Ambient or Refrigerated Shipments, Thermal Airbill (US)

Important: When ordering additional thermal label airbills, you must specify whether you need labels for ambient/refrigerated or frozen shipments.

Frozen Shipments, Thermal Airbills (US)

Important: Ensure you are using a label specific for dry ice for all frozen shipments.

For frozen shipments:

- Remove the thermal label from the backing.
- Keep the top portion of the label for your records (Figure 12).
- Place the adhesive label on the side of the bag or box. Place a Saturday Delivery sticker on the package if mailed on Thursday or Friday.

Important: Thermal label airbills contain a billing reference to the protocol and site number for tracking purposes; therefore, use airbills only to ship samples for the study for which they are provided.

Figure 12 – Frozen Shipments, Thermal Airbill (US)

Important: When ordering additional thermal label airbills, you must specify whether you need labels for ambient/refrigerated or frozen shipments.

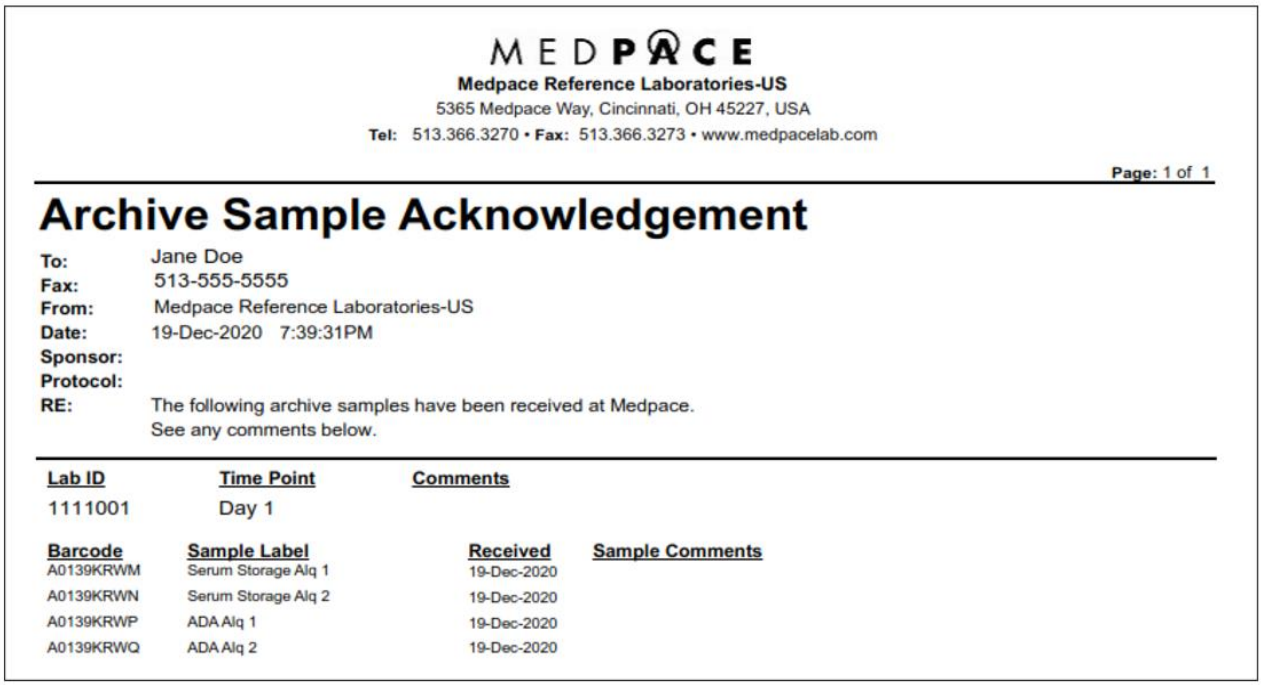
4.3.3 Scheduling Courier Pick-Ups

When scheduling courier pick-ups:

- A memo indicating the local courier contact information and the cut-off time by which the local courier must be contacted to ensure a same day pick-up is provided to each site as part of initial supplies. It is the site's responsibility to time collections so that samples can be shipped on the day of collection, if possible.
- Courier assignments are made based on efficiencies within each country or region. Sites may deviate from the courier assignment only with the written approval of the Sponsor or CRO.
- FedEx Account Number: 2986-1476-6
- **There are no pick-ups on Sundays or public holidays.**

5 Archive Reports

Archive reports are issued to sites on a daily basis, Monday through Saturday, upon accessioning of samples.



MEDPACE

Medpace Reference Laboratories-US
5365 Medpace Way, Cincinnati, OH 45227, USA
Tel: 513.366.3270 • **Fax:** 513.366.3273 • www.medpacelab.com

Page: 1 of 1

Archive Sample Acknowledgement

To: Jane Doe
Fax: 513-555-5555
From: Medpace Reference Laboratories-US
Date: 19-Dec-2020 7:39:31PM
Sponsor:
Protocol:
RE: The following archive samples have been received at Medpace.
See any comments below.

Lab ID	Time Point	Comments
1111001	Day 1	

Barcode	Sample Label	Received	Sample Comments
A0139KRWM	Serum Storage Alq 1	19-Dec-2020	
A0139KRWN	Serum Storage Alq 2	19-Dec-2020	
A0139KRWP	ADA Alq 1	19-Dec-2020	
A0139KRWQ	ADA Alq 2	19-Dec-2020	

Figure 13 – Archive Acknowledgement Report

STUDY-SPECIFIC INSTRUCTIONS

This section provides detailed instructions related to a particular study. Refer to Sections1– **5** of this manual for general instructions and information.

6 SBT777101-02 Contact Information

6.1 Re-sending of Laboratory Reports, Additional Supplies, or General Questions

For re-sending lab reports, additional supplies, or general questions:

- Contact Client Services at +1.513.366.3270/+1.800.749.1737
- Email MRL-US-PA@medpace.com
- Fax the SBT777101-02 Re-Supply Form included in Appendix G | Laboratory Re-Supply Form

6.2 Complex Protocol-related or Technical Questions

For complex protocol-related or technical questions:

Contact Person	Role	Telephone	Email
Bradley Meyer	Project Manager	1.513.366.3270 ext. 7616195	b.meyer@medpace.com
Amanda Rellahan	Sr. Project Coordinator	1.513.366.3270 ext. 7611504	a.rellahan@medpace.com

7 SBT777101-02 Quick Reference Chart

Refer to Appendix F | Quick Reference Chart for a listing of profiles/tests to be performed at each visit and abbreviated specimen collection and processing procedures, shipment temperatures, and shipment frequencies.

The total blood volume required for this study for samples analyzed or managed by Medpace is 624 mL.

8 SBT777101-02 Requisitions

Refer to Section **2** for general information and instructions on the use of requisition forms.

Each subject will be given a Laboratory Subject ID, which will be assigned sequentially at each site, be pre-printed on the requisition forms, and will remain consistent throughout the duration of the trial.

- The subject ID format for this trial will be S02-XYY-ZZZ
  (3 digit prefix – 1 digit country + 2 digit site – 3 digit subject)

The following information will be collected in the header of the requisition forms:

Visit	Information	Format	Notes
All Visits All Samples	Date of Collection	DD-MMM-YYYY	
	Time of Collection	_ _ : _ _ (24-hour clock) HH : MM	

	Sex at Birth	Male Female (Checkbox)	
	Year of Birth	YYYY*	
	Age	_ _ Years	
All Visits FFPE Skin Biopsy samples	Biopsy Site	Free Text	
	Biopsy Date of Collection	DD-MMM-YYYY	
	Transferred to Ethanol	Y/N (checkbox)	
	Diagnosis	Hidradenitis Suppurativa	Hardcoded Value
	Subject ID	S02-XYY-ZZZ	

8.1 Data Query Corrections and Resolution

If requisition forms are not completed in full or are illegible, MRL Data Coordinators will contact sites directly to resolve. The MRL team will escalate queries via email and/or phone communication only, not within an electronic portal.

If resolution is not complete within 3 business days, the MRL Project Management team will reach out to the Sonoma Clinical Team as well as the site for assistance.

9 SBT777101-02 Sample Collection and Processing

- The phlebotomist should become familiar with the lab kit supplies, order of draw, and sample processing instructions prior to collection.
- Check the expiration date of laboratory supplies in advance.
- Prepare the requisition forms required for the specific visit corresponding to the subject's ID.
- Phlebotomy should be performed using universal precautions and according to site guidelines.
- All tubes should be filled completely to ensure adequate volume for testing.

9.1 Venous Blood Collection

9.1.1 Order of Tube Collection

Refer to the Quick Reference Chart for proper order of collection. Tubes must be collected in the same order as listed on the Quick Reference Chart to avoid carryover of additives.

Discard Tube >> SST >> NaHep >> EDTA

9.1.2 Blood Specimens: Centrifugation

- We recommend using swinging bucket centrifuges for high-quality results.
- Refer to Appendix B | Centrifuge Conversion Chart (RCF to RPM) for sample-specific centrifugation time and force, in addition to instructions on the conversion from g(RCF) to RPM.
- Samples should always be visually inspected following centrifugation to ensure complete separation of the red cells below and a clear plasma/serum layer above.

- **Troubleshooting**: When looking at the tube in the upright position, if the gel does not form a horizontal barrier between serum (clear layer) and cells (see unspun or partially spun examples in Figure 14), ensure that clotting time before centrifugation and resting time after centrifugation are respected for all future collections. In addition, ensure centrifuge is well calibrated and that g(RCF) to RPM conversion was performed (refer to Appendix B | Centrifuge Conversion Chart (RCF to RPM)). Do not re-spin tubes except for SST tubes that did not separate. It may be necessary to increase the centrifugation force and time (max. of 2200 g for 15 minutes) for the next set of SST tubes.

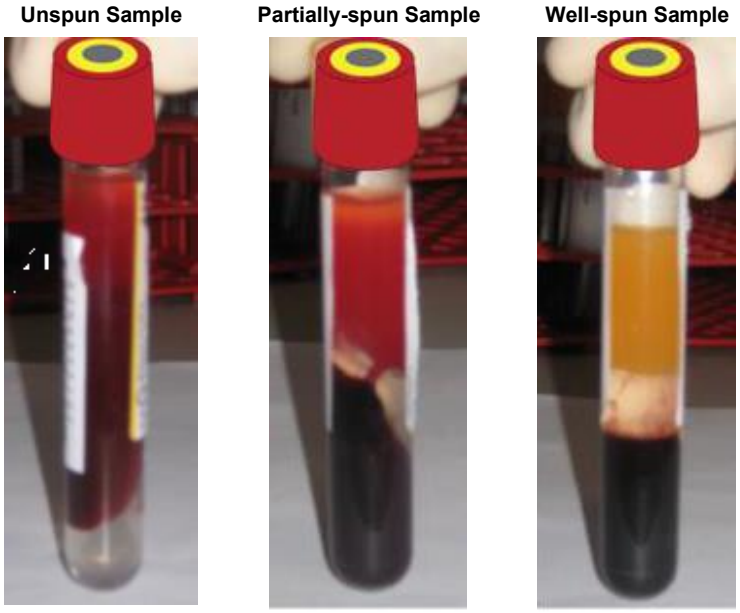


Figure 14 – Centrifuged Samples

9.1.3 Frozen Sample Requirements

Processing and Freezing

A 'frost free' or automatic defrost freezer is NOT acceptable for storage of any samples, as the samples will go through multiple freeze/thaw periods when the freezer performs it's defrost cycles. This then creates spuriously elevated results when the sample is analyzed.

To perform a freezer check for freeze/thaw cycles:

1. Add 2-3 mL of water to an empty blood collection tube or vial.
2. Freeze in an upright position overnight or until frozen solid (water will be at the bottom).
3. Invert the tube/vial so that the frozen water is now at the top.
4. Check the tube in 3 days:
    - If the water remains at the top, the freezer is maintaining temperature and is not going through thaw/defrost cycles.
    - If the water is now at the bottom, thaw/defrost cycles are occurring. Do not store samples in this freezer unit.

Storage

Frozen samples should not be removed from the (-20°C ± 5°C or -75°C ± 10°C) freezer for shipment until they can be transferred immediately into a shipping container containing a minimum of 4 KG of dry ice.

Shipping

To ship frozen samples:

5. Place the samples into the 95kPa safety specimen bags and place on top of a minimum of four pounds (2 KG) of dry ice.
6. Cover the samples with another four pounds (2 KG) of dry ice.

> **Important:** Pack frozen samples for shipment as close as possible to the time of courier pick-up. The longer they can remain in a stable freezer environment, the better. Samples should never be packed for shipment until the day of courier pick-up.

7. The shipping container should be sealed immediately to prevent evaporation of dry ice.

9.1.4 ADA

7.0mL Serum Separator Tube/SST (Red or Gold Top) – Serum Sample for ADA (Anti-drug Antibody)

STEP 1 Fill the tube completely.

STEP 2 Mix immediately by gently inverting the tube 5 times.

STEP 3 Allow the blood to clot in the upright position for 30 to 60 minutes.

STEP 4 Within 60 min of collection, centrifuge the tube for 10 to 15 minutes at 1800 g to 2200 g *(RCF not RPM)*. **The SST tube should NOT be refrigerated prior to centrifugation.** There should be complete separation of serum and blood cells via the separation gel. If the serum is not separated from the blood after centrifugation, re-centrifuge the sample until the serum is separated

STEP 5 Using a transfer pipette, aliquot 0.5mL of serum each into the first 2 x 2.0 mL Sarstedt cryovials and divide the remaining serum between the other 2 x 2.0 mL Sarstedt cryovials, leaving a small amount on top of the separator gel. Discard the collection tube.

STEP 6 Store at ≤-20°C until shipping

STEP 7 Ship cryovials to MRL frozen in weekly batches.

9.1.5 *Exploratory Markers - Serum*

4mL Serum Separator Tube/SST (Red or Gold Top) – Serum Sample for exploratory markers

STEP 1 Fill the tube completely.

STEP 2 Mix immediately by gently inverting the tube 5 times.

STEP 3 Allow the blood to clot in the upright position for 30 to 60 minutes.

STEP 4 Within 60 min of collection, centrifuge the tube for 10 to 15 minutes at 1800 g to 2200 g *(RCF not RPM)*. **The SST tube should NOT be refrigerated prior to centrifugation.** There should be complete separation of serum and blood cells via the separation gel. If the serum is not separated from the blood after centrifugation, re-centrifuge the sample until the serum is separated.

STEP 5 Using a transfer pipette, aliquot 0.5mL of serum each into the first 2 x 2.0 mL Sarstedt cryovials and divide the remaining serum between the other 2 x 2.0 mL Sarstedt cryovials, leaving a small amount on top of the separator gel. Discard the collection tube.

STEP 6 Store at ≤-20°C until shipping

STEP 7 Ship cryovials to MRL frozen in weekly batches.

9.1.6 *PBMC (collection)*

10.0mL Sodium Heparin Tube (Green Top) – PBMC sample for RCL, PBMC sample for exploratory biomarkers, and PBMC sample for cellular immunogenicity

STEP 1 Fill the tube completely.

STEP 2 Mix immediately by gently inverting the tube 8-10 times.

STEP 3 Do NOT centrifuge. Do NOT open tube.

STEP 4 Ship tube to MRL ambient **on day of collection** and submit PBMC Sample submission form located in Appendix H. This is in addition to the requisition form that is shipped with the samples.

9.1.7 Exploratory Markers - Plasma

4.0mL K2EDTA (Purple Top) – Plasma Sample for exploratory markers

(K2 Ethylenediaminetetraacetate)

STEP 1 Fill all tubes completely.

STEP 2 Mix immediately by gently inverting the tube 8-10 times and immediately place on wet ice.

STEP 3 Within 60 min of collection, centrifuge at 4°C for 10 to 15 minutes at 1800 - 2200 g *(RCF not RPM)*. There should be complete separation of the plasma and blood cells.

STEP 4 Using a transfer pipette, aliquot 0.5 mL of plasma into 4 x 2.0 mL Sarstedt cryovials (8 cryovials for Pre-Treatment) and freeze until shipment.

x4 or x8

STEP 5 Store at ≤-20°C until shipping

STEP 6 Ship cryovials to MRL frozen in weekly batches.

9.1.8 *PK ddPCR*
3.0mL K2EDTA (Purple Top) – Blood Sample for PK (pharmacokinetic)

(K2 Ethylenediaminetetraacetate)

STEP 1 Fill tube completely as a partial fill results in over anticoagulation, impacting results of testing.

STEP 2 Mix immediately by gently inverting the tube 8-10 times.

STEP 3 Do NOT Centrifuge.

STEP 4 Using a transfer pipette, divide blood evenly between 2 x 2.0 mL Sarstedt cryovials and freeze until shipment.

STEP 5 Store at ≤-70°C until shipping

STEP 6 Ship cryovials to MRL frozen in weekly batches.

9.1.9 FFPE Skin Biopsy (Lesional and Peri-lesional)

Refer to the Biopsy manual for detailed description of tissue processing.

FFPE Skin Biopsy (Fixed Tissue) samples will be placed in 1 x 20mL vial containing 10 mL of 10% Formalin (provided as a bulk supply). **This sample must be shipped to Mosaic Labratories L.L.C refrigerated on the day of collection.** If for some reason the sample cannot shipped on the day of collection leave the biopsy sample in 10% formalin for 24 hr. After 24 hrs the sample must be transferred to a 20 mL container pre-filled with 10 mL of 70% Reagent Grade Alcohol (Provided as bulk supply). The Sample can be shipped to Mosaic L.L.C after it has been transferred into 70% Reagent Grade Alcohol

Important: Also the refrigerant packs included with compressed boxes should be frozen for a minimum of 24 hours at -20°C ±5°C prior to use.

	Intended analysis	Format	Process
1	Fixed tissue (FFPE)	Loose in 10% formalin in a pre-filled and labelled vial	Place the biopsy directly into the pre-filled FFPE vial

9.2 SBT777101-02 Shipment Information

FedEx is the courier for all sites in the study.

Refer to Section 4 for instructions on how to package samples for shipment at various temperatures.

9.2.1 Ambient samples

Ambient samples are shipped with ambient packs on the day of collection.

The following samples will be shipped ambient for this study:

- PBMC

9.2.2 Refrigerated samples

Refrigerated samples are shipped with refrigerant packs on the day of collection. Each shipment should contain one (1) or two (2) refrigerant packs that have been frozen overnight for a minimum of twenty four (24) hours at-20°C ±5°C, NOT-75°C ±10°C, which would cause the samples to freeze during shipment. If using a saddle-bag refrigerant pack, one (1) saddle-bag per box is sufficient. If using individual refrigerant packs, use two (2) refrigerant packs per box.

The following samples will be shipped refrigerated (2–8°C) to **Mosaic** for this study:

- FFPE Skin Biopsy

9.2.3 Frozen samples

Frozen samples are stored at the site frozen (-20°C ±5°C or below) and shipped to Medpace Reference Laboratories on dry ice. Frozen shipments should be sent according to the schedule noted below. For weekly or monthly batches, it is recommended that shipments occur on Monday, Tuesday, or Wednesday only.

The following frozen samples will be shipped in weekly batches:

- ADA (Serum Sample for ADA (Anti-drug Antibody))
- Exploratory Markers - Serum (Serum Sample for Exploratory Makers)
- PK ddPCR (Blood Sample for PK (Pharmacokinetics))
- Exploratory Markers - Plasma (Plasma sample for Exploratory Markers)

10 Appendix A | CAP and CLIA Certificates

(page 1 of 2)

COLLEGE of AMERICAN PATHOLOGISTS

CERTIFICATE OF ACCREDITATION

Medpace Reference Laboratories
Cincinnati, Ohio
Traci Turner, MD,MT(ASCP)

CAP#: 7185149
CLIA#: 36D1023277

The organization named above meets all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to **May 18, 2026** to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Kathleen G. Beavis, MD
Chair, Accreditation Committee

Donald S. Karcher, MD, FCAP
President, College of American Pathologists

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
MEDPACE REFERENCE LABORATORIES LLC
5365 MEDPACE WAY
CINCINNATI, OH 45227

CLIA ID NUMBER
36D1023277

EFFECTIVE DATE
06/03/2022

LABORATORY DIRECTOR
TRACI TURNER M.D.

EXPIRATION DATE
06/02/2024

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Monique Spruill

Monique Spruill, Director
Division of Clinical Laboratory Improvement & Quality
Quality & Safety Oversight Group
Center for Clinical Standards and Quality

162 Certs2 050322

11 Appendix B | Centrifuge Conversion Chart (RCF to RPM)

A certain relative centrifugal force (RCF) in g's is required to separate cells from serum/plasma. Centrifuges typically measure revolutions per minute (RPM) and not g's. The number of RPMs required to obtain a given g is calculated by the following equation:

$$\text{RPM} = \sqrt{\frac{\text{RCF x } 10^5}{1.12 \text{ x r}}}$$

Centrifugal Force – The force that tends to make rotating bodies move away from the center of rotation (i.e., separation of cells and plasma/serum in a tube).

Relative Centrifugal Force (RCF) – The centrifugal force (see above), expressed as number of times greater than gravity (g). Example: 1200 x g, also written as 1200g.

Revolutions per Minute (RPM) – The number of rotations per minute of the centrifuge rotor (moving head).

Radius (r) – Swinging bucket centrifuges – the distance (in cm) from the center of the centrifuge head (post the head rests on) to the bottom of the bucket.

Fixed angle centrifuges – the distance (in cm) from the center of the centrifuge head (post the head rests on) to the middle of the sample compartment.

Centrifuge Radius (in cm)	Force of 1200g	Force of 1500g	Force of 1800g	Force of 2200g
8	3600 rpm	4100 rpm	4500 rpm	5000 rpm
10	3300 rpm	3700 rpm	4000 rpm	4500 rpm
12	3000 rpm	3400 rpm	3700 rpm	4100 rpm
14	2800 rpm	3100 rpm	3400 rpm	3800 rpm
16	2600 rpm	2900 rpm	3200 rpm	3500 rpm

After centrifugation, there must be complete separation of the serum/plasma and cells.

12 Appendix C | Biotin Interference

Biotin is a B vitamin that is found in a variety of foods. It helps turn the carbohydrates, fats, and proteins into energy. The amount of biotin required daily depends on the individual's age, and it is recommended that adults receive 30 µg/day [1].

High levels of biotin may cause interference with certain immunoassays using biotin-streptavidin technology [2, 3, 4]. Typical dietary biotin intake does not reach amounts capable of causing interference, but high dose biotin, as sometimes recommended in the treatment of certain diseases/conditions (e.g., multiple sclerosis (MS) and dermatologic conditions) may be sufficient to impact laboratory tests using biotin-streptavidin technology. Also, multivitamins, biotin supplements, dietary supplements for hair, skin, and nail growth may contain amounts of biotin capable of interference with laboratory tests. Such interference may cause falsely high or falsely low results depending on the assay. Physicians should advise patients to abstain from high levels of biotin intake for at least 48 hours before the blood collection for immunoassay tests [5].

The FDA provides recommendations for Health Care Providers in safety communications regarding biotin [2, 3] that can be accessed at www.fda.gov/medical-devices/safety-communications/update-fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication.

Laboratory Tests with Potential Interference by High Biotin Levels	
Adrenocorticotropic Hormone (ACTH)	Human Immunodeficiency Virus 1&2 p24 (HIV combi PT)
Alpha Fetoprotein (AFP)	Insulin
C-Peptide	Luteinizing Hormone (LH)
CA-125	Myoglobin
Calcitonin	Neuron Specific Enolase (NSE)
Carcinoembryonic Antigen (CEA)	Osteocalcin
Human Chorionic Gonadotrophin (ß-hCG)	Parathyroid Hormone (PTH), Intact
Cortisol	Pro BNP
Creatine Kinase MB Isoenzyme (CK-MB)	Procollagen Type 1 N-terminal Propeptide (P1NP)
Cytomegalovirus, IgG (CMV IgG)	Progesterone
Cytomegalovirus, IgM (CMV IgM)	Prolactin
Dehydroepiandrosterone Sulfate (DHEA-S)	Prostate Specific Antigen (PSA)
Estradiol	QuickVue Pregnancy Test
Ferritin	S-100
Folate	Sex Hormone Binding Globulin (SHBG)
Follicle Stimulating Hormone (FSH)	Telopeptide C Terminal, Type 1 Collagen (ß-Crosslaps)
Hepatitis A Virus Antibody (Anti-HAV), IgM, and Total	Testosterone, Total
Hepatitis B Core Antibody (Anti-HBc), IgM, and Total	Thyroid Stimulating Hormone (TSH)
Hepatitis B Envelope Antibody (Anti-HBe)	Thyroxine, Free (FT4)
Hepatitis B Envelope Antigen (Anti-HBe Ag) (Qualitative)	Thyroxine, Total (T4)
Hepatitis B Envelope Antigen (Anti-HBe Ag) (Quantitative)	Triiodothyronine, Free T3 (FT3)
Hepatitis B Surface Antibody (Anti-HBs)	Triiodothyronine, T3
Hepatitis B Surface Antigen (HBs Ag) (Qualitative)	Troponin I
Hepatitis B Surface Antigen (HBs Ag) (Quantitative)	Troponin T, High Sensitivity
Hepatitis B Surface Antigen Confirmatory (HBs Ag) (Qualitative)	Vitamin B12
Hepatitis C Virus Antibody (Anti-HCV)	Vitamin D, 25 OH

References:

[1] National Institutes of Health. Biotin fact sheet for consumers. ods.od.nih.gov/factsheets/Biotin-Consumer

[2] U.S. Food and Drug Administration. The FDA Warns that Biotin May Interfere with Lab Tests: FDA Safety Communication, November 28, 2017.

[3] U.S. Food and Drug Administration. UPDATE: The FDA Warns that Biotin May Interfere with Lab Tests: FDA Safety Communication. November 5, 2019.

[4] Roche Diagnostics. Biotin facts. biotinfacts.roche.com

[5] Chun KY. Biotin interference in diagnostic tests. ClinChem. 2017;63(2):619-620.

[6] U.S. Food and Drug Administration. Biotin Interference with Troponin Lab Tests – Assays Subject to Biotin Interference.

13 Appendix D | Commercial Invoice

Commercial Invoice

Complete and fax this form to Medpace Reference Laboratories at 001-513-366-3273 each time an international shipment is made.

Date of exportation:	
Shipper/Exporter:	**Consignee**:
Country of Origin/Export:	**Importer**: Same as above
International Tracking Number:	**Country of Ultimate Destination**:

Pkg. #.	No. of Vials	Unit	Description	Unit Value	Total Value
1		Each	Human Urine, non-infectious UN3373 Category B for diagnostic purposes only. No commercial value. Value for customs purposes only. Canadian HS Code 3001200000		$1.00
			Human Serum, non-infectious UN3373 Category B for diagnostic purposes only. No commercial value. Value for customs purposes only. Canadian HS Code 3002120011		
			Human Plasma, non-infectious UN3373 Category B for diagnostic purposes only. No commercial value. Value for customs purposes only. Canadian HS Code 3002120011		
			Human Whole Blood, non-infectious UN3373 Category B for diagnostic purposes only. No commercial value. Value for customs purposes only. Canadian HS Code 3002900040		
			Packed in Compliance with IATA Packing Inst. 650 / UN3373 Biological Substance Category B		
			Human blood, tissue or urine (human material that was neither inoculated with or exposed to infectious agents of agricultural concern, including zoonotic agents; the material contains no animal or non-human primate material and is not of tissue culture origin)		
			These are research specimens for investigational use only and are not for resale, having no commercial value. The declared value for customs purposes only is $1.00 (USD)		

Total # Packages	Total Weight	Total Specimen Volume (mL)	Total Invoice Value
1			$1.00 (USD)

THESE COMMODITITES ARE LICENSED FOR THE ULTIMATE DESTINATION SHOWN

Print Name _____ Title _____

Sign Name _____ Date _____

14 Appendix E | Alternate Specimen Handling/Shipping Arrangements

14.1 Alternate Specimen Handling/Shipping Arrangements

Sites in the following locations send specimen shipments to MRL Cincinnati, OH, USA: North America, and Central and South America.

These instructions apply to emergency or other unusual circumstances that interrupt or affect normal shipping or delivery of samples to the central laboratory. Sites will be notified by MRL or the Sponsor/CRO when circumstances are such that alternate specimen handling and shipping arrangements should be implemented. Be alert for a message with specific instructions. If a site has concerns about shipping and has not received a message, information should be obtained from their CRA, from their MRL Project Manager, or by checking the MRL website.

14.1.1 Suggested Contingency Specimen Handling

If safe transport cannot be assured within three to four days of collection, the Sponsor/CRO may direct that sites follow any of the suggested instructions:

- Perform safety chemistry, hematology, urinalysis, hemoglobin A1C, and other safety tests at a local laboratory.
- Retain an aliquot of 1 mL of safety chemistry serum, labeled with the chemistry specimen label, in a small transfer vial for later shipment to MRL. Freeze at -20°C ±5°C or below.
- Freeze serum or plasma for lipid profiles and reserves in the freezer at -20°C ±5°C or below.
- Maintain all frozen specimen at -20°C ±5°C or below until further notice.

14.1.2 Specimen Shipment to Alternate Central Laboratory

In emergency situations, sites in North America, and Central and South America might receive written instructions from the central laboratory or Sponsor/CRO to re-route specimens to the MRL EU location:

Medpace Reference Laboratories BVBA

Attn: George Andronos

Technologielaan 19

B-3001, Leuven Belgium

Tel: +32-16-407781

Fax: +32-16-407775

To re-route specimens to the MRL EU location:

- Obtain a blank courier airbill from the local courier.
- For receiver, enter the address of Medpace Reference Laboratories BVBA as listed above.
- For description of contents, enter:

BIOLOGICAL SUBSTANCE, CATEGORY B UN3373,
PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650

- Prepare **three copies** of a commercial/proforma invoice with the address of Medpace Reference Laboratories BVBA as the receiver of the package. The commercial/proforma invoice must contain the following information/statements (see Appendix D | Commercial Invoice):
    - Number of samples, Total sample volume
    - Human Blood and Urine Specimens for Clinical Research / Diagnostic Purposes, Not Infectious / Not Contagious
    - Biological Substance, Category B; Packed in Compliance with IATA Packing Inst. 650 / Diagnostic Specimens UN3373
    - Human blood, tissue or urine (human material that was neither inoculated with or exposed to infectious agents of agricultural concern, including zoonotic agents; the material contains no animal or non-human primate material and is not of tissue culture origin)
    - These are research specimens for investigational use only and are not for resale, having no commercial value. Declared value for Customs purposes only.
    - These commodities are licensed for the ultimate destination shown.

Medpace Reference Laboratories will provide you with the proper courier account number and will assist you in shipping the specimens correctly.

15 Appendix F | Quick Reference Chart

(page 1 of 2)

MEDPACE
Reference Laboratories

SBT777101-02
Quick Reference Chart

SONOMA BIOTHERAPEUTICS

Label	Collection	Study Period	Screening	Pre-Treatment [d]					Treatment and Safety Follow Up														ET
		Study Week	-10 to -7	-4 to -1					1				2		3	4	6	8	10	12	18	24	36	48/ES	
		Study Day (Visit Window)		-10 to -4	-7 to 1	1	2	4 or 5	7±1	11±1	14±2	21±2	28±2	42±2	56±2	70±2	84±3	126±7	168±7	252±7	336±7	
		Testing		Apheresis	Pre-Infusion	Biopsy																		
ADA	7.0 mL SST	Serum sample for ADA			X										X	X		X		X	X			X
Exploratory Markers - Serum	4.0 mL SST	Serum sample for exploratory markers	X		X				X						X			X		X	X	X	X	X
PBMC (collection) [b]	10.0 mL NaHep	PBMC for Cellular Immunogenicity, Exploratory Biomarkers, RCL	X (x2) Ex2		X (x4) Cx1 Ex2 Rx1		X (x2) Ex2	X (x2) Ex2	X (x2) Ex2	X (x2) Ex2	X (x2) Ex2	X (x2) Ex2	X (x3) Cx1 Ex2		X (x3) Cx1 Ex2 Rx1	X (x2) Ex2		X (x3) Cx1 Ex2 Rx1		X (x2) Ex2	X (x3) Ex2 Rx1		X (x3) Cx1 Ex1 Rx1	X (x2) Cx1 Ex1
PK ddPCR	3.0 mL K2EDTA	Blood sample for PK(ddPCR)			X		X[d]	X	X	X	X	X	X		X	X		X		X	X		X	X
Exploratory Markers - Plasma [c]	4.0 mL K2EDTA	Plasma sample for exploratory markers	X	X(x2)			X	X	X	X	X	X	X		X	X		X		X	X		X	X
FFPE Skin Biopsy (Lesional & Peri-lesional) [e]	4mm Punch and pelt dbh	X (optional) Lesional				X lesional							X lesional		X lesional	X lesional		X lesional		X lesional	X lesional		X lesional	X lesional
						X (Optional) peri-lesional									X (Optional) peri-lesional									X (Optional) peri-lesional

Footnotes

General Note: Samples collected outside the listed scheduled visits should use the Unscheduled Visit forms provided at the back of the requisition binder.

[a] The PK sample collected on study Day 2 should be collected at approximately the same time of day that the infusion of study drug took place on study Day 1 (+/- 1 hour). An un scheduled PK sample should be collected as soon as possible after a suspected infusion related reaction adverse event.

[b] 4 tubes will be collected at Pre-Treatment, 3 tubes will be collected at Day 28, Day 56, Day 84, Day 168 and Day 336. For all other visits only 2 tubes will be collected. X = total, C = Cellular immunogenicity, E = exploratory biomarkers, R = RCL, number of tubes for each collection designated for each visit as outlined in protocol SOA.

[c] 2 tubes will be collected at Pre-Treatment. For all other visits only 1 tube will be collected.

[d] The Pre-Treatment visit samples may be redrawn any number of times. For redraws of the Pre-Treatment visit samples please use the Pre-Treatment Reassessment Visit forms in the back of the requisition binder next to the Unscheduled Visit forms.

[e] Mandatory lesional biopsies should be collected at Pre-treatment, Week 4, and Week 12 visits. An additional optional lesional biopsy may be collected during the screening period, and optional peri-lesional biopsies may also be collected at Pre-treatment, Week 4, and Week 12. The Pretreatment skin biopsy (4-mm punch biopsy) is to be performed after the pre-infusion confirmation of eligibility, up to 7 days before study drug administration. During treatment and follow-up the skin biopsy can be performed at or up to 7 days after the scheduled assessment visit. For patients who discontinue the study prior to Week 12, a skin biopsy at ET is optional. Please photograph the lesion that is to be biopsied according to the instruction provided in the biopsy manual. Please refer to the Biopsy Manual for further information.

Order of Draw

MedSpace Reference Laboratories
Phone: 513.364.3270
Fax: 513.364.3273

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Quick Reference Chart
Date: 14Jul2025
Version 4

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MEDPACE
Reference Laboratories

SBT777101-02
Quick Reference Chart

SONOMA BIOTHERAPEUTICS

Sample	Tube	Collection & Processing	Aliquots	Shipping	Notes
ADA	7.0 mL SST	Fill tube completely with blood. Immediately after collection, gently invert tubes 5 times. Allow tubes to clot for a minimum of 30 minutes post collection, keeping tubes vertical. The SST tube should NOT be refrigerated prior to centrifugation. Within 60 minutes of collection, centrifuge at 1,800- 2,200xg (RCF not RPM) for 10-15 minutes to allow the gel barrier to migrate between the cell and serum layers. Using a transfer pipette, aliquot 0.5mL of serum each into the first 2 x 2.0 mL cryovials and divide the remaining serum between the other 2 x 2.0mL cryovials, leaving a small amount on top of the separator gel. Discard the collection tube. Store at ≤-20°C until shipping Ship cryovials to MRL frozen in weekly batches.	4 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
Exploratory markers - Serum	4.0 mL SST	Fill tube completely with blood. Immediately after collection, gently invert tubes 5 times. Allow tubes to clot for a minimum of 30 minutes post collection, keeping tubes vertical. The SST tube should NOT be refrigerated prior to centrifugation. Within 60 minutes of collection, centrifuge at 1,800- 2,200xg (RCF not RPM) for 10-15 minutes to allow the gel barrier to migrate between the cell and serum layers. Using a transfer pipette, aliquot 0.5mL of serum each into the first 2 x 2.0 mL cryovials and divide the remaining serum between the other 2 x 2.0mL cryovials, leaving a small amount on top of the separator gel. Discard the collection tube. Store at ≤-20°C until shipping Ship cryovials to MRL frozen in weekly batches.	4 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
PBMC (collection)	10.0 mL NaHep	Fill all tubes completely with blood. Gently invert 8-10 times to avoid clotting. Do NOT Centrifuge. Do NOT open tube. Ship tube to MRL ambient on day of collection	None	Ship to MRL ambient on day of collection	
Exploratory markers - Plasma	4.0 mL K2EDTA	Fill all tubes completely. Mix tubes after collection by gently inverting 8-10 times and immediately place on wet ice. Within 60 minutes of collection, centrifuge at 4°C at 1800g - 2200g (RCF not RPM) for 10-15 minutes. Using a transfer pipette, aliquot 0.5 mL of plasma into each of 4(8 for Pre-Treatment) x 2.0 mL cryovials and freeze until shipment. Store at ≤-20°C until shipping Ship cryovials to MRL frozen in weekly batches.	4 or 8 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
PK ddPCR	3.0 mL K2EDTA	Fill tube completely as a partial fill results in over anticoagulation, impacting results of testing. Mix tube immediately after collection, gently inverting 8-10 times Do NOT Centrifuge. Using a pipette, divide blood equally between 2 separate aliquots Freeze immediately on dry ice and keep at ≤-70°C until shipping. Ship cryovials to MRL frozen in weekly batches.	2 x 2.0 mL Sarstedt microtube	Ship to MRL frozen in weekly batches	
FFPE Skin Biopsy Lesional and Perl-lesional	6mm Punch and petri dish	See biopsy manual for instruction	2x 20.0 mL tube	Ship to Mosaic Refrigerated (4C) day of collection	DO NOT SEND TO MRL

Medpace Reference Laboratories
Phone: 513.366.3270
Fax: 513.366.3273

16 Appendix G | Laboratory Re-Supply Form

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MEDPACE REFERENCE LABORATORIES

LABORATORY RE-SUPPLY FORM – MRL UNITED STATES

22JUL2025 | V6

Scan completed form and email to MRL-US-PA@Medpace.com

Sponsor	Protocol Number	Laboratory Study Code	Request Date	Date Supplies Needed
Sonoma Biotherapeutics	SBT777101-02	SBT7102		

Site #/PI Last Name	Requester Name	Requester Email

Order Prepared By	Date Shipped	Tracking #

Delivery timeframe (from shipment date)
☐ **One Week** ☐ **Express**

Requests received *before* 3pm are *processed* *by the next business day.*
Requests received *after* 3pm are *processed within 2 business days.*

Courier
☐ **FedEx** ☐ **OCASA** ☐ **UPS**
☐ **Other:**

Internal Use Only		SUPPLIES	QUANTITY REQUESTED
Pack	**QC**		
		Laboratory Kits	
		• Screening | Kit A	
		• Pre-Treatment | Kit B	
		• W1D2, W1D7, W2D14, W3D21, W6D42, W10D70, & W36D252 | Kit C	
		• W1D4or5 & W2D11| Kit D	
		• W4D28, W8D56, W12D84, & W48D336/ES | Kit E	
		• W18D126 & ET| Kit F	
		• W24D168 | Kit G	
		Skin Biopsy Supplies	
		• Surgical Skin Marker	
		• 6mm Punch Biopsy Device	
		• 60mm Petri Dish	
		• Sterile Scalpel	
		• Fine Point Forceps	
		• 70% Reagent Grade Alcohol (1L bottle)	
		• 20mL SecurTainer (for FFPE samples transferred to Alcohol)	
		• 10% Neutral Buffered Formalin prefilled tube 20 mL/10 mL	
		• Sterile Transfer Pipettes	
		• Phosphate Buffered Salene (PBS) Solution (pH 7.2, 1L)	

MEDPACE
REFERENCE LABORATORIES

Internal Use Only		SUPPLIES	QUANTITY REQUESTED
Pack	QC		
		Shipping Supplies	
		• Pre-Printed MRL Frozen Airway Bills	
		• Pre-Printed MRL Ambient/Refrigerated Airway Bills	
		• Pre-Printed Ambient/Refrigerated Airway Bills to Mosaic Attn: Hillary Winkel/Jessica Macapulay 80 Empire Drive Lake Forest, CA 92630	
		• Medium Frozen Shippers	
		• 20oz. Saddlebag Gel Pack	
		• 20oz. Saddlebag Gel Pack Ambient Marked	
		• Uline Air Bubble Wrap Roll - 12" x 120', 5/16"	
		• 95kPA Bag	
		• UN3373, Biohazard, Overpack, Dry ice, Saturday Delivery Labels	
		• Blank Cover Up Labels	
		• Ambient Stickers	
		Requisition Binders	
		Subject #s _____ - _____ (range)	

	Special Instructions:

17 Appendix H | PBMC Sample Submission Form

MEDPACE
Reference Laboratories
www.medpacelab.com

PBMC SAMPLE SUBMISSION FORM

Sponsor:	**Sonoma Biotherapeutics**
Protocol:	**SBT777101-02**
Site Name:	
Site Number:	
CRC Phone:	
CRC Email:	

IMPORTANT REMINDERS:

- **Samples should be sent to MRL on the Day of Collection**
- **PBMC samples should be collected and sent Monday-Friday ONLY – NO weekend shipments**
- **Please include a copy of this form in the box with the sample shipment**

Subject Identification

S 0 2 - ☐☐☐ - ☐☐☐

Prefix Site Number Subject Number

FedEx Tracking Number(s) _____ _____

Date of Collection: ____ ____ / ____ ____ ____ / ____ ____ ____ ____
Day Month Year
(Example: 18 / Jul / 2012)

Time of Collection: ____: ____ AM/PM (circle)

Kindly fax and email this form before 3PM (EST)* to:

Fax: +1.513.366.3273 Attn: Sample Processing Lab
E-mail: B.Meyer@Medpace.com and MRL-US-PM@Medpace.com
***FedEx Tracking Number can be sent after 3PM (EST) to the above contacts.**

18 Appendix I | Lab Kit Resupply Schedule

SBT7102 (SBT777101-02)(Sonoma HS study)

		Shipment 1 - Pre-SIV (Initiate 3 Weeks before SIV)
Quantity	**Kit**	**Kit Description**
1	Kit A	Screening
1	Kit B	Pre-Treatment
1	Kit XS	Extra Supplies
		Shipment 2 - Pre-Screening (Initiate 3 Weeks before Screening Date)
Quantity	**Kit**	**Kit Description**
1	Kit A	Screening
1	Kit B	Pre-Treatment
1	Kit XS	Extra Supplies
Study Weeks 1-10		Shipment 3 – Pre-Dosing (Initiate 3 Weeks before Dosing Date)
Quantity	**Kit**	**Kit Description**
6	Kit C	W1D2, W1D7, W2D14, W3D21, W6D42, & W10D70
3	Kit D	W1D4or5 & W2D11
2	Kit E	W4D28, W8D56,
1	Kit F	ET
Study Weeks 12-24		Shipment 4 – Initiate Shipment at Patient Week 9, Delivery (2wk) Week 11
Quantity	**Kit**	**Kit Description**
1	Kit E	W12D84
1	Kit F	W18D126
1	Kit G	W24D168
Study Weeks 36-48		Shipment 5 – Initiate Shipment at Patient Week 33, Delivery (2wk) Week 35
Quantity	**Kit**	**Kit Description**
1	Kit C	W36D252
1	Kit E	W48D336/ES