



Shipment of Human Islets to Distal Research Centers

Purpose: To provide instruction for the shipment of viable human pancreatic islets to distal research centers.

Reagents and Materials:

Supplier	Material	Catalog #	Quantity/shipment
Mediatech	Miami M1 Media, 500 mL	99-933-CV	1
UW Pharmacy	Ciprofloxacin [10 mg/mL], 20 mL	899040	1
UW Pharmacy	Heparin [1000 U/mL], 10 mL	9997548	1
Origen	Permalife Bags	PL120	1
Origen	Permalife Bags	PL240	1
Origen	Permalife Bags	PL325	1
Sebra	Thermasure Ambient Gel Pak	Model 1290	2
ONSET	HOBO H8 K Temperature Logger	H08-001-02	1
	BoxCar software	NA	1
Thermosafe	Insulated shipping container	Model # 355	1
Fisher	Transparent Packing Tape	NA	1
Fisher	"Exempt Human Specimen" Labels	22-130-071	1
Uline	Bubble wrap	NA	1
UW CS	60 CC Syringe	NA	1
UW CS	Underpad Chucks Maxiflo Disposable #988	1216065	2
			1
Fisher	Ring stand	NA	2
Fisher	Cylinder clamp	NA	2
Fisher	Zip loc bags	NA	1
Office Depot	Plastic document sleeve	NA	1

Attachments:

- **Tissue Shipment Form (ICR)**
- **ICR Approved Investigator Contact List**
- **Islet shipment preparation picture guide**



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Protocol:

1. Samples are distributed between 24 – 72 hours after completion of an islet isolation.
2. Prior to initiation of shipment, quality control assessments must be performed on an appropriate aliquot.
 - Count and Purity –(Islet Counting)
 - Viability – (Viability by FDA x PI)
 - Morphologic assessment by digital photomicroscopy of dithizone stained islets.
3. If islets are deemed to be of sufficient quality and quantity for distribution; ICR investigators are identified for shipment. This is accomplished by:
 - ICR web-based distribution system
 - <https://www.infosci.coh.org/abcc-icr/>
 - Complete the required information under the “**Islets for Basic Science Distribution Only**” option.
 - Indicate that the islets will be shipped at 3:00 pm to ensure proper notification of acceptance of the islet offer in time to package the shipments.
 - Direct telephone call to collaborating scientists.
4. When investigators have been identified to receive shipments the following information must be confirmed:
 - Contact person for receipt of shipment
 - Islet quantity desired
 - Delivery date/time
 - Delivery address
 - Return of shipping materials
5. **Monday – Friday Shipments:** Islet shipments are prepared for the last FED EX pickup time of the day at 5:00 pm (Monday – Friday). Use the web-based FED EX shipping manager to schedule a pick up at the Islet Core Facility. The account number to bill is the recipient investigator account and the method of **shipment out** is FED EX Priority Overnight. The method of **return** should be standard FED EX Ground. Use the “Fast Ship” option to automatically generate labels.
6. **Saturday or Sunday Shipments:** The preference of the ICR is to place islets in culture until they can be shipped Monday – Friday. In rare cases an investigator may wish to receive islets on Sunday and be willing to pay the additional cost. Islets can be shipped on Saturdays for Sunday delivery or Sunday for Monday delivery using a special division of FED EX called FED EX Same Day. Arrangements for pickup and delivery must be made by telephone (1-800-399-5999). Provide to the



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Same Day operator the recipient name, address, account number, # of packages, weight, and pick up time. Pick up times should be scheduled for between 12 noon and 3 pm to allow delivery to the recipient between 8 pm and 1 am. NOTE: If a recipient's FED EX account is not registered for SAME DAY service that shipment may be cancelled.

- All media and islet shipment preparation must be completed following strict adherence to aseptic technique while working within the biosafety cabinet.**
- Based upon the number of shipments and the quantity of islets per shipment, aseptically prepare the Shipping Media according to the formula below.

Component	Volume for 500 mL
Miami Media for Shipping	490 mL
Ciprofloxacin [200 mg/20mL]	5 mL
Heparin [1000 U/mL]	5 mL
pH	7.2 – 7.4

- Remove a sample for testing of pH and confirm that it is 7.2 – 7.4. If the media pH is out of range, adjust by the addition of 5M NaOH or 5M HCL and sterilize by filtration prior to use.
- Ambient gel pack use for maintenance of temperature during shipping:
 - Warm weather shipping:** At least **2 hours** prior to the FED EX pickup, remove 6 ambient gel packs per shipment from the 4⁰C cold room and place at room temperature. The gel material should appear “slushy” when placed in contact with the bagged islets upon final packing.
 - Cold weather shipping:** At least **2 hours** prior to the FED EX pickup, remove 6 ambient gel packs per shipment from the 4⁰C cold room and place in a 25⁰C water bath. The gel material should appear completely liquid when placed in contact with the bagged islets upon final packing.
- Place in the biosafety cabinet sterile fields, ring stand(s) with cylinder clamp(s), 60 cc syringes, Permalife bags, and pipet aids.



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12. Use the following table to prepare islet aliquots for shipment using the Permalife bags:

Bag	Nominal Media Volume	Maximum Media Volume	Maximum Islet Loading Density [IEQ]
PL120	120 ml	180 ml	10,000
PL240	240 ml	375 ml	20,000
PL325	325 ml	1000 ml	30,000

13. Between **3 and 4 pm** aseptically remove required number of islets from tissue culture flasks and pool the entire amount into one or more 500 mL conical centrifuge bottles. If both Top and Bottom layer aliquots are to be shipped prepare them separately.
14. Pellet islets by centrifugation at 1000 rpm for 1 minute at room temperature without braking.
15. Aspirate media and resuspend pelleted islets by gentle tapping. Add a volume of freshly prepared Islet Shipping Media to the islets to reach a concentration of 1000 IEQ/mL. *Example: 150,000 IEQ to be distributed, resuspend in 150 mL shipping media.*
16. Remove the plunger from a 60 cc syringe and place the barrel in the cylinder clamp connected to the ring stand.
17. Connect the appropriate Permalife bag to the 60 cc syringer via the luer lock adaptor.
18. Transfer the correct quantity of islets [IEQ] to each Permalife bag by pipeting through the 60 cc syringe into the bag.
19. Wash the conical tube with an additional 50 mL of Islet Shipping Media and pour into the bag through the 60 cc syringe.
20. Add the appropriate quantity of additional Islet Shipping Media to the bag to reach the "Nominal Media Volumes (120, 240, or 325 mL).
- Examples:
 - i. 5000 IEQ – PL120 bag, 5 mL islet aliquot, 115 mL shipping media
 - ii. 10000 IEQ – PL 240 bag, 10 mL islet aliquot, 230 mL shipping media
 - iii. 30,000 IEQ – PL325 bag, 30 mL islet aliquot, 195 mL shipping media



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21. Hold the filled Permalife bag upright, push out all trapped air (or remove using a 60cc syringe) and cap the bag luer lock ports tightly and place in the 25°C 5%CO₂ tissue culture incubator until all shipments are ready for final packing.
22. **Fill the remaining islet shipments using the same procedure as described in steps 8-19.**
23. Initialize the HOBO temperature data logger(s). This requires connection to a laboratory computer and use of the BoxCar software. Setting is for readings every 10 seconds for up to 24 hours and the name to enter is the Principal Investigator of the laboratory to whom the islets are being shipped.
24. Complete the "Tissue Shipment Form" with all required information. Contact the UW OPO (265-0356) to obtain the donor demographics and serology reports.
25. Complete a FED EX shipping and return labels for each shipment using the web-based FED EX shipping manager.
26. Prepare the final shipping container using the following guide:

Thermosafe insulated container	
Top	Tissue shipment form and FED EX return label within a plastic sleeve
	Styrofoam Cover
Ambient gel pack (on the side)	Bubble wrap (5 -10 squares)
	Absorbent pad
	Ambient gel packs (2)
	HOBO temp data logger within a Ziploc bag
	Permalife bag containing islets
	Ambient gel packs (2)
Ambient gel pack (on the side)	Absorbent pad
	Bubble wrap (5-10 squares)
Bottom	

27. Seal the outer cardboard container with transparent packing tape.



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28. Place an "Exempt Human Specimen" label on the outside of the cardboard container.
29. Place the FED EX shipping label on the top of the sealed container.
30. Place the final shipping container outside of the Islet Core Facility for pickup by FED EX.
31. Remain with shipments until picked up by the FED EX driver at approximately 5- 6 pm.
32. Place a copy of the completed Islet Shipping Form in the UW Islet Transplant Program Shipping Binder.
33. Fax a copy of the Islet Shipping Form to Martha Antler at the ABCC (626) 930-5440.
34. Confirm receipt of the islet shipment by email. Place a print out of the receipt confirmation in the Shipping binder with the appropriate Islet Shipping Form.

References:

Dangerous Goods Regulations (DGR). 48th Edition (2007), IATA

Guidance Document: Infectious Substances, IATA, 10/11/2006

http://www.iata.org/nr/rdonlyres/2f939c1e-b406-4ece-adb9-922f867803c5/0/guidance_doc62dgr_48.pdf