Sep 23, 2020

Collection, Packaging and Cold Shipping of Fresh Non-Islet Pancreatic (Acinar) Tissue

Integrated Islet Distribution Program[1]

[1]Integrated Islet Distribution Program, City of Hope

1 Works for me dx.doi.org/10.17504/protocols.io.bimpkc5n

Integrated Islet Distribution Program

Integrated Islet Distribution Program and Human Islet Phenotyping Program

Integrated Islet Distribution Program
Integrated Islet Distribution Program, City of Hope

ABSTRACT

This SOP defines a standardized method for packaging and cold shipping of research quality, fresh Non-Islet Pancreatic (Acinar) Tissue (NIPT) to approved investigators of human isolated islet preparations, for use in the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) sponsored research in the Integrated Islet Distribution Program (IIDP). This protocol is written to assist the participating islet isolation centers and investigators who are part of this program.

Integrated Islet Distribution Program (IIDP) (RRID:SCR_014387)

Note: This SOP was developed by the IIDP with assistance from Dagmar Klein, PhD, at University of Miami who has been working with acinar since 2011 when it became clear, as far as shipping and culture was concerned, that protease inhibitors must be used in the medium otherwise the tissue will digest itself.

DOI

dx.doi.org/10.17504/protocols.io.bimpkc5n

PROTOCOL CITATION

Integrated Islet Distribution Program 2020. Collection, Packaging and Cold Shipping of Fresh Non-Islet Pancreatic (Acinar) Tissue. **protocols.io** https://dx.doi.org/10.17504/protocols.io.bimpkc5n

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Citation: Integrated Islet Distribution Program (09/23/2020). Collection, Packaging and Cold Shipping of Fresh Non-Islet Pancreatic (Acinar) Tissue. https://dx.doi.org/10.17504/protocols.io.bimpkc5n

Responsibilities:

- It is the responsibility of the IIDP CC to both follow and ensure adherence to the procedures outlined in this SOP. In order to accomplish this, the IIDP CC will interact with the relevant personnel from each of the participating centers.

- It is the responsibility of each IIDP center to follow the procedures listed in this SOP and to work to the best of their ability to follow all requirements.

Definitions:

- ***Integrated Islet Distribution Program (IIDP) (RRID:SCR_014387):*** The IIDP is a program commissioned and funded by the NIDDK to provide quality human islets to the diabetes research community to advance scientific discoveries and translational medicine. The IIDP consists of the NIDDK Project Scientist and Program Official, the External Evaluation Committee and the CC at City of Hope (COH). The IIDP CC integrates an interactive group of academic laboratories including the subcontracted IIDP centers.

- ***IIDP Coordinating Center (CC):*** Joyce Niland, Ph.D., IIDP Principal Investigator leads CC staff to coordinate the activities of the IIDP and assists the participating centers and investigators in the distribution of human islets.

- ***Islet Equivalent (IEQ):*** An IEQ is defined as an islet with a diameter of 150 microns. The number of IEQ in each size class is calculated by multiplying the number of islets by a conversion factor for each micron size.

- ***Approved Investigators***: Researchers who have requested islets from the IIDP for basic science studies and whose research protocols have been reviewed and approved by the IIDP.

- ***Islet Allocation System (IA):*** This is the online system administered by the IIDP to allow fair distribution of basic science islets to approved investigators. This interactive system, used by the IIDP Centers and the Approved Investigators, facilitates and tracks the distribution of human islets.

- ***Non-Islet Pancreatic (Acinar) Tissue (NIPT):*** During a standard human islet isolation, the digested tissue goes through a purification process that allows the majority of the isolated islets to be separated from the acinar and other pancreatic tissues. This is commonly done using density gradients and a COBE centrifugation processor. The lighter density tissues, including the majority of human islets, are collected from the lighter density gradients, leaving the remaining pancreatic tissue, in the COBE processor bag that still holds the denser gradients and tissue. This non-islet pancreatic tissue is commonly referred to as the “acinar” tissue, although in reality, it contains not only the acinar tissue but also connective tissue, blood vessel fragments, ductal fragments as well as imbedded islets.

MATERIALS

NAME	CATALOG #	VENDOR
Corning™ Ciprofloxacin Hydrochloride	MT61277RG (Corning™ 61277RG)	Fisher Scientific
Human AB Serum (ABS) HI	100-512; Heat Inactivated	Gemini Bioproducts
PIM(G)® (5 mL Glutamine/Glutathione)	PIM(G)®	Prodo Laboratories, Inc
PIM(T)®	PIM(T)®	Prodo Laboratories, Inc
MP Biomedicals™ Ciprofloxacin Hydrochloride or equivalent	MP219902005	Fisher Scientific
Sigma T9128-Trypsin Inhibitor from Glycine max (soybean)	501784544	Fisher Scientific

MATERIALS TEXT

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Phase 22 PCM Flex Pack

Phase 22 cold packs to maintain temperature at 22C

TCP Reliable Manufacturing	**FMIS76000**

•Most used for applications that need to maintain a controlled room temperature
•Phase change temperature is 22°C
•Provides thermal protection when shipping products between 15-30°C

PETG Media Bottles with Closure

60 mL PETG Media Bottles with Closure

Thermo Scientific™ Nalgene™ Square PETG Media Bott	**03-311-1W**

PETG Media Bottles

Media Bottles with Closure

125 mL PETG Media Bottles with Closure

Thermo Scientific™ Nalgene™	**03-312-1**

PETG Media Bottles

Square PETG Media Bottles

250 mL PETG Media Bottles with Closure

Thermo Scientific™ Nalgene™	**03-312-3**

PETG Media Bottles

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Bottle Top Filters with PES Membrane or equivalent

0.2 µm Bottle Top Filter

Thermo Scientific™ Nalgene™ Rapid-Flow™ Sterile Di **09-741-09**

0.2 µm membranes for sterile filtration; PES is the best membrane for cell culture fluids; lowest protein binding to maintain protein balance, lowest extractables to maintain media purity

Durasorb™ Underpads

Underpads

Covidien **22-031-340**

Wings™ Fluff Underpad 17 x 24 in.

Reclosable Zip Bags

Clear Reclosable Zip Bags

RD Plastics **19-130-6043**

PE (Polyethylene) Reclosable bag (8 x 10 in.)

Uline Corrugated Boxes

Corrugated Boxes (Inner Shipping Box)

Uline **S-4344**

7 x 5 x 5" Corrugated Boxes

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Insulated Foam Shipping Kit
Insulated Foam Shipping Kit

Uline **S-7359**

Insulated Foam Shipping Kit - 8 x 6 x 9"

Uline Cold Pack
Cold Pack

Uline **S-7361**

Reusable, leakproof refrigerant gel stays colder than ice. Thick 4 mil poly. 6 x 4 x 3/4"

Uline Industrial Tape
Uline Industrial Tape - 2 Mil, 2" x 110 yds, Clear

Uline **S-423**

2 Mil, 2" x 110 yds, Clear. DURABLE: Industrial Tape stands up to heat, humidity and cold.

Custom Cold Chain Complete Card
Temperature Monitoring system

Tip TEMPerature Products **WMSSEN044;**

Custom Cold Chain Complete Card

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Tip TEMPerature Products
WarmMark Ascending Temperature indicator

WarmMark Ascending Temperature indicator **WMS SEN 009**

Maximum exposure above 37°C/99°F

ColdMark Descending Temperature Indicator
Descending Temperature Indicator

Tip TEMPerature Products **CLMSEN004**

Falling Temp Monitor Changes Color Permanently; 2°C/36°F

Laser Labels
Uline Laser Labels - White, 8 1⁄2 x 11"

Uline **S-5045**

Box of 100 Single Labels, White, 8 1⁄2 x 11"

EQUIPMENT

NAME	CATALOG #	VENDOR
Media Bottles with Closure	03-312-1	Fisher Scientific
Reclosable Zip Bags	19-130-6043	Fisher Scientific
Square PETG Media Bottles	03-312-3	Thermo Scientific
Bottle Top Filters with PES Membrane or equivalent	09-741-09	Thermo Fisher Scientific
Durasorb™ Underpads	22-031-340	Fisher Scientific
Phase 22 PCM Flex Pack	FMIS76000	
Laser Labels	S-5045	Uline
Uline Corrugated Boxes	S-4344	Uline
Insulated Foam Shipping Kit	S-7359	Uline
PETG Media Bottles with Closure	03-311-1W	

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NAME	CATALOG #	VENDOR
Uline Industrial Tape	S-423	Uline
Custom Cold Chain Complete Card	WMSSEN044;	Tip TEMPerature Products
Tip TEMPerature Products	WMSSEN009	Tip TEMPerature Products
ColdMark Descending Temperature Indicator	CLMSEN004	Tip TEMPerature Products
Uline Cold Pack	S-7361	Uline

SAFETY WARNINGS

Please see attached SDS (Safety Data Sheet) for hazards and safety warnings.

Ciprofloxacin Hydrochloride **Corning Cipro SDS-2014Jul22.pdf**

MP Cipro_MSDS_199020_USA_EN.pdf

Precautionary statements:

- P280 - Wear protective gloves and eye/face protection
- P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P337 + P313 - If eye irritation persists: Get medical advice/attention.
- P273 - Avoid release to the environment.

GemCell™ U.S. Origin Human Serum AB **GemCell Human Serum AB.pdf**

GemCell™ human serum AB is collected from healthy male donors of the AB serotype at FDA-licensed facilities in the United States.

Hazardous Components:

- Biohazard contains human source material. Handle as though capable of transmitting infectious agents.
- Toxicity: Not Established.

Target Organs/Systems: Product could possibly irritate the skin, eyes and respiratory system. Do not ingest this product.

Trypsin inhibitor, from Glycine max (soybean) **Trypsin MSDSAction.pdf**

- Laboratory chemicals, Synthesis of substances
- Not a hazardous substance or mixture.
- Avoid dust formation. Avoid breathing vapours, mist or gas.
- For personal protection:Use equipment for eye protection. Handle with gloves. Respiratory protection is not required.

BEFORE STARTING

References:

- IIDP Quarterly Newsletter, Volume 10, Issue 2. Overview of NIPT Program.
  Newsletter_Vol_10_Issue_2.pdf
- IIDP Quarterly Newsletter, Volume 10, Issue 3. Overview of NIPT and Flash Frozen Islets Program.
  Newsletter_Vol_10_Issue_3.pdf
- Tip Temperature Products website: http://www.tiptemp.com and product inserts
  SW Gen1 WM instructions.pdf **ColdMark_instructions_Oct2016.pdf**
- Prodo Labs, Inc. Protocols and Website: http://www.prodolabs.com

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Scharp DW, Arulmoli J, Morgan K, Sunshine H, Hao E (2019). Advances in Human Islet Processing: Manufacturing Steps to Achieve Predictable Islet Outcomes from Research Pancreases. OBM Transplantation, Volume 3, Issue 1(Current Advancement of Islet Cell Transplantation in the Treatment of Diabetes Mellitus).. http://file:///tmp/10.21926/obm.transplant.1901052

Preparation of Supplies and Reagents

1 The IIDP will provide each center with the following supplies necessary for NIPT fresh shipping:

- Gemini Human AB Serum (ABS) -Heat Inactivated (HI)
- PIM(G)® - 5 mL – Glutamine/Glutathione
- PIM(T)® - 500 mL – Transport Media
- Ciprofloxacin Hydrochloride. Either MP Biomedicals™ MP219902005 or Corning™ MT61277RG (61277RF is available in 1 gm bottles and 61277RG in 5 gm bottles, however due to the relatively short shelf life (12-18 months), usually 1 gm bottles are supplied).
- Sigma T9128 Trypsin inhibitor from Glycine max (soybean) – lyophilized powder
- Thermo Scientific Nalgene 0.2 µm bottle top filter
- 30 mL vessel for shipping NIPT
- 60 mL vessel for shipping NIPT
- 125 mL vessel for shipping NIPT
- 250 mL vessel for shipping NIPT
- Corrugated, cardboard, inner box for shipping (7x5x5")
- Kendall Durasorb Underpads #949
- Ziplock Bags, 8x10, 2 mil
- Cold Chain Complete card with WarmMark ascending indicator adhered to card
- ColdMark descending indicator
- Insulated shipping container (8x6x9") (outer box)
- Phase 22 pouches-cryopak: small, ambient temperature pouches @ 8° C (four per shipment box)
- 8 oz cold packs @ 8° C (eight per shipment box)
- 8 oz cold packs @ -20° C (two per shipment box)
- Shipping tape (2 mil)
- 8 x 11" Labels for outside of boxes

2 Supplies provided by the IIDP Centers:

- NIPT for distribution
- Hanks Buffered Salt Solution (HBSS) – no additives.
  (Note: Either HBSS with or without calcium, magnesium, and phenol red can be used)
- 15 mL, 50 mL, or 250 mL conical tubes (depending on final volume of islet prep)
- Wide mouth pipettes and pipettor
- Routine lab supplies for transferring NIPT

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- Markers for labeling vessels
- IIDP Box Labels from IIDP template
- Tissue Shipment Forms
- Completed FedEx Shipping Labels
- Islet Allocation Tissue Shipment Forms for appropriate recipients

3 **Receipt of Supplies:**

The majority of supplies should be stored in appropriate dry, temperature-controlled environments (room temperature **16 °C** to **28 °C**).

- The Prodo Labs PIM(T) should be stored, in the dark, between **2 °C** and **8 °C** upon receipt but is stable at room temperature.
- The Gemini AB serum and the PIM(G) vials should be stored at **-5 °C** to **-20 °C** in the dark.
- The ciprofloxacin can be stored on the shelf but filter sterilized suspension aliquots should be stored at **-5 °C** to **-20 °C** .
- The Cold Chain Complete card with the WarmMark indicator on the card and the separate ColdMark indicator can both be stored at room temperature, or between **12 °C** to **32 °C** , to ensure against accidental triggering of either indicator.
- The T9128 Trypsin inhibitor from Glycine max (soybean) – lyophilized powder should be stored between **2 °C** and **8 °C** upon receipt.

Preparation of Ciprofloxacin, Media, and Trypsin inhibitor

4 ***Preparation of Ciprofloxacin:***

Aliquots of Ciprofloxacin can be prepared prior to the isolation. Prepare the ciprofloxacin according to the directions in the table. Filter sterilized suspension aliquots should be stored at **-20 °C** .

Pre-Preparation of Ciprofloxacin Powder for Addition to Media

- Remove 0.5 gm (500 mg) of ciprofloxacin hydrochloride from the bottle and QS to 50 mL with Distilled water. This will give a stock concentration of 10 mg/mL.
- Mix with a stir bar and stirring plate until totally dissolved.
- Filter sterilize the solution using a 0.2 µm filter.
- Aliquot into sterile tubes, 5 mL samples, label as stock solution, and freeze at -20 ºC for later use.
- The expiration date of the solution is indicated on the Certificate of Analysis and/or the bottle. Document expiration date as date of CoA.
- Diluted solution is good for 1 year frozen (if less than CoA expiration date) and 1 month thawed.

Record ciprofloxacin preparation on ***Attachment 1: Solutions Preparation Sheet***, of this SOP.

Attachment 1-Solutions Preparation Sheet.docx

5 **Preparation of PIM(T) Media:**

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- Prepare one 500 mL bottle of PIM(T) media prior to the isolation per Attachment 1.
- Thaw and add 5 mL of PIM(G)
- Thaw and add 12.5 mL of AB serum (2.5% v/v)
- Thaw and add 0.5 mL of prepared ciprofloxacin sterile aliquot per Attachment 1.
- Once all additives have been added to the bottle of PIM(T), it is now referred to as PIM(T) complete.

Record media preparation on ***Attachment 1: Solutions Preparation Sheet***, of this SOP.

6 **Preparation of Trypsin inhibitor:**

The T9128 Trypsin inhibitor from Glycine max (soybean) – lyophilized powder should be stored between **2 °C** and **8 °C** upon receipt. Aliquots of Trypsin inhibitor can be prepared prior to the isolation. Prepare the Trypsin inhibitor according to the directions in the table. Filter sterilized suspension aliquots should be stored at **-20 °C**

Pre-Preparation of Trypsin Inhibitor for Addition to Media:

- Weigh 1 gm (1000 mg) of Trypsin inhibitor from the bottle and QS to 100mL with serum free PIM-T (no additives). This will give a stock concentration of 10 mg/mL.
- Mix with a stir bar and stirring plate until totally dissolved.
- Allow to stand on ice at least 30 min before filter sterilizing.
- Filter sterilize the solution using a 0.2 µm filter.
- Aliquot into sterile tubes, 5 mL samples, label as stock solution, and freeze
- at -20°C for later use.
- Stock solution is stable at -20°C.
- Inhibitor must be added fresh to the medium before culture or shipment.

Record Trypsin inhibitor preparation on ***Attachment 1: Solutions Preparation Sheet***, of this SOP.

NIPT (Acinar) Broadcast

7

Begin "Acinar Tissue Broadcast" on "IIDP Secure Access Center" website as soon as the islet isolation is confirmed.

8 Enter donor and isolation information on IIDP secure website under "Non-Islet (Acinar) Tissue Broadcast". Complete "Donor Information" and "Isolation and Distribution of Non-Islet Pancreatic Tissue" forms.

9 The "Donor Information" form is the same as for islets and all entered information will be auto-populated to the subsequent "Islet Broadcast".

10 Relevant information entered on the "Isolation and Distribution of Non-Islet Pancreatic Tissue" form will be auto-populated to the "Islet Broadcast".

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11 Complete information regarding NIPT will be available as freshly isolated [Collection, Packaging and Cold Shipping of Fresh Non-Islet Pancreatic (Acinar) Tissue (current SOP)] and/or flash frozen [Packaging and Shipping of Flash Frozen Non-Islet Pancreatic (Acinar)Tissue].

12 Complete the broadcast records and proceed to "Broadcast Now".

Note: Set deadline for approximate time of when the purification step will be completed so that the total amount of accepted NIPT will be known prior to when the tissue is to be prepared for shipment or freezing. this deadline can be set before starting the isolation. *Freshly isolated NIPT should be sent out on the day of the isolation or at the next available FedEx pickup, within 24 hours of isolation. This will limit freshly isolated NIPT broadcasts to Sunday evenings through Thursdays (or Fridays if investigators will accept Saturday deliveries.)*

13 Set the "NIPT Broadcast Deadline" to the assumed time when the purification will be completed. This will ensure that the NIPT will have minimum holding time prior to packaging of the freshly isolated samples or of freezing the requested NIPT. [Packaging and Shipping of Flash Frozen Non-Islet Pancreatic (Acinar)Tissue].

14 When the “Deadline of Broadcast” is met, an automated email will be sent to center asking to “View Acinar Offers” and to “Confirm the Shipment” or “Cancellation” of each request.

Collection of NIPT for Transport

15 

The NIPT (the tissue remaining in the COBE purification bag) should be transferred under sterile conditions, into two 250 mL conical tubes, as soon as feasible during the islet isolation process. Top with HBSS, cap, invert to mix and dilute Ficoll, and centrifuge at **180 x g, 4°C, 00:02:00**

16 Obtain PIM(T) Complete prepared in Step 5.

17 Obtain the Trypsin inhibitor from Step 6. Thaw aliquot.

18 After centrifugation, calculate the pellet size, evacuate supernatant. If deadline has not yet been reached and the total amounts of NIPT accepted is not yet known, suspend up to 20 mL of pellet to 10 times the pellet volume with PIM(T) Complete plus inhibitor (200 mL). Lay conical of the NIPT suspension on its side at **4 °C** to avoid pelleting of NIPT while waiting to confirm acinar shipments.

Note: As interest in the program expands and recipient requests increase, more tissue may need to be held.

19 Once deadline has been reached and final amounts of accepted FRESH and FROZEN NIPT is confirmed, calculate the amount of PIM(T) needed. Complete that which is needed for all shipments. Add 1 mL of Trypsin inhibitor stock (Attachment 1) to each 100 mL of PIM(T) Complete for NIPT shipping (~150 mL of media/1 mL NIPT total requested). This will give a final working concentration of 100 µg/mL of Trypsin inhibitor in the media. Resuspend only the amount of NIPT needed to complete the requests in 10x the volume of PIM(T) Complete plus inhibitor. *Example: If there is one request for 3 mL and two for 1.5 mL, only resuspend 6 mL of NIPT in 60 mL of PIM(T) Complete **plus inhibitor**. This*

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will save on the cost of the inhibitor and media.

Preparation of Shipping Vessels

20 As investigator's requests are determined through the broadcast system, prepare appropriate amounts of fresh NIPT into proper sized shipping vessel from the diluted samples in Step 19 above.

- For 0.5 - 0.75 mL of requested NIPT pellet, add 5 - 7.5 mL of NIPT suspension to 60 mL bottle for shipment.
- For 0.76 – 1.5 mL of requested NIPT pellet, add 7.6-15 mL of NIPT suspension to125 mL bottle for shipment.
- For 1.6 – 3.0 mL of requested NIPT pellet, add 16 - 30 mL of NIPT suspension to 250 mL bottle for shipment.
- For 3.1 – 5.0 mL of requested NIPT pellet, add 31 - 50 mL of NIPT suspension to 500 mL bottle for shipment. Any empty PIM(T) media bottle can be used for shipping these large amounts of NIPT.
- Distribute appropriate volume of NIPT into shipping bottles.

21 Top off the volume of each shipping vessel with PIM(T) Complete plus inhibitor stored at **6 °C** to **10 °C** up to the halfway point of the neck of each shipping bottle

- 60 mL bottle - 75 mL of media plus NIPT
- 125 mL bottle - 167 mL of media plus NIPT
- 250 mL bottle - 300 mL of media plus NIPT
- 500 mL bottle - 550 mL of media plus NIPT (Use sterile PIM Media bottle)

22
- Label each bottle with RRID #, Date, volume of NIPT, and PI Name
- Record appropriate information on the batch record.
- Keep the shipping bottles with NIPT in the refrigerator 6 °C to 10 °C until ready for packaging.

Packaging of Fresh NIPT

23 Stage all materials needed for packaging the NIPT and ensure all ice packs and CryoPak pouches are at the proper temperature.

24 The Cold Chain Complete card is shipped with the WarmMark indicator attached. Store the card at least **5 °C** / **9 °F**) below the **activation temperature of the adhered WarmMark of** **37 °C** (therefore less than **32 °C**). Room temperature is acceptable.

Attachment 2-Cold Chain Complete Handling Instructions 2020.pdf

24.1 The ColdMark is provided separately because it is always active and should be stored at least **2 °C** / **50 °F** above **activation temperature of ColdMark of** **2 °C** (therefore more than **12 °C**). Room temperature is acceptable.

24.2 When ready to use, *adhere the ColdMark indicator to the card and attach the WarmMark.* **ACTIVATE** the WarmMark by folding up and pulling out the tab until completely removed.

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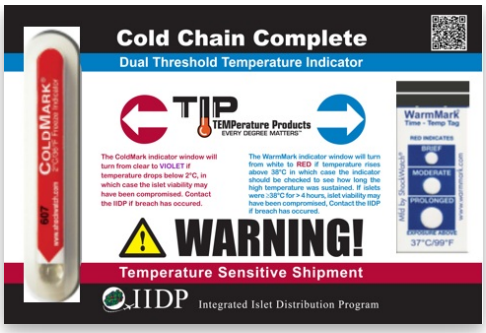

Cold Chain Complete Card

24.3 ⚠

Immediately place the Cold Chain Complete Card (TipTemp Indicator) and the acinar shipping bottles together into a Ziploc bag and seal.

Do not place ColdMark indicators on or near -8 °C frozen cold packs while preparing to ship to prevent accidental triggering of cold indicator.

25 Line the inner cardboard (#4434) box with absorbent pad.

Attachment 3-NIPT Packaging Tips.pdf

Attachment 4-Packaging NIPT for Cold Shipping.pptx

25.1 Place the bagged shipping bottle(s) containing the NIPT in the Ziploc bag into the absorbent pad lined, inner cardboard box.

25.2 Surround bottle(s) with six **8 °C** cold packs, one on bottom, one on each of the four sides and one on top.

25.3 Mark the direction for upright bottle. Seal the inner box with shipping tape and stand upright.

25.4 Place one **8 °C** CryoPak pouch and one **-20 °C** frozen ice pack (stored in the freezer) in the bottom of the Styrofoam box.

25.5 Place the inner cardboard box containing the NIPT on top of the pouch and pack, ensuring that the bottle inside as well as the inner cardboard box, is lying on its side to ensure the maximum surface area for the acinar tissue to settle and centered in the shipping container. *Note: the inner box and bottle are opposite of the way islet tissue is shipped.*

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25.6 Place one **8 °C** CryoPak pouch and one **-20 °C** frozen ice pack on the top of the inner box.

25.7 Add a second layer of cold/frozen packs on top, one **8 °C** CryoPak pouch and one **-20 °C** frozen ice pack, on top of the first layer. ***NOTE-All packs should be placed in an alternating method, to ensure two of the same packs are not next to each other in the configuration***

25.8 Place the Styrofoam lid on top.

25.9 Place Tissue Shipment Form on top of Styrofoam lid.

25.10 Close the flaps of the shipping box and seal with shipping tape. Attach "Cold Live Cells" label to box.

Attachment 5-Generic Institution Box Label IIDP.pdf

25.11 Attach FedEx label with recipient FedEx number to box and ship **priority overnight.**

Completing the Distribution Records

26 The shipping center will enter the NIPT to be shipped (Confirm Recipient screen) and will enter FedEx tracking numbers Broadcast System. In addition, the shipping center should process the shipment by using the on-line FedEx process and click the prompt to alert the recipient of the FedEx tracking number. This will help the recipient investigator follow their shipment through the FedEx system and free up time for the centers and the IIDP.

Note: If the investigator has picked up the NIPT at the distributing center then the center should check "Yes" in the "Direct Pickup" column and "Yes" under "NIPT Shipped?" once they are picked up.

27 The investigators will have the FedEx tracking numbers listed in their "History of Acinar Tissue Offers" table.

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