

# **Purified Human Pancreatic Islets, CIT Digestion Solution – A Standard Operating Procedure of the NIH Clinical Islet Transplantation Consortium**

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**DAIT, NIAID, NIH**

**SOP  
ATTACHMENT**



<b>Document No.</b> 3106, B01	<b>Revision Number</b> 00	<b>Effective Date</b> 07 July 2008	<b>Supersedes Date</b> N/A	<b>Page 1 of 1</b>
<b>Document Title:</b>  <b>PURIFIED HUMAN PANCREATIC ISLETS, CIT DIGESTION SOLUTION</b>				

Manufacturing Site: \_\_\_\_\_ Date: \_\_\_\_\_

1. **Materials:**

<b>Material</b>	<b>Source</b>	<b>Lot #</b>	<b>Expiration Date</b>	<b>Quantity Required</b>	<b>Quantity Used</b>
<b>Phase I Solution</b>	Mediatech, 99-678-CM			1 L Bottle	Bottle
<b>Heparin Sodium Injection USP</b>	_____ Units/mL			10,000 units (_____ mL)	mL

2. **Procedure**

- 2.1 In a BSC place a 1 L bottle of Phase I Solution.
- 2.2 Add Heparin to the bottle to obtain a final concentration of 10 Units/mL (10,000 Units total).
- 2.3 Cap the bottle and mix by gentle inversion 5 times.
- 2.4 Label the bottle with:
  - "CIT Digestion Solution"
  - Islets Lot Number
  - "Store at 2°C to 8°C"
  - Date Prepared
  - Expiration Date (the end of the day after preparation)
  - Initials of the person who prepared the solution
- 2.5 Store the bottle(s) of solution at 2°C to 8°C before use.

Total Volume Prepared: \_\_\_\_\_ mL

**Prepared by:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Reviewed by:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Islets Lot Number: \_\_\_\_\_