

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

## **The NIH CIT Consortium Chemistry Manufacturing Controls Monitoring**

**Committee:** J. Ansite, A.N. Balamurugan, B. Barbaro, J. Battle, D. Brandhorst, J. Cano, X. Chen, S. Deng, D. Feddersen, A. Friberg, T. Gilmore, J.S. Goldstein, E. Holbrook, A. Khan, T. Kin, J. Lei, E. Linetsky, C. Liu, X. Luo, K. McElvaney, Z. Min, J. Moreno, D. O’Gorman, K.K. Papas, G. Putz, C. Ricordi, G. Szot, T. Templeton, L. Wang, J.J. Wilhelm, J. Willits, T. Wilson, X. Zhang

## **The NIH CIT Consortium**

**Emory University:** J. Avila, B. Begley, J. Cano, S. Carpentier, E. Holbrook, J. Hutchinson, C.P. Larsen, J. Moreno, M. Sears, N.A. Turgeon, D. Webster

**Massachusetts General Hospital:** S. Deng, J. Lei, J.F. Markmann

**NIAID:** N.D. Bridges, C.W. Czarniecki, J.S. Goldstein, G. Putz, T. Templeton, T. Wilson

**NIDDK:** T.L. Eggerman

**Northwestern University:** P. Al-saden, J. Battle, X. Chen, A. Hecyk, H. Kissler, X. Luo, M. Molitch, N. Monson, E. Stuart, A. Wallia, L. Wang, S. Wang, X. Zhang

**University of Alberta, Edmonton:** D. Bigam, P. Campbell, P. Dinyari, T. Kin, N. Kneteman, J. Lyon, A. Malcolm, D. O’Gorman, C. Onderka, R. Owen, R. Pawlick, B. Richer, S. Rosichuk, D. Sarman, A. Schroeder, P.A. Senior, A.M.J. Shapiro, L. Toth, V. Toth, W. Zhai

**University of California–San Francisco:** K. Johnson, J. McElroy, A.M. Posselt, M. Ramos, T. Rojas, P.G. Stock, G. Szot

**University of Illinois, Chicago:** B. Barbaro, J. Martellotto, J. Oberholzer, M. Qi, Y. Wang

**University of Iowa (Data Coordinating Center):** L. Bayman, K. Chaloner, W. Clarke, J.S. Dillon, C. Diltz, G.C. Doelle, D. Ecklund, D. Feddersen, E. Foster, L. G. Hunsicker, C. Jasperson, D-E Lafontant, K. McElvaney, T. Neill-Hudson, D. Nollen, J. Qidwai, H. Riss, T. Schwieger, J. Willits, J. Yankey

**University of Miami:** R. Alejandro, A.C. Corrales, R. Faradji, T. Froud, A.A. Garcia, E. Herrada, H. Ichii, L. Inverardi, N. Kenyon, A. Khan, E. Linetsky, J. Montelongo, E. Peixoto, K. Peterson, C. Ricordi, J. Szust, X. Wang

**University of Minnesota:** M.H. Abdulla, J. Ansite, A.N. Balamurugan, M.D. Bellin, M. Brandenburg, T. Gilmore, J. V. Harmon, B.J. Hering, R. Kandaswamy, G. Loganathan, K. Mueller, K.K. Papas, J. Pedersen, J.J. Wilhelm, J. Witson

**University of Pennsylvania:** C. Dalton-Bakes, H. Fu, M. Kamoun, J. Kearns, Y. Li, C. Liu, E. Luning Prak, Y. Luo, E. Markmann, Z. Min, A. Najj, M. Palanjian, M. Rickels, R. Shlansky-Goldberg, K. Vivek, A.S. Ziaie

**University of Wisconsin:** L. Fernandez, D.B. Kaufman, L. Zitur

**Uppsala University:** D. Brandhorst, A. Friberg, O. Korsgren

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Address correspondence to: Camillo Ricordi MD, Chairman, CIT Steering Committee, ricordi@miami.edu

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## SOP ATTACHMENT



<b>Document No.</b> 3106, B02	<b>Revision Number</b> 00	<b>Effective Date</b> 07 July 2008	<b>Supersedes Date</b> N/A	Page 1 of 1
<b>Document Title:</b>  <b>PURIFIED HUMAN PANCREATIC ISLETS, CIT PURIFICATION SOLUTION</b>				

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

1. Materials:

Material	Source	Lot #	Expiration Date	Quantity Required	Quantity Used
<b>Cold Storage/Purification Stock Solution</b>	Mediatech, Product No. 99-677-CM			790 to 799 mL	mL
<b>PentaStarch, 10% Solution</b>	Mediatech, Product No. 99-723-CM			200 mL	mL
<b>Heparin Sodium Injection USP</b>	_____ Units/mL			10,000 units (_____ mL)	mL

2. Procedure

- 2.1 In a BSC place a sterile 1 L bottle.
- 2.2 Add 790 to 799 mL of Cold Storage/Purification Stock Solution to the bottle. (Volume will be adjusted based on volume of Heparin added so that total volume is 1 liter.)
- 2.3 Add 200 mL of PentaStarch, 10% Solution to the bottle.
- 2.4 Add Heparin to the bottle to obtain a final concentration of 10 Units/mL (10,000 Units total).
- 2.5 Cap the bottle and mix by gentle inversion at least 5 times.
- 2.6 Label the bottle with:
  - "CIT Purification 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
- 2.7 Store the bottle of solution at 2°C to 8°C before use.

Total volume prepared: \_\_\_\_\_ mL

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

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

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