

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. Naji, 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 APPENDIX



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Document Title:

RAW MATERIAL SPECIFICATION, COLD STORAGE/PURIFICATION STOCK SOLUTION

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container label and Certificate of Analysis must specify: "Cold Storage/Purification Stock Solution" and must have same lot number.
Vendor	Visual Inspection	Mediatech, Inc., Cat. No. 99-677
Review of Vendor's Certificate of Analysis	Visual Inspection	<p>All requirements on the Certificate of Analysis must be met.</p> <p>Osmolality: 305 – 325 mOsm/kg H₂O @ 22 – 25°C</p> <p>Density: 1.026 – 1.032 g/cm³ @ 22 – 25°C</p> <p>pH: 7.2 – 7.5 @ 22 – 25°C</p> <p>Endotoxin: ≤ 2.0 EU/mL @ 37°C ± 0.5 °C</p> <p>Sterility: Pass</p> <p>USP Safety Test <88>: Pass</p> <p>Mycoplasma Test: Negative</p> <p>Appearance: Clear, slightly yellow solution</p> <p>The Certificate of Analysis must be signed and dated.</p>

2.0 Packaging, Labeling & Storage

- Sterile 1 L bottles
- Cold Storage/Purification Stock Solution, for investigational use, not for injection
- 2°C to 8°C, do not store in strong light

3.0 Formulation:

Components	Concentration
Sterile Purified Water USP	q.s. to 1 L
D(+)-Raffinose 5 H ₂ O	17.83500000 g/L
L-Histidine	4.65600000 g/L
NaOH	4.60000000 g/L
Lactobionic Acid	35.83000000 g/L
KOH	0.39300000 g/L
CaCl ₂ 2 H ₂ O	0.07400000 g/L
MgSO ₄ 7 H ₂ O	1.23300000 g/L
NaH ₂ PO ₄ H ₂ O	3.45000000 g/L